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ON GENETICS, HEALTH AND SOCIETY

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I N D E X

I N D E X (Continued)

Genomic Data Sharing (continued)

Public Comment Session

Concluding Business

P R O C E E D I N G S

OPENING REMARKS

CHAIRMAN TEUTSCH: Good morning, everyone.

Welcome back for our second and final day of the meeting and of the committee.

First let me thank everybody for, I think, a very productive day yesterday. We had some excellent discussions and I think we made some good progress on what it is we want to say in our final letter to the Secretary.

Today we'll be covering genomic data sharing first in the morning and then we'll be spending the preponderance of the time getting our thoughts together for the letter that we do want to send to the Secretary and getting that squared away. And at the end of the day we will have Dr. Collins here with us and we're looking forward to that.

So, hopefully, all of you who are here on the committee can stay to the end. We definitely need as many of you as possible so we have a quorum and can get our work completed.

But first off in our agenda is the continuation of our work on data sharing and the concerns surrounding that. This has been very ably led by Charmaine Royal who we have not let off the

hook and so she has been continuing in that capacity.

So, Charmaine, thank you and let me turn it over to you.

GENOMIC DATA SHARING

PERSPECTIVES ON GROUP RISKS AND BENEFITS RELATED TO GENOMIC DATA SHARING

OVERVIEW OF SESSION

CHARMAINE ROYAL, PH.D., SACGHS MEMBER

DR. ROYAL: Good morning, everyone.

(Slide.)

It is good to be here. I'll tell you when I first heard that the committee was sun-setting two thoughts came to mind. At first I thought 'Oh, man! Just when we figured out what we're going to do and they take it away.'

And then soon after that another thought came, 'Oh, wow! The Secretary figured out that our mission is accomplished.' Our mission was to figure out what to do, what we're going to focus on and we've done that. So our mission was accomplished.

But, you know, we have so much work to do in this area. And I'm hoping that today with the speakers that we have, who are going to help us think through some of these issues, we will come up

with some salient points that we want to communicate in terms of where we go with data sharing in the groups that we've identified as really important in thinking about genomic data sharing.

So I'm just going to do a quick overview and then we're going to have our panelists. They are going to come and speak and then we're going to have a discussion with them, and then we are going to have committee discussion.

(Slide.)

So what have we done up to this point?

In October of '09 a steering group was formed to look at issues related to genomic data sharing and we talked about organizing a session on that in the February meeting.

And at that meeting we had people come to talk about different models of genomic data sharing and the policies that currently exist in relation to those models.

In June we formed a task force to look at groups. We decided that we were going to--at the meeting in June we talked about focusing on group harms and at that time we really had a broad definition of group. We talked about prisoners and disease groups and racial/ethnic groups.

But during July--the time from July to September as the task force convened and we had our conference calls we decided to focus on racial, ethnic and indigenous groups. And since then we've been developing the plan for this meeting.

(Slide.)

So our task force includes SACGHS members, David Dale, Gwen, Rochelle, Barbara, Sheila; and we have ad hoc members, Kevin Fitzgerald, Sylvia, who is not here, and Julio; and our ex officios, Mike Amos, Michael Camone, Douglas Olsen, Michele and Laura Rodriguez.

And I must thank the members of our task force for their input in shaping the agenda for this meeting but not just the agenda, in shaping the entire agenda for what we're going to focus on in genomic data sharing.

I particularly want to say thanks to Symma who has been just a phenomenal convener of the task force and very helpful in helping put our ideas together and putting the session together.

(Slide.)

So what are we going to do today?

First we're going to try to look at some of the issues related to the involvement of

indigenous, racial and ethnic groups in genomic research, and looking at the broad sharing of data related to these groups.

We're going to try to think about what is currently being done in the U.S. in this area in protecting groups and minimizing risks from genomic research.

And we're going to look to see whether there are policy areas that we need to address, we need to fill, we need to make recommendations about what needs to be done.

I missed the other countries part. We're going to talk about the U.S., what's happening n the U.S. We're also going to talk about policies in other countries and specifically today we're going to talk about Canada because a lot of countries have dealt with this and have tried to come up with policies related to this issue.

And then, finally, we're going to try to come to some agreement about--pretty much about what we need to communicate to the Secretary.

(Slide.)

So a little bit of background in terms of our focus on racial, ethnic and indigenous groups: I'll start by doing a little bit of definition. So

when we talk about “indigenous groups” we’re talking about--for all of these we’re pretty much talking about groups in the U.S. since that’s what we were charged with addressing.

Indigenous groups for the most part are Native American groups in the U.S.

Racial groups--we’re not going to get into the debate about what is a race and who is a race and who is not. In racial groups we’re thinking about it the way the OMB categories--OMB defines it in the census. So those are the groups we think of as racial groups.

Ethnic groups in the sense of ethnic groups of Hispanic/Non-Hispanic but we could also expand ethnic groups to include Ashkenazi Jews, the Amish and other such groups.

So that’s kind of the scope of our definitions.

(Slide.)

So why do we need these groups in genomics research?

A lot of people will say, ‘Well, you geneticists have said we’re 99.9 percent the same so we could just look at one group and figure everything out or we could just study Africa and

figure it out." There is some merit to that because we know that if we study Africa we'll capture most of the variations that we have in humans.

And to respond to that question about Africa there is a project starting, H3 Africa, that NIH and the Wellcome Trust have just launched to look at genomics in African populations. So we're going to be getting some information back.

But we need other groups because we know that as populations moved out of Africa they developed different frequencies of different alleles. So there are still things about groups that might be related to genetics in these particular groups based on geography and ancestry that might be important in health. So we can't throw the baby out with the bathwater. We still need to have--to really understand genomic variation and its contributions to health. We do need to have a spectrum of populations in our studies.

And even thinking about genomic research in these groups that we've identified I often think about it as 3 Ys in terms of--3 Ws really in terms of doing genomics research in these populations.

And one is the "what." What is the variation? What is the scope of genetic variation

in these populations? It can be a purely academic scientific exercise. What is the variation in populations?

And the next one is “whether” and whether these variants have a role in disease and health because some of them have and some of them don’t.

And then the other question is “why” or “how.” How do these variants that we find in populations that are greater in frequency in some populations, how do they contribute to disease?

And I think most of us would agree that genetics is not the whole picture. Genetics is only part of it and so as we think about genomics research in populations I would really want us to keep in mind that for the most part we’re not talking about just looking at genomics as the be all and end all of how we think about these things.

And “why” is genomic data sharing important? One researcher can’t do everything. So with the wealth of information coming from genomics we do need to have various researchers involved in the research.

Risks and potential benefits. We talk a lot about risk and we’ve heard a lot about risks for these populations. And the benefit--the easy answer

in terms of--to the question “what benefit is there?” If there are things found then we’ll be able to help populations and to deal with diseases and address those issues. But the question of benefits is one thing but how do we apply those benefits is quite another and just a major question.

I mean if we find things that are common in these populations, do we develop a drug and tailor it specifically to that population? It raises a lot of questions about how we apply whatever benefits we find.

And then in terms of policies there are policies about including these groups in genomics--in research broadly, not just genomics, but there’s not a whole lot about how we do that. A lot of people have been asking those questions. How best do we do that in policies and guidelines to help move it along?

(Slide.)

So for this session we have four speakers, experts in this area, in various aspects of this area, who are going to talk about their perspectives and perspectives of others and perspectives of the communities in participation of these groups in genomics research.

And we're going to have a talk from Rebecca Tsosie on indigenous groups and perspectives there.

Racial and ethnic groups, Vence Bonham is going to give us a talk there.

We're going to talk--the next one will be Canadian policies by Laura Arbour. She's going to be third. And then, finally, we're going to have Morris Foster, who is going to help us think about policies in the U.S., existing policies, whatever they might be and where we might go in terms of policies in the U.S.

(Slide.)

So there are some central questions that arise and that we will discuss as we go through this today.

Why is it important for these groups to participate in genomics research?

How might these groups benefit from genomics research and data sharing?

What constitutes group harm? We talk a lot about harm and there are different perspectives on what harm is.

What are the risks of genomic data sharing to groups?

And how are researchers and IRBs and others addressing these groups?

(Slide.)

In what settings are decisions about research participation and genomic data sharing made at the group level? How do we balance the wishes of the community and the wishes of the group with that of the individual?

Are existing policies in the U.S. adequate for addressing these issues and can we look at other countries' policies in terms of helping to guide us with what we do in the U.S.?

(Slide.)

So our next step in terms of what we're going to today is to talk about what specific policy issues are the most critical as we think about what we're going to communicate to the Secretary and our component of this letter to the Secretary. What specific issues are most critical in addressing this issue? And what should we--what type of advice should we give in terms of addressing this issue?

I'm going to stop here and we're going to have our panelists come.

I don't know if there are any questions or anything in terms of the background and, if not,

then we're going to move right into our talks.

So our first speaker is going to be Professor Rebecca Tsosie. And she is Professor of Law and Distinguished Research Scholar and Executive Director of the Indian Legal Program and the Sandra Day O'Connor College of Law in Arizona State University.

And the bios for all of these folks are in your folders.

Professor Tsosie has written a lot on Native American perspectives, not just related to genetics.

She has talked and written about Indian genetics but, as a whole, in terms of cultural perspectives, issues related to rights and doctrinal and traditional issues that we need to think about in terms of Native Americans.

It's my pleasure to have her here and to have her come and talk a bit about her perspectives on this topic.

PERSPECTIVES OF INDIGENOUS GROUPS ABOUT PARTICIPATION IN GENOMIC RESEARCH AND DATA SHARING

REBECCA TSOSIE, J.D., PROFESSOR OF LAW,
SANDRA DAY O'CONNOR COLLEGE OF LAW
EXECUTIVE DIRECTOR, INDIAN LEGAL PROGRAM
ARIZONA STATE UNIVERSITY

MS. TSOSIE: I actually do not have a power point so the first thing I want to say is how incredibly honored I am to be here.

I spent the day yesterday listening to all of you and I just want to tell you how impressive you are. The level of dialogue and communication and your backgrounds are just so incredibly important. I realize that you've put a lot of time and thought into these issues over many years and I really commend you for that.

I'm actually very sorry to hear that the belief is that your committee has served its purpose because I can tell from the discussion yesterday that you all have a lot of leadership to offer on these issues and I know that you're going to continue doing that in the work that you do so I really mean that from my heart.

I also want to thank all of the folks who have been working on the task force and for being

willing to invite people in with other perspectives to inform these very important issues about data sharing.

So in that spirit I want to tell you that the thoughts that I offer today about the perspectives of indigenous people are really what I'm hearing in the field as I go to various meetings and I have to tell you that I haven't been talking a great deal to scientists.

So yesterday as I heard what is possible to do with genomics, the case study about the little boy that has Crohn's disease and how you could bring that level of--ease his suffering. I mean that is incredibly powerful healing work that is possible with genomics.

So I take it that we all have a common interest in making sure that the promise of this technology is done in a way that does achieve the maximum possible benefit to people and alleviate the pain and suffering that individuals are experiencing and that groups might experience if things are done in a way that is discordant with what they think of as being their rights and their autonomy.

So in that spirit I'm going to explain to you what the perspectives are and then really look

forward to the discussion with you where we can enter a dialogue about that.

The first thing that I want to suggest is that that whole perspective of who indigenous people are--and I know that, Charmaine, obviously the focus here is on the federally recognized Indian Nations of the United States and that's Alaska Natives and American Indian Tribal Nations. There are some 564 or 565 maybe by now. There's one tribe pending this week.

So, you know, that's what we're looking at here in terms of those sovereign governments that have legal systems. They have court systems. They have governments. You can dialogue with them as governments.

Internationally we have over 5,000 groups that might be defined as indigenous and so one of the questions is can we have an indigenous perspective on these issues. And I want to suggest to you that there have been a number of dialogues among indigenous communities globally and nationally for a very long time about medical research ethics.

There were sort of three pivotal time periods. There is what I would term sort of the era in which a lot of historic "wrongs" took place.

Obviously that informs the way that indigenous people view genomics. Even though that's an incredibly new technology it is informed by the experience that groups have had dating back.

So yesterday when you guys talked about the attitudinal surveys, I just thought it was so amazing that people didn't know (a) about the discrimination act, GINA--right. But then they thought, "Well, what's the point? I mean some cowboy is going to come in and change it." That's what Americans think about the law.

And then "Oh, but the insurance companies can always get around the law even if…" So those are attitudes informed by the experience of Americans who probably have some difficulty with their insurance company or have a cynical view about their politicians. That's important data--right--because that tells us what people's experience is.

How do we know what indigenous experiences are unless we talk to indigenous people? Right? So, good for you guys. You guys are actually willing and able and ready to do that. So the historical experience is relevant.

Then there was the whole era of genetic technology, right? The Human Genome Project was

amazing.

And then there was the ill-fated Human Genome Diversity Project in which people thought, well, we'll go out there and we'll just kind of say to indigenous people, "Look, we'd love to study you and see what the variation is." And indigenous people said, "Oh, no. That's not appropriate whatsoever." And there was a huge political outcry among indigenous people. A lot of international meetings on that.

What came out of that in the international forum, and then I'll talk about why that's relevant in the domestic forum--what came out of that is the UN declaration on the rights of indigenous people that was adopted by the UN General Assembly in 2007.

I believe it's Article 31 that says "indigenous people have a right to their genetic resources." They have a right to control that and that means the samples and the data. So that's the international consensus. It may not be the perspective of every group but it certainly is the political consensus represented by that document and all the negotiations, 20 years of negotiations that went into that.

Now what about in the domestic arena?

Well, indigenous people, the federally recognized tribes and the non-recognized tribes, are drawing on the declaration even though the U.S. is reconsidering its decision to basically not sign on to it. Now Obama's administration is in the process of seeing whether or not we can sign on but, even if they don't sign on, the tribes here still believe that that is a charter of rights that really exemplifies what it means to have that central right and that central right is the right of self-determination. And all of the federally recognized tribes agree that that is the fundamental basis of the right to engage with the United States Government as autonomous governments but within the federal system as it exists today.

Now, what do the federally recognized tribes think about genetic resources?

So if you go to the National Congress of American Indians, which is really the organization that serves the political interests of all of the federally recognized tribes who are members of that organization, which is most of them, there is a resolution, a 2005 resolution that says that the tribal governments retain ownership and control of their samples and data. So we have consensus,

international and national consensus, on that premise.

Now, what does that mean for the discussion that we're having here today? So I'm going to offer some thoughts on that and I know that they will have to be brief because there's obviously a limited amount of time. So I have some notes here on what I want to share with you.

Okay. So in the context of historic wrongs--so are they relevant today? And on this level I would suggest that there is a view dating back to the early days of this country that Native people are subjects for the rest of American society to actually gain information of, and that is something that violates their rights. And that's just a premise.

So in 1868 there was a Surgeon General order, official order that demanded collecting Indian crania from the battlefields. Now we all know how you have to do that. And then all of those crania were sent back Washington, D.C. Now, when were those crania returned? And the answer is when--in 1990 the Native American Graves Protection and Repatriation Act was passed. There was then a legal right to repatriate human remains if cultural

affiliation could be proven.

One of the huge issues in implementation of that statute is whether or not genetic DNA analysis of those remains is appropriate in the affiliation process, whether new scientific testing is permissible after the enactment of that statute.

See there are a range of issues just with repatriation of human remains that lead into genetic resources.

Moving on I'm just going to give anecdotes of the experience.

So in the 1950s obviously there were a number of experiences of Native communities with studies detailing the effect of radioactive materials waste. What does that do to the human being? So there were studies in Alaska that exposed Native people to radioactive substances. Now, a scientific committee said, "Well, it was a safe dose?" Well, all they know is that it was dumped on their land and it wasn't taken out until 1992.

In New Mexico and Arizona in the Southwest there were a number of studies down out there and the Navajo people who worked in those uranium mines were not told about the dangers that they were being exposed to and the U.S. Public Health Service

studied them covertly to see what the effect was. All of that, of course, came out in congressional hearings that led to the tort legislation but see that's the relatively recent experience.

Now, you've had disclosures like we did within the last couple of weeks that that syphilis study, the Tuskegee model, was happening in Guatemala. We didn't know that--right. So what does that tell us? Well, there's a lot of stuff that happened that really doesn't look so good and unless somebody finds out and brings it into the open then it's not being acknowledged. So we wonder what else is being tested.

Now you might say, "Well, we've changed. This isn't the 1950s. You know, this is 2010." And the Havasupai case, which was recently settled and involved my own institution, ASU, in terms of research misconduct in this diabetes study with the Havasupai people that led to all sorts of unauthorized uses of their genetic samples and material. That is the modern representation of what can go wrong and that has--creates a tremendous political obstacle for the type of research that you're engaged in supporting because of the idea that it's just going to go amuck. You know, we

won’t have any control over the samples. We won’t have any control over the data.

So as I listened yesterday what I really got from that discussion is that efficiencies of this system depend on wide-scale genomic association studies--right. That is essentially an efficient model. It also depends on having a database that is centrally accessible and that this data is input. That makes sense.

What are you going to tell people about the way that samples and data are used in that national repository which may be subject to secondary uses?

Are you going to tell them that their interests are protected, not protected?

Who owns it?

Does the government own it?

Do the primary researchers own it?

Do the people still own it?

Now, I take it that that is what you all are exploring in the context of what might concerns be of these groups, whether they be racial, whether they be ethnic, whether they be--and so to an extent Native people can get lumped into that discussion and you can say, “Well, what do they think?”

I don’t want to start there because I want to suggest that the real lesson of the Havasupai case was that there are both individual harms that come from a lack of effective informed consent and a lot of those people did not read or speak English in the way that we’re used to a lot of people in this society reading and speaking English. So they depended on what was disclosed to them and what was disclosed to them was diabetes only.

Now they find out that they’ve been harmed and there were tremendous--tremendous individual harms about the misuse of their actual samples due to that cultural view that they have that your body is an intact whole and that when these things are taken out and different things are done to them that creates a physical harm to you and to all of your blood relatives. I mean you could say, “Well, what kind of a belief is that?”

But if that is really what the subject believes then the researcher should care about that.

Had they even thought to ask about that?

So there are the individual harms.

But Havasupai says, “No, it’s not just individual harms.” There are harms to the tribal government because that was antithetical to what

they as a government had agreed to, to let these researchers come on to their land and do this research study. And there are cultural harms and there are political harms. And I would suggest that that is not exceptional.

There was a reason why President Obama called the President of Guatemala and apologized--right--because that was harm to Guatemala as well as all those individuals that were dealt with that way in the research study.

So we have to understand tribal governments in the same way. They are governments. They have political rights. They have cultural rights and the types of harms that we are talking about are transcendent of individual and also group harms on that level. Without that central lesson built into U.S. policy we will continue to see things happen that we really could have avoided had we given more thought and attention to those issues right at the outset. So that's the central point that I want to make.

Now, I'm also going to suggest to you that in terms of thinking about the specific harms, I know that that's something that we need to address, I'm going to give sort of four levels that I think

that we have to understand that.

The central point I want to make about those four levels is that just as you guys were talking yesterday about the fact that the regulatory structure wasn't a good fit for genomics research, that the reimbursement structure wasn't a good fit for genomics research, these are the same types of issues.

The legal structure that we have now, the policy structure we have now is not a good fit for resolving these issues. So that puts a burden on us to think about what changes need to be made to law and policy to effectuate the interests that I'm going to represent.

So, the first one is that the interest that Native people have expressed about the integrity of the human body. Again that is a pervasive cultural belief. You may, in fact, find indigenous groups that are willing to consent to research for specific purposes--great. But there is a baseline concern about the samples that are taken, the physical samples that are taken and the need to repatriate those.

Obviously that is happening internationally; the Yanomami research that was done

many years ago, those samples, seeking to repatriate them. The case in British Columbia I think that my colleague, Laura, is going to address, repatriate the samples. Havasupai, repatriate the samples. So it's that level of discussion about the actual samples.

The law right now says, "Look, if you willing give up your body to research you give up any property interest." Well, that isn't a good fit for indigenous structures.

The second point that I want to make is with respect to the use of the data. So the pervasive belief--and why the U.N. declaration comes out the way it does is that in a lot of indigenous world view is that it's not so easy to separate the tangible resource from the intangible resource right. Intellectual property rights and tangible property rights; that's American law. They don't separate the physical from the intangible components of that.

And so therefore the issue of widespread data sharing -- while it is very efficient and it serves the industry I would think of biotechnology and bioinformatics--I mean that actually free-sharing serves those interests but it disserves the

indigenous interest in maintaining control over the intangible data, the information that is gleaned from that. So they are making a claim for control over that.

Now, why is that true? Well, a couple of reasons. First of all, it is very easy to tie data through interpretation to images that are essentially replicating old stereotypes.

So this happened in New Zealand, I believe, when there was a study to determine whether there was a warrior gene among Maorians, you know. Let’s try to explain violence. Well, you know, that’s the type of thing that reinforce the stereotypes about alcoholism, about all of these things. I mean no other group is going to be treated in that way but Native people are used to that and they don’t want a continuation with this type of research. I think that is absolutely well founded.

The interest of privacy: That is something that is an individually based model within American law. It certainly doesn’t extend after the person is dead. Again those conceptions about privacy are very different in Native systems.

So if you look at Native law, tribal law,

you will often times find what appear to be sort of tort categories which transcend our notions of privacy but they are in some sense related to those notions about how you can commit harm, for example, by stealing somebody's name and misusing that name. That name is linked to an individual. If that individual is deceased there's a harm that results from that. So again we have to consider that.

And, finally, I would say that we need to think about the meaning of sort of exploitation within our legal system. So do we want sort of to acknowledge a broader view that if the harms that a group suffers are different than the harms that the dominant society suffers? And cultural harm is certainly going to be a different type of harm.

Do we just disregard that, in which case we continue to exploit the fundamental nature and belief system of that group?

Or do we acknowledge that that is okay and we are going to craft a policy to deal with that?

And so I really congratulate the work that is happening in Canada that Dr. Arbour is going to talk about. The DNA on loan concept, I think, really gets to say, 'Hey, we're not going to continue to exploit.'

The final point I want to make is sort of in that notion of there is an idea about what it means to create a justice or kind of an equitable benefit.

So in terms of the commercialization of human DNA, that is something that is very much contested among a lot of indigenous groups and maybe other groups as well. That idea that commodification of the body is wrong.

If you look at the laws of the United States I think that we accept that notion to an extent--right. We don't allow the for profit sale of organs, for example.

So if we can understand a policy issue as a process of where do you draw the line and then work with groups to determine that line drawing process, it is not so disparate after all, that there are kind of fundamental beliefs about the sanctity of the human body and things that emerge from the human body. And really as a society we need to be sensitive to the way that cultures construct that.

And that leads me to the very final point that I want to make which is what we are talking about here is a process of formulating an

intercultural legal framework that takes into account that the ethical systems expressed by different groups may be distinctive but they are worthy of respect. So when we talk about legal rights that ought to be informed by our responsibilities to each other.

And I really in that spirit again thank you for the opportunity to talk to you today.

Thank you very much.

(Applause.)

DR. ROYAL: Thank you so much, Rebecca. I think we'll have some discussion later on, on some of those points. Thank you so, so much for you perspectives.

At this time we're going to have Mr. Vence Bonham who is going to come to talk with us about perspectives on race and ethnic group involvement in genomic research.

Mr. Bonham is Associate Investigator in the Social and Behavioral Research Branch in the Human Genome Institute, NHGRI. He's also Senior Advisor to the Director on societal implications of genomics and heads the Education and Community Involvement Branch in the Human Genome Research Institute. Vence has written a lot and done a lot

of work related to racial and ethnic groups.

One of the big projects he is working on is looking at physician attitudes and knowledge about genetic variation and how that translates into their practice. It's great to have Vence and I'm happy to have my colleague here to talk about these issues.

PERSPECTIVES OF ETHNIC AND RACIAL GROUPS ABOUT PARTICIPATION IN GENOMIC RESEARCH AND DATA SHARING

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NATIONAL HUMAN GENOME RESEARCH INSTITUTE,

NATIONAL INSTITUTES OF HEALTH

MR. BONHAM: Well, good morning. Good morning to everyone. It's good to be back today on the last day of the committee here to talk about, I think, issues that are important to the field of genetics and genomics that we need to think about from various perspectives of how do we move forward with research and improving the health of the citizens of our country and people of the world.

(Slide.)

So, as Charmaine stated, I play various

roles and I'm actually coming to you this morning with both of my hats on.

As a researcher because I'm going to talk a little bit about some of my own research that I did in the Communities of Color in Genetics Policy Project, a project that I did in Michigan in collaboration with Toby Citrin and others in the State of Michigan and the State of Alabama. I'm going to share some of that data.

I'm also coming from the perspective of an administrator in the Genome Institute that's involved in our community engagement activities. I want to share with you some of the general themes that have come from some of our activities and programs, and talk to you a little bit about our programs and how I think they help us facilitate a conversation of the perspectives of different communities.

Again, the title that I was provided was "Perspectives of Racial and Ethnic Groups about Participation in Genomic Research and Data Sharing." So it's really this broad question of the conversations we've had both at the Genome Institute as well as a researcher with different communities on issues of importance.

(Slide.)

So let me start from the perspective of the Genome Institute and some of the work that we're doing to engage communities, diverse communities, both racial and ethnic communities, around issues of genetics and genomics, and their importance to their community, and what are the issues of importance to them, and concerns that they have.

I highlight this web page, which is on genome.gov, which has information about the Community Genetics Forum program that the National Human Genome Research Institute has now had for seven years.

We've held four different forums. The first one was in Seattle, Washington. The second was in the State of North Carolina and Dr. Evans was involved in that activity. The third was in the Midwest. It was actually done in the State of Iowa, Michigan, Indiana, and Ohio, and involved a lot of telecommunication and multiple meetings. And then the most recent one was in the State of Utah that occurred earlier this year. And actually today at the CTSA meeting a video is being presented by the Director of the CTSA at the University of Utah about that Community Genetics Forum and some of the issues

of how they engage diverse communities.

I'm going to share with you some themes and these are some of the things that came up at these forums, as well as in other programs that we've had to reach out to targeted audiences across this country. So we recognizes as an institute the importance of having dialogue with different communities, with different populations about their perspectives about genomics, the value and importance for their health, and their concerns and perspectives about the research.

I am not going to present to you any specific data that I've been involved in or from the forum around--specifically around data sharing but I will share with you some of the work from the Johns Hopkins Genetics Policy Center, which I think at this point in time is the only large sample of quantitative data that is providing information about racial and ethnic groups and data sharing. However, there is research going on by other grantees at the Genome Institute currently.

(Slide.)

So racial and ethnic group perceptions of risk: I highlight risk here of participation in genetics and genomics research because I want to

come back and talk about benefits also. It's not all about risk and so I think as we have this conversation this morning and think about data sharing policies and what actions are needed we need to really think about this issue both from a risk perspective as well as the benefit perspective in thinking about working with diverse communities but I want to take a moment and talk a little bit about the issue of research ethics violations.

The professor and I did not have a chance to talk before our talks this morning but you're going to see some common themes on what she stated and what I'm stating. I think that's a message to all of us that we're hearing these common themes and that they're not unique to just one population.

I want to raise the issue that is the underlying issue that we've heard in many of our forums as well as in research that I've done around the issue of just disparities in health care and how the issues of disparities in health care link to research and the perception of research and participation in research and what research means. So the discrimination, the recognized differences in quality of care, issues of access, issues of who benefits from the research that goes on that clearly

the unequal treatment issues in health care have identified.

The issue of privacy, some of the voices of some communities around privacy.

And then, finally, the issue of stereotyping I just want to talk about for a second.

(Slide.)

So the historical basis for racial and ethnic group concern. This is not new but I think it's important for us to put it on the table and to talk about it as part of a conversation about participation in genomics research and data sharing.

(Slide.)

The history of genetics research in our country, the history of biomedical research and how it has harmed certain communities. So some of you may say, 'Oh, my god. Here we go again, you know. We're talking about the syphilis study. Yes, okay, that was before you know. Can we get beyond this?' No.

(Laughter.)

And so it is important to talk about and it's important for several reasons. One, it was the United States Public Health Service's syphilis

study; not the Tuskegee syphilis study. It was not Tuskegee Institute, Tuskegee University, even though they did play a role; it was the U.S. Government. So I think that's real clear as an advisory committee to the Secretary that the history of real violations of the ethics (sic) of individuals is put on the table that the U.S. Government led these programs.

And the U.S. Public Health Service's syphilis study is important at two levels. One is the deception for the men and the failure to provide treatment but also the original purpose of that study was to understand differences in syphilis between Blacks and Whites. And how do we understand that as we talk about biological and genetic issues and difference in understanding disease?

(Slide.)

So this is a quote from some of the research that I've done with the Community of Color Genetics Policy Project. "I'm not trusting anything the government does that's supposed to be helpful to Black folks. I just don't trust anything they do and I would advise anybody that takes any advice from me to not be involved with anything to do with the government until we are absolutely sure what

they are going to do with it. I don't want to have my information in any databank. I am just very distrustful. We need to remember what they did to our men in Tuskegee."

This is voice of a participant, just a general member of the public, of their concern linking biomedical research generally to some of the harms that have occurred.

So I think one of the question for us as we move forward and seek to have more diverse communities involved in genomics research, how do we address this issue in a way that is appropriate and respectful to move forward and to be clear that that's not what's happening now?

So that's the question I think that it raises.

(Slide.)

So it is so important because of what happened just last week. So this is Dr. Collins' quote that was in *The New York Times* on Saturday. The issue of history repeating itself, history expanding itself. This is interesting because one of the myths about the U.S. Public Health Services syphilis study is that they gave those men syphilis and that has been a conversation, and there's a lot

of research out there about people believing that's what happened that the government gave them syphilis. Clearly there's no data, there has been nothing found in the historic record that that ever occurred with regards to that study in Macon County, Georgia. But now today this is what we have to face as both researchers, as policy makers, as leaders that we do have now an example, a documented example where it seems very clearly that the U.S. Government gave syphilis to individuals in Guatemala.

So I think about those focus groups and dialogue groups that I had in Michigan and Alabama. And I can just hear the individual saying, "See, I was right. This is what happens. This is what our government does to us."

So I think the challenge for us again is how--as we think about diverse communities and genomics research and data sharing, how does this context--this historical context that is part of our current day conversation fit into that?

(Slide.)

So another quote from the Communities of Color project. "Historically it has always been the lowest person in society that gets tested. We've got to be wary as to who is going to be the guinea

pigs in this deal. It's probably going to be us."

This whole feeling of being the guinea pig, of being used for the benefit of others is an issue, a theme that came up in the research, and it's a theme that came up in many of the forum conversations around participation of their communities in genetics and genomics research.

So this broader concept of how we understand this issue of the individual and the potential benefit and why should they participate in genomics research and why should they share and commit to share their data with others.

(Slide.)

So the second area is this question around how this fits with the issues of disparities more generally, the issue of healthcare, the difficulties of the healthcare system, participating in the healthcare system, having access to care, and how actually the question of minority communities, racial and ethnic minority communities participate in genomics research fits within limitations and struggles of individuals with regards to health care and perceived and real differences with regards to the treatment received.

And this is the Institute of Medicine

study from 2003 that is now really kind of the leading document documenting differences in treatment based on racial and ethnic groups or populations within the United States. It's kind of a basis for much of the research that's going on around understanding disparities in treatment within the United States today.

(Slide.)

So willingness to share data. So I want to share now some of the work from Dr. Hudson and John's Hopkins Genetics Policy Center that I think is key to understanding and having some empirical data. So bringing the qualitative data and the qualitative perspective along with quantitative data. I think one of the challenges I say is--and I guess a question to this committee is do we need more of this research to better understand what's really going on? But this clearly is a beginning with regards to identifying data.

So in this paper that was published in *The American Journal of Human Genetics* in 2009, which I would recommend to all of you, it talks about differences based on racial and ethnic groups. So you see here in this table it divides by both income, on gender, education, and race and ethnic

group. I want to actually just focus on the race and ethnic group and look at the specific questions that they had as part of their study.

So they asked the question: "I would allow these researchers to use my sample and information for research." And then they asked it based on specific groups.

"Academic or medical researchers in the U.S." So 85 percent of the Black/Non-Hispanics said yes; 89 percent of the Hispanics; and 93 percent of the Whites.

"Government funded research." The Blacks, 71 percent said, yes, they agree with that statement; 78 percent of Hispanics; and 81 percent of the Whites.

And then "Pharmaceutical companies." 71 percent of the Blacks; 69 percent of the Hispanics; and 76 percent of the Whites.

And you see that there is more trust and willingness to share their data and provide their data to academic medical researchers and government funded than pharmaceutical company research. There are other studies that have supported this same finding with regards to the differences based on who has access to the research.

Then the other question is “If it could not be identified I would be willing to have my information and research results available on the internet to anyone.” So 49 percent of the Black/Non-Hispanics agreed with that statement; 46 percent of Hispanics; and 50 percent of the Whites.

So I think there are two messages to take away from this. One is we do see a difference but it’s not a big difference. People are willing to share their data. People are willing to participate in research. And so it becomes this question of how do we frame things in a way that will facilitate and support that in an appropriate way. But I think this is some initial data that will be helpful as this conversation goes forward of how you make sure that we have the diversity of our country in the genetics and genomics research that’s going on and the issue of sharing that data with others.

(Slide.)

So again from that same paper they found that 37 percent of the respondents said that they would be afraid that the information collected by the study could be used against them. Black/Non-Hispanic and participants under the age of 60 were significantly more likely to share this feeling.

Again this is a common theme we heard in our community forums, the concern about privacy, concerns about who is going to have access to my DNA, who is going to have access to my data, how is it going to be used, is it going to be misused in some kind of way.

And so this question of whether our data sharing policies should be one generalized policy or are there ways to create policies that are unique to specific research and specific communities I think is a question or part of the dialogue that needs to occur at a policy level.

(Slide.)

So let me take a minute and talk about benefits and some of the voices and issues and perspectives in the communities about the benefits. I guess I want to frame it this way: A message we've heard across forums, Community Genetics Forums, messages we've heard within our qualitative research is that communities do not want to be left out. They want to improve the health of their communities. Research is recognized as important in communities and benefitting the health of the community. So the question of just not participating in research is not the position that

I've ever heard from racial and ethnic minority populations and groups either in our forum settings or in the research that I've been involved with. There is an interest in being involved and there is an interest in having communities benefit.

The benefit is really about better understanding the disease and its impact on their communities and so this question of recognizing that certain diseases may have a higher impact on their community and concern about that. Communities are concerned about diabetes. We just had this forum in the State of Utah. We worked with five different populations, Tonga, Mexican-American, American Indian, African-America in the State of Utah, and they were concerned about diabetes and they were concerned of how diabetes was impacting their community. So understanding the burden of disease is something of interest to racial and ethnic minority communities. They want to use the research to improve their health and the health of their community, and the health of their families.

So this is not a message that, you know, we should not seek to work with more diverse communities within this country and that, you know, we're really wasting our time and we're wasting our

time to have those dialogues. The question is how do we make it clear and concise what are the potential benefits for the communities and articulate that in a way that's based on facts and is also based on research?

(Slide.)

So my last quote from the Communities of Color Project: "At a very broad level everyone should benefit from genetic technologies, especially those who have a specific need for this type of technology. I would hope the benefits are made available to all humankind and not just the benefit of a specific population. It should benefit people irrespective of gender, socioeconomic status, political affiliation and status." That's the voice again of someone in the community, not a genetic researcher, not a policymaker, someone sharing their perspective of how they see the role of genetics and genomics research within their community.

So I think that's our challenge as researchers and our challenge as policymakers to make this real for individuals. This question of benefit with the recognition that we can't say a lot of things about benefit because we don't know but thinking about it in the perspective of a targeted

research that may address areas where there are disparities, the issue of addressing conditions that have much higher prevalence in certain communities I think is part of the steps of the commitment to individuals who participate in genomics research and their willingness to share data. So if the research is about things of importance to them versus maybe an issue that's not of importance. Again going back to the issue of the American Indian community, the Havasupai was very interested in diabetes. They were not interested in telling the story of migration and population genetics. That was not their intent and so this question of how do we frame a policy in a way that will provide a respect for what the participants want.

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And that's where I want to really kind of end of my talk is about this kind of moral contract that I think we have as researchers with our research participants about what we do with the data and what is the purpose and how do you communicate the intent. I think that's the challenge when we have general expectation that the data will be used for whatever and that hopefully that will benefit everyone. Certain communities have a history of

knowing that that doesn’t always happen and so are there certain circumstances that we really need to frame things differently and what is our moral obligation to the individual research participant?

So those are my comments, perspectives, voices of communities with regard to these issues. I think one of the things that we are seeking to do at the Genome Institute is to have a dialogue and to listen to communities and to share with communities what is happening, what is exciting about the field of genetics and genomics, and how it potentially can be of benefit to their community but for us to also listen very carefully of what are their concerns, what is some of the history and how do they see this research going forward as taxpayers and as members of our country.

So thank you.

(Applause.)

DR. ROYAL: Thank you very much, Vence, really for reminding us of the importance of the dialogue and, hopefully, that dialogue will help shape where we go in terms of how we address some of these concerns.

Our third speaker is Dr. Laura Arbour. She’s Associate Professor of Medical Genetics at the

University of British Columbia and head of Medical Genetics with the Vancouver Island Health Authority. She is a geneticist and a genetic counselor--yay for the genetic counselors--whose work focuses a lot on genetic conditions in aboriginal peoples in Canada but she has also been involved in the process of developing policies in Canada related to the involvement of aboriginal groups and she's going to talk a bit about that work as well as her perspectives.

Dr. Arbour?

CANADIAN POLICIES THAT ADDRESS THE INVOLVEMENT OF GROUPS IN GENOMIC RESEARCH AND DATA SHARING

LAURA ARBOUR, M.D., ASSOCIATE PROFESSOR, DEPARTMENT OF MEDICAL GENETICS UNIVERSITY OF BRITISH COLUMBIA

DIRECTOR, MEDICAL GENETICS VANCOUVER ISLAND HEALTH AUTHORITY

DR. ARBOUR: Thank you very much for inviting me.

(Slide.)

I was actually asked to do this by Rod McInnes (ph), who is the former scientific director of the Institute of Genetics at the CIHR, the Canadian Institutes for Health Research, and he felt

that somebody on the ground who has been doing this might be a better speaker for this. But he's actually going to be talking on the same issues during the presidential address of the ASHG (ph) up the road in just about a month. So it would be great for you to hear that, too.

So I will talk specifically about our approaches and our policies with regards to aboriginal people in Canada. Although this is generalize-able to other groups, the policies themselves have dealt only with the aboriginal groups of Canada.

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And so much of what has already been said this morning really applies to our work in Canada. We separate our data only according to aboriginal versus not. So we don't separate our epidemiological data or health data on the basis of any other ethnic group or race. So what we do know is that there is great health disparity with the aboriginal groups of Canada. There is a greater burden of chronic disease, infectious disease, nutritional deficiency, shorter life spans. But it's not all just about genetics and, as a matter of fact, there's quite a push for research in social

determinates of health because that really is the larger component of what the issues are but to research only that also creates disparities and does a disservice to the people not to involve genetic research.

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However, as Rebecca well noted and was noted in the last talk, around the world indigenous groups are asking for genetics research to be done differently and Rebecca mentioned the Havasupai and the Yanomami, which I have trouble pronouncing. Rebecca has trouble pronouncing Nuu-chah-nulth, which is the first one on there.

I just want to say as early as 1996 when I was at the DNA sampling conference in Montreal there were protests about the use of DNA with indigenous groups around the world and it was mainly of the Human Genome Diversity Project that was being protested. I, of course, had been doing some research. Even though I was just a clinical fellow at the time I had already done some research with aboriginal groups and I was really curious about what was going on so I listened to what their concerns were.

When I moved to British Columbia I started

doing some work with the Nuu-chah-nulth and some of the other West Coast tribes on a condition called primary biliary cirrhosis and it was right at that time that we learned that, in fact, in the 1980s that some 800 blood samples had been drawn from the Nuu-chah-nulth and arthritis research was the research that had been planned and there was no arthritis research that came of it and instead the UBC researcher moved on to Utah and then eventually to Oxford. It was mitochondrial ancestry research that was carried out. This was right at the time when the Canadian Institute for Health--Institutes for Health Research had just started their Institute for Aboriginal Peoples Health so they have a specific institute that only deals with the aboriginal health issues. This became quite clear that we really needed to address these issues in order to be able to move on.

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So that--this will really be about our last decade, from about 2000 and around that time, about how with the Canadian--with the support of the Canadian Institutes for Health Research, the Institute for Aboriginal Peoples Health and many others that we have been building relationships

between policymakers, researchers and aboriginal groups having discussions. And the main question is can biomedical genetic research be carried out in a collaborative manner acceptable to First Nation, Meti and Inuit? These are the three major aboriginal groups that we speak of in Canada.

At that time and at the beginning there were many groups in Canada and the United States, American Indian and Canadian aboriginal who were feeling that they wanted to put a moratorium on any kind of genetics research until these issues were sorted out. So we needed to act.

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At the time we knew that there were many concerns with genetic research. It was felt that there were health disparities that weren't being addressed and research monies were being--were displacing that kind of important research. There were concerns with academic--with commercial and academic exploitation and people becoming professors on the backs of aboriginal people and maybe not getting any benefit to the communities. Huge issues of trust, people flying in and out to carry out research. And I first started to identify myself as a pediatrician often enough because geneticists had

a very bad name. And research results, of course, may be stigmatizing depending on the type of research that is being done and Rebecca gave some excellent examples of that.

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The issues around culture were really important to understand. I'm a clinical geneticist and DNA is DNA. It was really important for us to have a mindset that that isn't necessarily so for all groups around the world. This is a quote that we used often in our discussion: "To us any part of ourselves is sacred. Scientists say it's just DNA. For an Indian it's not just DNA, it's part of a person. It is sacred with deep religious significance and part of an essence of a person." And very important to sort of understand the differences when regarding the way that DNA is used in research.

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So a series of discussions started, and I should say that the NIH actually played a role in two more of these that most of us were involved in and I don't have down here. One that was in Colorado and one that we actually held in Vancouver.

But the first one was just before the

Canadian Institute--before the CIHR Institute for Aboriginal Peoples Health started. This was actually sponsored by our National Council of Ethics in Human Research.

This is our governing council that really is an educational source and sets guidelines for research ethics across the country. They knew that there were issues that were going on and they wanted to address research involving individuals and community genetics as a focus so they started this conversation across the country and invited international guests to talk about the issues.

By the time the next--the follow up conference had occurred, we were then able to use the Nuu-chah-nulth case as an extremely important education case. How do we move from there? How do we bring it out in the open? How do we have open forums discuss what the issues are here? And how do we address the issues that they don't happen again? So the focus of the next one was really very much the Nuu-chah-nulth case.

From there we actually learned from the Colorado NIH ELSI conference and we had heard then from one of our colleagues who suggested such a thing called The Tribal Control DNA Bank. This was

a catchy thought and what we thought is that in Canada we would actually use that title and say--and engage many of the aboriginal groups to say how can we carry out specifically genetic research in a way that is going to be acceptable, what does it mean for DNA samples, and what does it mean for the information that comes from it. So we had two Canadian workshops sponsored by the Institute for Aboriginal Peoples Health to really get this going.

Dr. Jeff Reading, who was the scientific director at the time of that institute, felt we could not even fund genetics research until we had these issues on the table and had resolved them.

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Many topics of discussion and what we did was we really listened to the cultural perspectives. We heard about what was going on currently in genetics research in aboriginal communities, about past policy guidelines, case studies, community perspectives, and we even wondered could DNA be considered cultural property, and we had a legal analysis on that. We focused very much on DNA sampling and storage.

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And what we really tried to understand was

why was there disconnect with expectations. So why was it that this blood that was collected for arthritis research, on ancestral research, scientific research was done, why was it so offensive to the aboriginal groups that the research was being carried out on?

What we had to do was really also look at ourselves. Who are we as biomedical scientists and what are we focusing on and what is our expectation?

So we came up with some summaries that biomedical research is often disease-focused and the main purpose is to add to the body of scientific knowledge. Subjects are recruited and are necessary to provide data but they are not necessarily participants in the way the research is being carried out. They often waive any rights to profit while participating.

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And the data and samples become in the custody of the researcher and become owned as the researcher develops their own archive. Results are published and this is sort of a knowledge dissemination occurrence in peer reviewed journals.

They are not specifically directed back to the community where the health disparity might be

occurring. And so with this, what we tried to understand is that there might be expectation from the aboriginal communities maybe at divide with what the biomedical model might be.

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And this is when we actually looked at all of the various codes of conduct that were being developed in Canada in aboriginal groups and these predated a lot of our discussions, and these were across the country and almost every umbrella group were looking at research that--ways that they wanted research being done but not specifically about genetics. As a matter of fact none of these even addressed biological samples.

(Slide.)

But what they did talk about is a methodology. This is not specific to aboriginal communities. This is well-known and a well accepted type of research and has already been talked about, community-based participatory research. If you've never read Robert Chambers wonderful book from 1997 that talks about northern academics going down to the south world to carry out research to hopefully improve things in the south world and finding out they weren't really making a difference and then

questioning why is it?

Why--how are we doing things differently, why isn't this working and why aren't the improvements occurring? And it's a matter of stepping back and stepping out of our own sort of tower and listening to what the issues are, including people in the question, in the research questions, the way that the research is being done, sharing the data, sharing an understanding of what the results are, respecting that the community has specific needs, and that there are beliefs that may not be our own, capacity development.

In other words, you can't just walk into a place and carry out research without thinking about how you're going to develop--how capacity is going to be developed so that they can actually take it over themselves. So, all of these main principles were actually utilized in the guidelines, the Canadian guidelines.

(Slide.)

But again they did not talk about DNA sampling and it is a reasonable expectation that once you actually have the system of the circle, this continuous circle and this continuous conversation that it doesn't separate just because

you’re drawing blood, just because there’s a biological sample that’s part of that.

The biological samples are really part of this continuum and when we look at the Nuu-chah-nulth case that’s truly where it fell apart. We had an excellent anthropologist/geneticist who was intending to do research in a very participatory manner with the Nuu-chah-nulth so he went in there.

He talked about physiotherapy, about community programs. The consents were very community participatory--made in a participatory manner. They had community members actually working on part of the research.

But where it fell apart was once the blood was drawn that’s when the biomedical model kicked in and that’s where the separation--disconnect occurs. This is not a part. So aboriginal people are considering this all to be part of the continuum and as biomedical researchers we’re saying, “Oh, but this is our biomedical model. This is where disconnect is.” And this is what we really had to consider over the last ten years and what this means for policies in Canada.

(Slide.)

And this is where from 2003 to 2007 the

Canadian Institute for Health Research worked on developing guidelines for health research involving aboriginal people. So these were adopted in 2007 and started to really kick in just at the beginning of the year in 2009. So it has been a long process and had to go through a vetting process that also included of course legal counsel. So a very big process but what we were, were 12 individuals. The majority were aboriginal, although there were researchers from all aspects. It was led by Doris Cook who was a Mohawk policy analyst from Health Canada before she joined the CIHR. It was co-chaired by Francine Romero, who some of you may know, from the United States and also Larry Chartrand, an AP scholar. So big input from the aboriginal voice and vetted through hundreds of aboriginal communities in Canada that were connected through our umbrella research programs.

So these research guidelines are very similar to the participatory approach that I spoke about. The clincher is that for individuals who are being funded by our CIHR they have to adhere to these guidelines. If they don't adhere to the guidelines their research funding will not be released by the ethics boards or they could have

their research funding taken back if there is a violation of it. So this is quite binding what has been actually developed through there.

(Slide.)

I can honestly say supported at every level of the CIHR. So there really has been buy in for this.

I think I have another five or ten minutes here so, in fact, I'm just going to go through a few of the relevant articles.

"A researcher should understand and respect aboriginal world views."

"A community's jurisdiction over the conduct of research should be understood and respected." (Many of the issues that Rebecca spoke about)

"Communities should be given the option of a participatory research approach." If a community says, 'You know, we don't want you doing the research. We're just way too busy. We have treaty negotiations underway. We've got other things that we want to deal with.' That's fine. A waiver occurs. They don't have to have a participatory approach but they need to have an option of that.

They retain inherent rights to any

cultural knowledge and this is particularly important for social science research and also ancestral DNA research, too.

"Research should be of benefit to the community." And, of course, the researcher would not be doing it just for altruistic reasons. The researcher is doing it because this is also of interest to them.

"A researcher support education and training of aboriginal people in the community, including training and research methods and ethics." Clearly all of our projects--there is pressure that we need to be able to ensure that there is an opportunity for aboriginal students to play a role in this.

(Slide.)

A researcher--now knowledge dissemination: "A research to the extent reasonably possible translate all publications into the language of the community." Hugely expensive for me to do that into Inuktituk but I have to do it. It's a part of our agreement.

"A researcher should ensure that there's ongoing, accessible and understanding communication with the community." I should say that the CIHR

does understand the expense of these issues so we are able to put this into our funding request.

(Slide.)

Secondary use of data: And this is where the clincher is. “Biological samples require specific consent from the individual donor and, where appropriate, communities.” If the identifiers have been removed and there is no way to identify the individual, then if there is an ethnic group like the Dene that has been identified as part of this research, you will go to the Dene organizing group to say, “Now that we’ve completed our work on CPT1 it also looks like there’s important work on tuberculosis that could be done and can we do this?” And so then it is vetted through basically the group of stakeholders who would have some responsibility for that.

“Where the data or biological samples are known to have originated…” Yes. “…the researcher should consult…” so that’s exactly what I just said.

(Slide.)

And this is a concept. So Article 13 is not really different than the articles in 12 or the components of 12. This is really the mindset. So the mindset says “I have this DNA. This DNA--I have

been loaned this DNA t carry out a particular type of research. I haven't been given this DNA. This DNA is not a gift. I have been loaned this for a particular type of research."

So the mindset says "because this is not mine then it makes sense to go back to the owner and ask the question." So what this does is it just changes our mindset about how we regard things. This--you could go the step of saying, "Well, we want a tribal controlled DNA bank so all DNA stays in one area where this is controlled by this organization that actually makes all the decisions."

Or what you can do is try to change the mindset of the whole culture of research and say "We're going to do things differently," and then that might not be required. So this is the way that it has been adopted by the CIHR.

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Interpretation and acknowledgement: The groups are participants and so they have a role in being acknowledged, especially if they're involved in the research from every step of it and there usually will be one or two key people from communities who are involved at that level.

(Slide.)

I like to use the analogy I have academic colleagues from around the country and it is really appropriate for me to be running the collaborative questions with them about the research methods, about the results, about the very early drafts of paper. Well, if you just--again the communities are our collaborators. If they are cons

I came from McGill. Dr. Charles Scriver did this right from the beginning when we were doing high school screening for genetic conditions in the 1980s. He went to the community leaders. They were always part of the picture. So this isn't that much of a stretch of what we were doing. So this slide to me really does say what all those articles do except it puts it into one picture. This really is a continual conversation that never ends and it is--there are many questions about how to do this outside of a specific community context, and I could talk about that because there are ways to do that, too, and they are dealt with in the policy.

(Slide.)

You may have a copy of our Tri-Council Policy Statement, which is Chapter 9. This is one step up from the CIHR. So this--what this is, is interesting. The CIHR--they really guide and

control us as individual researchers. The Tri-Council is this policy statement on ethical conduct where every major funding agency in the country, so the Natural Sciences and Engineering Research, the Social Sciences and Health Research or Social Sciences and Humanities Research Organization, and the CIHR all have to adhere to Chapter 9.

Chapter 9 has been under revision for many years and has now adopted the articles of the CIHR. They have not specifically said DNA that I've seen in their last version but what they have demanded is that the articles under 12 are accepted, which actually is the same concept. So in other words an institution, any researcher or any institution that doesn't adhere to these guidelines could then have their funding from all three rescinded. So, in fact, this is an even much more powerful statement because it's institution based.

(Slide.)

So this quote comes from one of our--from our colleagues Joe Kaufert and Kathy Glass, our legal colleague and anthropologist, who worked a lot in informing the work that we've done. And after their first NCARE conferences their final quote was "With respectful dialogue and considerable hard work

traditional aboriginal values can co-exist with mutually productive connections between genetic researchers and communities." And many consistent people have been involved in this. It is a collective that has worked on this.

(Slide.)

What we want to do and what we aim to do is really have research that is enabled but protected and this is just some examples from our own Community Genetics Research Program in the University of British Columbia that are now based in Victoria where we are carrying out several genetics projects. A Long QT Syndrome in a very large--two very large communities in Northern British Columbia, a predisposition to sudden arrhythmia death; Primary Biliary Cirrhosis in the Pacific West Coast; Genetic and Nutrient determinants of congenital heart defects in the Inuit of Nunavut.

And we're looking biological causes of infant mortality, not excluding of course all of the social causes. We're looking a lot at social--at infant mortality in general across the north but also on a fatty acid oxidation variant.

So we are able to enable research and have it carried out with this methodology and finding

across the country that it is effective.

(Slide.)

There's our group.

I think that's about it for my time.

(Applause.)

DR. ROYAL: Thank you very much, Dr. Arbour, for really providing a framework for us to think about these things in terms of policies. Canada has really thought this through. I'm sure we have a lot to learn.

Our last but definitely not least speaker is Morris Foster and Dr. Foster--when you look at his bio you see a whole lot of administrative stuff at the top there. He has become quite the administrator but I've known him as an anthropologist and prominent researcher on areas of genetics and communities--involving communities.

He's Deputy Director of Prevention and Control in the Cancer Institute there in their Diabetes Center, the Director of Outreach and also Associate Vice President for Research in the University of Oklahoma. But Dr. Foster has a long history of writing and talking about and offering insights into how we involve communities and groups in genetics and genomics research and he's going to

help us to think about how we might conceptualize the policies and guidelines in the U.S.

Morris?

PERSPECTIVES ON U.S. POLICY NEEDS FOR GENOMIC RESEARCH AND DATA SHARING THAT INVOLVES GROUPS

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DEPARTMENT OF ANTHROPOLOGY,
ASSOCIATE DIRECTOR, CENTER FOR APPLIED SOCIAL RESEARCH, UNIVERSITY OF OKLAHOMA

DR. FOSTER: Thank you, Charmaine.

(Slide.)

I was telling Charmaine earlier that the first time I was in this room was 13 years ago in a meeting in 1997 that talked about genetic variation and many of these same topics came up in a smaller part of that meeting but they've been with us some time so I feel that I have aged with the debate.

(Slide.)

There are a number of challenges. You've heard already many of them. Obviously social groups are not constituted based on biological characteristics but--and here's the big but--social groups nonetheless tend to have non-random frequency distributions of biological characteristics,

including genetic variants. And those distributions often go unmistaken both by the public and by some geneticists for biological definitions of group membership or at least in the way that geneticists write about and use social labels it implies that there is some unique relationship between the biological characteristics and group membership.

(Slide.)

But social groups have differing kinds of groupiness. “Groupiness” is a technical term that social scientists use.

(Laughter.)

There are some groups that are very well constituted and very well organized, and indigenous and American Indian communities are often are of this sort where there are government-to-government relationships, where there are various kinds of elective representative bodies, many of the tribes that I work with in Oklahoma now have IRBs, where you have clear paths to follow in working collaboratively. But there are many other groups that aren’t as “groupy,” that don’t have representatives, organizations or entities that you can go to, and it’s much less clear how you consult and collaborate with those kinds of groups.

But no matter what group you're talking about there's a great deal of heterogeneity and viewpoints. In some communities it is less heterogeneous but still there is some heterogeneity there. In others it's very heterogeneous. And one of the challenges that Charmaine and I and others who have been working through the ELSI program from NHGRI have tried to work on is how do we hone our social scientific tools to explore that heterogeneity and to represent it. I think that's still a work in progress.

Nonetheless, as others today have pointed out, group labels when used can have uniform implications for all members or for everyone who is ascribed to being a member of that group. So even though there may be heterogeneity of viewpoint within the group, the label itself tends to stereotype and tends to be taken as the more monolithic representation of viewpoint and membership and characteristics than perhaps it may be.

(Slide.)

The debate about race and ethnicity in genetics has been going on for a long period of time and by some accounts, the most recent iteration, for

more than 100 years. Many scientists continue to naively use social labels for biological data. You can just open up any issue of any genetics journal for this year and see uses of social labels that still lack scientific rigor, that are still convening labels rather than meaningful labels in a scientific setting. The media and public continue directly to link race and ethnicity with unique biological characteristics. Again you can see media reports of *New England Journal of Medicine* studies or epidemiological studies in the last year and see that that continues to be the case with the media.

At the same time individual risk for disease often are more important than group risk for understanding personal health and even with that caveat, from a personal point of view, nonrandom frequency distributions of biological characteristics among social groups are meaningful. I have a number of anthropological colleagues who would like to say “let’s not talk about groups at all, let’s not talk about race and ethnic identities at all in biomedical studies” but they ignore this point that biological characteristics are not randomly distributed across the social landscape. So there is some meaning there that we have to pay

attention to.

Population stratification from a genetic point of view is a valid analytic approach for dealing with aggregate data. It is still important to think about population histories and population differences at an aggregate level with respect to frequency distribution when we do association studies and other kinds of studies.

So health disparities at the group level are a product of both non-random social and non-random biological frequency distribution of contributing factors. Again a number of my social science colleagues would like to talk only about the non-random social distributions and not about the non-random biological distributions.

(Slide.)

If there were a straightforward solution to the challenges of using group labels in biological and biomedical research we likely would have adopted it by now. We haven’t. The debate seemingly goes on and on without providing us with solutions.

(Slide.)

In that discussion of societal implications concerns about group risks have

outweighed concerns about group benefit. So we've had a lot of discussion in the literature about how to protect groups from collective harm as a result of the inappropriate equation of social labels of biological data.

We haven't had a lot of discussion, although you've begun to hear it today, about how do we ensure that non-majority groups have equal access to genetic-based diagnostics and therapeutics? I think that an important area going forward is not to ignore the issue of collective risk but to pay more attention, as we seem to be moving towards some actual clinical benefits as we heard some yesterday, more attention to the social justice issue of how we ensure that the benefits of these emerging diagnostics and therapeutics are equally distributed in, hopefully, a non-random way--sorry, a random way equally distributed across all different kinds of groups.

(Slide.)

In the U.S. concerns about group risks have been complicated by respect for individual autonomy. Except where you have a legally constituted group such as an Indian Tribe that has a government-to-government relationship group consent

has not been taken to trump individual consent. Guidelines for community consultation and other stakeholder approaches have not fully resolved the challenges of representativeness in heterogeneity. And that is to say having been someone who has done a number of community consultations and done a number of stakeholder studies we still haven't fully ensured that the participants in those consultations are representative of their community, are fully representative, and that we can find the full range of different viewpoints from those exercises in the communities we work with.

Obviously the smaller the community, the better organized the community, the more likely that we will come out with a representative collection of viewpoints. But as we work with African American communities, with communities that have hundreds of thousands or millions of members it is very difficult to say that what we get out of our consultations are, indeed, fully representative or even partially representative.

And self-reported identity almost never is further interrogated. And I don't mean to say by that that self-reported identity should be skeptically questioned but rather that the identity

that someone reports in a moment of time may not be the identity they would have reported ten years ago or ten years from now. How we frame identity, how we assert identity is itself, because it's social, often a changeable and evolving thing. Nonetheless, in genetics studies self-reported identity is treated as a very static and monolithic thing and it's not given its full social characteristic. It tends--instead tends to be transmuted into more of a biological characteristic.

(Slide.)

Also in the U.S. group benefit has been complicated by legal definitions of inclusiveness. All of you who have sat in NIH study sections have come up to the end of the discussion of a proposal and had to evaluate the proposals that involved human subjects for whether it fit the OMB guidelines for racial and ethnic inclusion, for the inclusion of minority groups. And almost always the PI has said that--some formulaic phrase that participants will be recruited to reflect the racial and ethnic profile of the local communities from which they will be recruited.

What that usually means then is that they will be included but they may not be included in

numbers to be statistically or scientifically meaningful. They will be included to satisfy the OMB guidelines but it probably won't, unless it's a minority focused study, actually have any scientific value to that inclusiveness.

So identities that are legally and political relevant may not be biologically or biomedical relevant. Again particularly in the context of specific research questions and this is an important thing to pay attention to because as you propose guidelines for inclusiveness or whatever process one might want to propose you also want to think more practically how will PIs actually connect those policies. How will study sections and NIH centers and institutes actually hold people or not to those? And the usual practice is that people will find a formulaic way to deal with it without dealing with it in a meaningful scientific way.

(Slide.)

So is the race and genetics debate a fundamentally non-Darwinian creation that is incapable of adapting and evolving? Much of the race and genetics debate has been just round and round a very circular debate in the literature and it doesn't usually come out with any step forward.

I don’t want to invoke the notion of progress because that might be not really a Darwinian notion if we know that progress is relative to the immediate environment but it just seems that we have these meetings--again I’ve done this for 13 years at NIH and we don’t seem to really go much forward with it. So I’m going to suggest that several scientific developments may suggest a way forward.

(Slide.)

Increasingly, many studies are using genotype, not self-reported identity to do the population stratification, and that’s possible because--although this is still a debate in the literature--we’ve seen that genotyping is more accurate than self-reported social identity to stratify populations. And it’s also possible because of the significant decreases in the cost of genotyping so you can use a very inexpensive filter on your samples to do this without having to rely upon self-reported identity.

The potential risk though is that genotype such as ancestrally informative markers could become surrogates for social and ancestral identities, and actually you see that a lot on the direct-to-consumer genealogy and ancestry websites. While

this may be a good scientific strategy that brings the science away from relying on socially and politically relevant social identities it may nonetheless be reified out there in the public and in the public extension of genetics, which is the internet, to really create a new way of actually using biological characteristics, the ancestrally informative markers, as definition of group membership.

(Slide.)

We're also seeing arguments that rare variants and rare structural rearrangements may be more important than common variants as contributors to some common diseases. And if that, indeed, is that the case or if that is even partially the case it really re-emphasizes the benefit to members of non-majority groups to take part in genetic research and to share their data.

So if diabetes, for example, is not the result of a few common variants but rather of rarer variants that are more in a greater frequency distribution in some populations than others then doing genetics research in those other--in those populations becomes more of a benefit and more of a

social justice question than we previously had thought.

This also refocuses the scale of relevant groups on smaller populations with more recently shared ancestral histories. So it's not all African Americans. It may be African Americans in Oklahoma or African Americans in Philadelphia. And those smaller scale populations are actually--actually prevent less of a challenge for things like community consultation and community collaboration because you're not dealing with millions. You're dealing with thousands.

The potential risk, of course, is that rare could again be mistakenly interpreted to mean unique or group specific. So what I try to do when I talk about genetic variation to students is to talk about frequency distribution--greater frequency distribution and less frequency distribution rather--of a particular variant in a particular population rather than implying that a variant is rare in a population or is a rare Navajo or whatever variant because that's not really the case.

(Slide.)

Will personal genomics save us all? Well, of course, personal genomics will save us all.

(Laughter.)

It will, though, provide some greater emphasis on individual data than on aggregate group data. It will perhaps shift greater emphasis to individual risk rather than group risk for a particular disease. And obviously we're going to have much more individual data.

However, as we see with the direct to consumer providers they tend to rely on convenient reductionary (sic) categories when interpreting personal data and they use very "groupy" ancestry analyses so that you can go to one of these sites--I think maybe it's 23--one of them, and have yourself genotyped. And they will offer membership in either a sort of social media club of other people who have the same variant that predisposes you to a particular disease or they will put you in touch with a network of other people who have the same mitochondrial variant.

It is a reductionary (sic) process. They are just using biological data, genetic data in this case, to create new kinds of social groups which will themselves be "groupy" in their own ways. So that is actually a potential risk that personal genomics has for perpetuating the use of biological

data to define social entities or social groups and in that case to create social groups.

(Slide.)

So here are some policy suggestions: I think we need to continue to hold geneticists and other scientists in using social labels in association with biological data appropriately and only when scientifically meaningful.

I think there have been improvements in this area over the last 13 years that I've been involved with this discussion. I think particularly the improvements have been primarily generational. You see younger geneticists who are more sensitive to these issues and I think it's because they have actually been educated in programs where these topics get talked about where 20 or 30 years ago they weren't as much talked about.

Clearly we need to continue to educate the media and the public about the significance of the non-random frequency distribution of biological characteristics by social groups. We need to give them some different ways--and this is an awkward way of doing it--an awkward phrase. We need to give them different, easier, convenient ways of talking about genetic variation than they currently use. So

it’s not the Jewish gene but a different way of saying that that doesn’t imply that it’s unique to people of Jewish ancestry.

We need to continue to develop social science approaches to community consultation and stakeholder analyses that are more robust with respect to having representative samples of people who participate--people who are representative of their communities and that also bring out the heterogeneity of viewpoints within communities. It’s not that we want to bring the community to a consensus, rather it’s we want to understand the different viewpoints among community members.

I think we need to disentangle the legal and regulatory requirements, such as the OMB categories, from scientific design and evaluation for scientific proposals.

I think we should emphasize smaller scale groups and the non-random frequency distribution of biological characteristics among those groups. I think actually we’re going to be driven to that smaller scale in any event as we are able to generate larger and larger amounts of genetic data about individual patients and individual participants.

And I suggest not mandating policy prescriptions because we've seen what the OMB mandate did and we've seen how people work around that. I think that when you mandate a policy prescription for these kinds of issues you end up with a one size fits all approach that, in fact, of course doesn't fit all. And you see researchers and you see people who evaluate research proposals and you see institutes that fund research proposals finding ways to deal with it that actually minimize the impact of the change that you're trying to make.

Thank you.

(Applause.)

DR. ROYAL: Thank you very much, Morris, for giving us some things to think about in terms of policy.

We're going to take a 15 minute break and then we'll come back for discussion with the panel.

CHAIRMAN TEUTSCH: So just to keep us all oriented we have--a couple of things. One is we've run a little bit over so we'll probably have a slightly shortened discussion period because we have to get to some of our thoughts about what we want to actually transmit. So that will be the focus of this morning's discussion.

Everyone is invited to partake of some cake which has been bestowed upon us by the staff actually of SACGHS in recognition of the committee's work. It's a little ironic since they do all the work and we should be thanking them, and we'll get to that later.

(Laughter.)

But, hopefully, everybody will enjoy that and thank them.

(Whereupon, at 10:20 a.m., a break was taken.)

CHAIRMAN TEUTSCH: Okay. Folks, let's regroup.

I will be turning this over to Charmaine. We'll have a chance to direct--what's that?

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: She's having a social event back there so I'll recruit her back.

But we'll have a chance to direct a few questions to our speakers and then go on to talk about what we might want to say in our letter.

Charmaine, would you like to MC the Q&A?

COMMITTEE DISCUSSION WITH SPEAKERS

DR. ROYAL: So we are going to open it up now to discussion and questions for our panelists.

I know Morris has to leave soon.

So if you have questions for him, Morris, Dr. Foster, you may want to direct them to him early in the process.

So we'll just open it up to you for questions that you might have for our panelists.

Again, thank you all for your talks. You've really brought a lot of issues to the fore that we need to think about. Thanks.

Rebecca is reminding me what has been--what--six or seven years since we--I was at ASU at a meeting that Rebecca had invited me to and so it's good to see you again.

But Rebecca is reminding me to just say that you're not--don't be afraid to ask questions. I mean very often people feel a little touchy around these issues and these topics, and you feel like, oh, I don't want to ask that because I'm going to offend them. She has reminded me of something that the two of us always talk about is that we need to be open about these issues so ask any questions that you have.

CHAIRMAN TEUTSCH: Rebecca doesn't know us very well, does she?

(Laughter.)

DR. ROYAL: Paul?

DR. BILLINGS: So this is actually directed to the panel at large though I started thinking about it during Professor Foster's speech or talk. I'm interested in the discordance in the adoption of the technology of DNA-based technologies in different parts of the lives of people. So, for instance, the use of DNA forensics or DNA to solve in a judicial matter, let's say inclusion or exclusion in a certain group, may be slightly more advanced or more adopted in a practical sense than let's say the use of DNA or its demonstrated utility in a clinical sense.

And I just wonder whether for certain groups that discordance is confusing or sets up expectations about the power of the technologies or the lack of power of the technology which might have to be considered.

DR. FOSTER: So I guess one way to look at this is--one of my colleagues, close colleagues, at Oklahoma is John Mulvihill who is a medical geneticist, and John's medical genetics service regularly sees tribal families who are referred by either the IHS or the tribal health systems. Sometimes he asks me to sit with him and talk with

family members about these issues.

When it is about a very tangible condition and a very tangible syndrome that people can--family members can say, “Oh, I know Uncle so and so who had that,” and so on. When you think about it in terms of inheritance rather than DNA and you think about--you talk about it that way, it’s a very different matter than when I go to a tribal meeting and talk about doing a genetic study that is distanced from people’s experience.

So I think it has a lot to do with how people experience it, whether it’s something in prospect and very mysterious because of that, or something that’s very, very concrete to the situation.

Rebecca may know this better than I but I have heard that there is a tribe on the East Coast that has recently decided to include DNA ancestry testing as one source of information for tribal membership. I’m not sure if that’s a true report or not but it has been discussed before by some tribes.

MS. TSOSIE: That’s one of the consequences, I think, of that notion that somehow there’s a way to actually determine tribal membership through DNA. I know that has been very,

very contested. Right now the whole idea of tribal identity is a political construct. In fact, some tribes are composed of confederated tribes so there could be 12 different historic tribes and all of those bloodlines are represented there. So the idea that somehow you can test to see if you're actually that tribe and then maybe disenroll (sic) people who don't meet the standard or enroll people.

We did have a call to the program last year. Somebody had gotten a result that they were Native American on one of those computer ancestry tests and wanted to know what they could do to get their monthly check. We were like, "Well, gee, you know, that's a new one."

So I think that that is certainly a concern and I'm not sure if that tribe who was considering it actually followed through. I know they were considering it.

DR. DALE: I'd like you to discuss ownership, ownership of information and materials because we work at the interface of medicine, medical care and biological materials. I'm thinking about those as broad implications. I used to go to the barbershop and I'd leave my hair.

(Laughter.)

But I say that in jest. In Medicine we sample bits of bodies all the time and save the samples for various periods of time, and we--for instance, if you have your gall bladder removed it may end up in a tissue block that's saved indefinitely as long as the hospital lasts.

Now, so does that suggest to some of your concepts that from the individual or tribal perspective that ownership lasts forever for everything that leaves your body or where do you draw the line?

MS. TSOSIE: I will respond to that and then ask Laura to respond as well because I think that concept that you guys built into the code is meant to deal with that concept.

The way that I understand property--and I actually teach American property law as well as federal and Indian law so I have to think about property a lot.

So the way that we're taught within American property law to think about property is that it's a bundle of rights with respect to different people that are making claims to a particular resource. So it's not as though it's a static thing. Oh, my property is the car. No, it's

what are the rights. I have the right to sell it, to title it, to convey it, to lease it, whatever.

In that sense Native people, too, have concepts of all of those rights that people have with respect to a resource and that's why the analogy to cultural property is very instructive because the idea is that there is some categories of property in which the interests might be collective or they might result in the fact that you can't alienate it or that there are certain duties that you have which we might equate with stewardship or appropriate use.

Human body tissue, blood--there are a lot of Native groups here and in Latin America who think--you know, you have to be very careful with your hair, your blood--I mean you take care of that and you be sure that you know where it is and how it's disposed of because it has the essence of you in it. So it's not the type of thing that says, "Hey, I can sell it to the highest bidder." It's "No, that's part of me and, therefore, we've got to deal with that differently."

Now I know that one of the issues that I wanted to raise that I ran out of time or I don't know what I was thinking but there are national

repositories that serve the criminal justice system, the military, newborn blood testing. You know, I think that all of those have Native resources attached to it and to the extent that a Native person discovers--I know there was a military case where, you know, the claim was could you retain, in effect, ownership and control over that. As a religious claim maybe if you fit the constitutional standard for a First Amendment claim--right. But we have to deal with those categories of the law.

And I think that what I'm seeking is a policy statement that says at the gate maybe we should consult about those differences and figure out how to, you know, retain the rights or arrange the rights accordingly.

DR. ARBOUR: Thanks for that.

Those were the questions that we really struggled with over the years and it's not something that you can really address very well in a few minutes although Rebecca has just done a great job of it but we had hours and hours of discussion because for us again the clippings of hair means nothing but then we heard over and over again it meant a lot with many of these groups. We knew that we had to sort out these issue and we did have legal

scholars come and try to help us sort out the issues of whether this does become some sort of cultural property.

We know that we're not dealing with everything. We know that there are pathology samples all over the country and, as Rebecca said, there are newborn screening samples all over the country so we know that we haven't dealt with that.

But in the context of what we were working with, which was going forward with research in a way that enables and protects, we were able to come together with this concept to say that we, as researchers, may have a different concept of ownership and that we need to come together.

So as you read through the guidelines you'll see there's partnership there. It's not unilateral ownership by one. There's partnership so once you're involved you also are a partner in that. So you're not giving--your sort of traditional--as a matter fact one young researcher came up to me and said, "But I have rights as a researcher, you know." And so we're not giving up that. We established this with a level of partnership so that's--we really had to move forward with that and to try to

analyze what property meant to us and what property would mean to others especially in the context of biological samples.

DR. ROYAL: Gwen?

MS. DARIEN: So I hope I'm not going totally off topic but Vence's talk really reminded me of this, which is the harm of nonparticipation. I have done a lot of work in cancer health disparities and one of the issues--one of the things that I coauthored a paper with Mary Scroggins on was about unconscious bias and what it does in terms of participation in clinical trials and clinical research from minority--from ethnic and racial minority communities. And Vence's piece about genetic research reminded me of some of the research that we wrote about in *Cancer Research*, which is that people were absolutely willing, particularly the African American and Latino communities were studied, to participate in clinical trials but they were never asked. So I think that the other side--the flipside of it is by not participating there is also group harm.

So I don't know--Vence?

MR. BONHAM: You're absolutely right and I totally agree. I think as groups think about policy

this question of not taking the stereotype position that African Americans are not going to participate or Latinos are not going to participate or, you know, groups are not going to participate, but how do you do that? How do you reach those communities so that they actually are involved and participating in the research? I think that's exactly right and I think it's going to be a major issue around the field of genomics that we have to take the steps to make sure that we're reaching out in an appropriate way to recruit the participation of different communities.

We already know with our genome-wide association studies that it's very clear that the majority of those studies have been in European ancestral populations. Part of that is from a scientific design but part of it is also I think from a perspective of research participation and the challenges of getting individuals to participate in studies.

DR. ROYAL: Barbara, and then Marc.

DR. McGRATH: Thanks. A great morning and everybody I talked to during the break said the same thing so thank you all for doing this and Charmaine for organizing it.

One thing that didn't come up that used to come up a lot in this discourse particularly after the Human Genome Diversity Project was the notion that--and you alluded to that, Dr. Foster, about when the clinical benefits of genomics come to fruition these will become greater. I don't know if we're there yet but there was a lot of talk about the resources that are spent on genomic technologies could better be serving these communities who have more basic health care needs, many of them, not all, more basic health needs. So the diversion of resources to an area that may not be their priority issues, is that--where is that discussion these days?

DR. FOSTER: You know I still hear that particularly around diabetes and genetic studies of diabetes because that's a very big issue in tribal communities in Oklahoma.

I think that's a larger public policy question because if the money wasn't spent on genetics studies it wouldn't directly go into diabetes treatment but that's still a tension.

I think as we see more actual benefits coming to the clinic, and they're not coming very quickly but at some point you'll have a tipping

point, then I think a bigger issue will be the way in which the Indian Health Service and Tribal Health are underfunded to take advantage of those. I mean typically IHS and Tribal Health get new therapeutics, new diagnostics five or ten or even more years after they are more readily available and that's a very economic reason for that.

MS. TSOSIE: And I actually wanted to weigh in on that, too.

I think that the two comments that have been made actually I want to think about together. It strikes me that that idea about the harms of non-participation is because there is some distrust about how the research is being designed, like what are you studying. So an example of that is the response to this idea of personalized medicine, and I know that that's very timely and people are thinking about it in a consumer-driven way a lot. Like what's the benefit not only to health but to consumers and knowing what's going to be a good therapy.

In the Native community we are--you know, it's not even the access to what was the latest thing ten years ago. You're thinking--well, personalized medicine is probably--you know, 50

years down the road. You know, why should we buy on to that?

So I think the research design is important and that idea of Native health as being group system based--that's the other thing I want to mention in terms of our ideas about genomic governance. We have to take into consideration that there are Native health systems that predate the Indian Health Service. The Indian Health Service is an overlay on the Native system. And now what you guys are doing is transcendent because it's genomics as the possibility of health benefit. We're navigating three tiers of systems trying to figure out what's good policy for Native people. So that's part of the challenge.

DR. ROYAL: Vence?

MR. BONHAM: With regards to the African American and Latino communities that we've been involved in doing research the same issue comes up. "You know, I'm just trying to get through the day. You know, why should I be involved in research? And you're taking, you know, this money and it's going off and we need to have basic health care in our community." And I think we have a responsibility to be clear on exactly what percent

of funds are really going towards genomics research and how does that fit into the larger research that's going on around biomedical research.

Then I think the issue of how you think about genomics research and understanding how environment and the genome interact, and the issues around that, and that we need to be able to articulate that both to potential research participants but to the broader community and policymakers really framing how the work fits into the larger field of biomedical research to improve health.

DR. ROYAL: Marc, the last question.

DR. WILLIAMS: So, you know, in hearing Morris talk about the fact that there will not be a one size fits all solution, which I think clearly is the case because, you know, when we think about--what I hadn't appreciated before is the--you know, the legal and governmental implications of the relationship of Native governments to in this case the United States Federal government and how things may need to be defined differently and have certainly been defined differently in Canada relating to health research, and to think about groups that maybe have significant heterogeneity of

belief, such as African Americans and Hispanics. And then, you know, sort of intermediate groups where there are communities like the Amish or the Hutterites where there's clearly a community but not in a sense of having a government that one would interact with but where there is the need to engage the community around the rules of engagement.

It can get very complex and so I guess what I'm trying to ask is, you know, are there-- policy in some ways is easiest to do if you just do one size fits all and clearly we're saying it doesn't. So how do we deal with that tension? Are there any ways that--any ways forward to address the issue of--that Morris raised that we've been doing this for 13 years and we haven't seemed to, you know, get anywhere?

DR. ARBOUR: Yes. Yes, a big question. There isn't one size fits all and even within aboriginal groups there's going to be different governing structures. It's very, very different with the Inuit compared to First Nations and half of our First Nations' populations of Canada live in urban centers and they're not specifically governed by their ancestral tribal group.

The concept, though, of involvement, the

concept of participation, of consultation, of really listening I don't think should be different. It doesn't matter what group and it doesn't matter whether there is a governing body or not. There's always a way to be able to try to understand and listen to what the issues are and how to address it.

So when I wrote the DNA on loan article, as I mentioned to you, one of the reviewers said, "So why is this just about aboriginal health and why not for everybody?" And in that article I actually go through three different paradigms. One is community-based, one is sort of a population base which might not be one community but many communities within a population, and then how to deal with those that just happen to have a condition and it has nothing to do with them being indigenous or not.

Sort of the middle ground of that really is to have just a general level of respect in consultation and consider just the same issues that we've all been talking about that our beliefs are not necessarily the beliefs of others, and it becomes the routine.

I grew up in community genetics of Quebec and it was just that's what my genetic training at

McGill for genetic counseling, for medical genetics residency, for fellowship and then going on to be a clinician, and it's just natural. It feels like an appropriate way to do things.

MS. TSOSIE: And I want to thank you for raising that. I think that is one of the pivotal issues going forward. Not in the sense of getting, you know, so frustrated that you think "Wow, this is so complicated. I don't know. Forget it. That's for the next. No, you guys are the leadership." You guys have started this dialogue and that's the dialogue that needs to happen.

So just affirming the work that Dr. Arbour has done in Canada I would say here in this country we have a framework already for what you've started there at least with respect to Native people. I'm going to defer to Vence to talk about how other groups might be represented here.

But we have an order, an Executive Order, that demands consultation with American Indian and Alaska Native governments any times there's a U.S. policy that affects their interest. Well, this one does so let's have a formal government-to-government consultation.

Also there are tribal laws on the books.

There are tribal IRBs.

And we had a discussion, Dr. Foster and I, about the fact that some tribes in the Southwest, like the Navajo Nation in the wake of Havasupai issued a ban on genetics testing. I mean so that's a ban. Whereas others in Oklahoma are willing so long as the research they consent to and they buy into the research design.

So we have that diversity of tribal laws among the governments and I think that that was something that came--that was very fruitful from the process that led to DNA on loan.

DR. WILLIAMS: So maybe if I can follow up with a little bit more precise area. I mean in some ways what we do is we legislate to exceptions.

CHAIRMAN TEUTSCH: Actually I'm going to cut this off because we've got to get on to some of the--what we're going to do with this topic and we have a limited--we only have about 35-40 minutes. So I--

DR. ROYAL: And we might come back to them, Marc, because I think--

CHAIRMAN TEUTSCH: Yes, there are a lot of issues here and they are really challenging.

Charmaine, I know you have some things you

want to put out on the table in general.

DR. ROYAL: Right, we do. And, again, to go--Marc's question is very topical in terms of how we move forward. So I think we'll get back to it and talk about that but I want to thank our panelists again for their talks this morning.

(Applause.)

COMMITTEE DISCUSSION

DR. ROYAL: And you're welcome--the committee is going to discuss it but you're welcome to stay and join in if needed. Okay. Thank you very much.

All right, so we have a few things that we came up with in terms of what might go into this letter to the Secretary and they--I'm going to just run through these slides pretty quickly and then we'll come back to discuss them. And based on our conversations yesterday I guess we'll figure out whether we just go with the top bullet points or whether we get into the details that we have put below.

(Slide.)

So our first slide there in terms of recommendations or just topic areas within this broader topic of genomic research and data sharing

involving racial, ethnic and indigenous groups, one issue is the adequacy of current knowledge about the perspectives of groups in genomic research.

Our two points there is that--one of them is do we need more research in terms of what groups feel about or they think about genetic and genomic research? And then the second bullet is has the research that has been done, which we know is not a whole lot--there has been some with African Americans, done with Hispanics and some with Native American groups--but has the research that has been done been effectively incorporated into policy?

(Slide.)

The next point is the importance of considering cultural perspectives in the design of genomic research studies. This whole thing of community engagement, and we didn't talk a lot about that but there has been a lot of work on community engagement--using community engagement as a tool to involve groups and to hear about their perspectives. There has not been enough about how successful this approach has been in informing us about cultural perspectives and the question about do we need more work on community engagement. People do it in different ways. There are different models of

engaging communities. Which ones work? Which ones don't?

How can we achieve balance between the cultural perspective of the group and the researchers and the goals of research? And a major area particularly for many indigenous groups I know is the area of ancestry inference and migration studies and that kind of thing. How do we balance what researchers want or are interested in with what communities think?

(Slide.)

Then the question about the role of IRBs and the regulatory groups that we already have in place and whether IRBs are carefully considering issues related to groups. Is there additional guidance that IRBs may need in terms of group harms and addressing them? Can these policies be flexible enough to address the issue of diversity, which I think that gets at some of what Marc was asking about in terms of policies and how do we make them so that they respond to the diversity within these groups? And how can we effectively inform individual research participants about the implications for their groups?

(Slide.)

And then the adequacy of policies in the U.S., the ones that do exist that even include any issues about groups. How adequate are they? Should we think about expanding OHRP scope to include groups? Currently their focus is the individual and should we recommend that they consider groups as well or are there additional policies that we need relating to groups?

(Slide.)

And then, finally--I think this is the final one. I can't remember--relates to the policies of other countries and Laura talked about what Canada has done. Are those applicable to the U.S. in terms of even the process and then again the policies? Some of the tribes that are in Canada are also in the U.S. Are those policies that apply to the tribes in the U.S. relevant to the same tribes--to tribes in Canada relevant to those same tribes in the U.S.? And do policies, for example, the Canadian policies, are they even relevant to us in terms of how we think about formulating policies here in the U.S.

So that was a brief going through. So we're going to just go back to the first one and then talk about what we think. I don't know if

there are any general thoughts about how we might approach this, whether we just go with those top five or whatever our big areas are in terms of our recommendation or whether we get more specific into these questions that we think might need to be addressed by some other group. I mean SACHRP (ph), I think, is a natural group that we could think about currently focusing on individuals but maybe we need to recommend SACHRP expanding their scope to include groups.

(Slide.)

So the first one, the adequacy of current knowledge about the perspectives of groups-- again if there are other issues that the committee thinks that we don't have here that might be key to a document that we send to the Secretary, we are also open to that as well.

DR. EVANS: What are we going to do with all our leftover time?

So I would ask--I think there are two issues that are encompassed by that first bullet and that is that I suspect that we do need more research among both groups that have been identified but also about other groups.

I guess the other thing I would point out

is it seems to me there is a really woeful lack of knowledge among researchers about even the data that we've already approved. So I think that that adequacy of current knowledge also gets to the inadequacy of knowledge among the--within the research community and there's a tendency to just--you know, as Dr. Foster said--you know to check off the box and not really appreciate the different perspective.

DR. ROYAL: Sorry, David.

DR. DALE: I will comment. I think just a couple of points. The answer--the simple answer is yes. We saw in the surveys that have been conducted the word "research" has connotations and even there anyone who is trying to do this needs to dig deeper into whether--what somebody thinks of when they think of research. I think it's terribly important for us to pay attention to that aspect because it has a negative label for many people. Whereas, in fact, people who understand what a researcher is trying to do might have a more positive reaction to a proposed study. There is a lot of subtlety there.

DR. ROYAL: Yes, that's a good point. I think, David, you're talking--you're speaking more to the type of research and the depth of the

research that we do probably moving beyond just quantitative to doing more qualitative work where we probe the perspectives and the underlying values and beliefs that inform those perspectives.

DR. DALE: Well, I think even many of the people around this table would say don't do research on me. Whereas, if you understood what was actually going to happen that might benefit you or your group you would know--you might say yes.

DR. ROYAL: Any other thoughts on that bullet?

Okay. So, in general, we think that that's probably a point that we need to make that there is inadequate research and we need more and we also need to ensure that that research gets translated and communicated to the researchers in terms of them being able to apply some of this even before we get to it.

Okay, Symma, something? What is it?

Steve, Sarah, something?

Okay. Okay. I mean, I'm just hoping that we're going in the right direction.

CHAIRMAN TEUTSCH: I think our challenge is going to pull those ideas together in something we can agree to because we won't be able to do much

after that. So, hopefully, Symma is capturing this and my guess is we'll need to at the end of this afternoon to go over some wording to make sure that the ideas here are framed in a way that we can get approval by the end of our session this afternoon.

DR. ROYAL: All right. We're trying to get there. Okay.

(Slide.)

The importance of considering cultural perspectives: This I think builds on the first one or it's connected to the first one but in the design of research, and speaking specifically to the issue of community engagement and how we even find out about community perspective and how we actually do research with communities is a question. There are researchers that ask all the time "I want to do a research project. How do I do community engagement?" There are no real guidelines about how to do this. Do we need some? I don't know.

DR. EVANS: I think this should be highlighted. In my mind it's maybe the most important thing because I--you know, I took part in one of the community engagement efforts that Vence and NHGRI organized, and you can accuse these things of being kind of really soft and touchy-feely but

the reality is that the only way we're ever going to solve any of these problems is through interacting with each other so that you understand the perspective and you begin to give some credence to it. So I think that should be highlighted. I think that--I don't know how effective it is but I don't know of a more effective way of getting researchers to understand that they can't gainsay the beliefs of a group even if they think those beliefs are crazy by their own lives.

DR. ROYAL: Gwen?

MS. DARIEN: So maybe this is a really simplistic approach to this but I think that these are incredibly thoughtfully positioned issues. In some ways I think that the--a very simple approach would be to decide whether these are the bullets that we think are important, change them from questions to declarative sentences, and then sequence them in order of priority.

CHAIRMAN TEUTSCH: I think that's our job for the morning.

MS. DARIEN: Rather than--I think that we're--rather--I mean not that we shouldn't discuss them but I think that the--I think that the questions are really--could be turned into

statements.

DR. BILLINGS: Could I just also add that--which is a little bit like what Sheila was saying yesterday about other things. Do we want to--do we want the message to be what is kind of new or actionable or something the Secretary is unaware now that they need to be aware of it seems to me. I mean--so to some extent in prioritizing the messages some of this stuff is underway, some of this stuff clearly has some history both in this institution and in the academic and outside world. Is there--but is there something--and obviously that needs to be reemphasized. It remains important but is there something else that's new and unique or something else looming that will drive this even more?

DR. ROYAL: When you say "something else looming," Paul, I mean in terms of--

DR. BILLINGS: One thing clearly is the--as my question was trying to get at--it's the proliferation of technology in other spheres. That's one thing that's clearly happening and, you know, the phenomenon of ancestry worship through the internet or whatever but--which is a new thing but there may be other things and it's changing valences (sic) in some way.

DR. ROYAL: I mean I think this whole talk about public health genomics is an area that--and Steve talked about that yesterday as something that we really haven't addressed as a community--as a committee and I think this fits very well into that. If we think about the public health we've got to include everyone. So I think this feeds right into that notion. How do we achieve public health and genomics' role in that? And so this whole issue of engaging these groups I think--I think that's probably an angle that we could take.

DR. BILLINGS: And, you know, frankly, the whole notion of groups which has a long tradition in the public health and in genetics for sure is under attack in some way by the personalized medicine forces that see every trial as an *n of 1* trial. And so there's an interesting tension going on.

DR. ROYAL: There's a tension there, absolutely.

DR. BILLINGS: Yes.

DR. ROYAL: Yes. I think this would fit very well.

DR. McGRATH: I'm going to be sort of pragmatic and look at the first two issues as kind of connected and I think it's easy to say community

engagement is good but you don't want it to be another box that a researcher checks that this study has these minority groups and there's community engagement. So we kind of learn from that.

And if you think about community-based participatory research was an idea--a good idea, nobody objects to it, but the field--the discipline only progressed when more research dollars were funneled to studies that did it and then the science advanced.

Now we've got principles that you can buy a book and solve the principles and it has moved. It's now a science. It seems like community engagement might be the same way. So the pragmatic message might be to either institutionally support or with resources, whatever, fund research that does what number 1 and number 2 do, which is increasing cultural perspectives and--I have forgotten the language of the first one.

DR. EVANS: Yes, to incentivize, encourage the Secretary--

DR. McGRATH: Yes.

DR. EVANS: --to incentivize community engagement as a way to accomplish this.

DR. ROYAL: Marc?

DR. WILLIAMS: Yes, I'm not sure where to put it. This gets back to the issue I was going to raise. I mean as we think about all of these things and we talked about the general topics, I mean I think 95 percent of reasonable people sitting around the table would look at those and say this makes sense. This is a good idea. But we always suffer from the actions of those that are either ignorant or apathetic or are truly just--are going out to ignore things but do something that then, you know, leads us to decades in the case of Tuskegee studies of, you know, having to try and pick up the pieces.

And the challenge with policy as I see it is that policy in some ways encodes what the vast majority of people believe is reasonable and will do something to try and speak to that, whether it's pro forma or really truly, you know, from the heart to do that. But we suffer from the ills and the sins of the five percent and so do we need to think about something on the other side to convey to communities that might be--perceive themselves to be at risk for untoward effects so that if something does happen in a study that involves their community that really is outside of the bounds of what people think is reasonable that there is some official sanction that

doesn’t take 50 years to, you know, come to light and that everything is covered up.

I mean, I’m thinking about how we deal with violations of IRB--you know, that we’ve--where we’ve seen where there have been very significant consequences that have come to certain institutions that have clearly gone outside the bounds of what we consider to be reasonable.

Is there a place in the discussion for, you know, the stick as opposed to the carrot if you will?

DR. ROYAL: That probably gets to our last couple of slides about the policy and how do we formulate policies or whether they are best practices or whether they are guidelines, whatever. I think that fits there, how we bring all of this together to determine how we address this. Not just--as you said, not just in terms of the research itself but what recourse the community itself has. So I think the policy discussion--we could move to it but we’ll get there in a minute I think.

I’m wondering if we--I’m going back to thinking about what Gwen said and I don’t know--I mean should we--I mean we can move on from this one. Should we just go to-- because I think we just have

two after this or something. Should we just go through and then--okay. So let's just do this because the policies are the last one, which is where I think the bulk of our discussion would be.

(Slide.)

So, this one, in terms of policies for IRBs is a specific policy before we go to federal policies or guidelines. Do we think that IRBs need to have a greater role or a greater mandate in terms of how they address groups? And then how--I mean the whole issue of addressing the heterogeneity in groups I think comes into play not just with IRBs but in general how we deal with that. I mean do we think that targeting the IRBs is an effective way of trying to get to some of these?

Marc?

DR. WILLIAMS: To this specifically I think that the challenge that IRBs are facing is that they're being asked to do more and more things relating to is the science valid, is the privacy--and to keep assuming that the IRBs are going to be able to sustain this or have the expertise to really be effective in evaluating these issues I think is a real challenge. I know from our local institutional IRBs that these are issues that seem to come up all

the time but we just don't have the capacity or the expertise to really be able to address all of the things that are sort of being forced on us to do. So I would tend to push back a bit to say that maybe the IRB would be looked upon as playing an essential role.

DR. ROYAL: What do others think?

David?

DR. DALE: Having chaired the IRB at the University of Washington and been active here for a long time, I worry about this. That is if we had, as someone said, a checkbox for approval by the group to which this person belongs, I can see the religious group, the church group, the ethnic groups, the bigger family group or the tribe. What it would serve to do is to leave people out who belong to any group because it would be a barrier for participation.

I think there must be some other mechanism which I would prefer it to be the investigator having sensitivity to the person who is participating in the research as opposed to some approval process involving IRBs.

DR. ROYAL: We can't leave it just to the investigator to do this. There has got to be

something in place to make the investigator want to be accountable or need to be accountable.

DR. DALE: I appreciate that but I also appreciate the obstacles in terms of doing research and how that nearly all of us have somebody we look up to who might be regarded in the diversity of America as the person I have to check with before I can agree.

DR. EVANS: You know, it seems to me that the IRB has a role in this. They are a natural type of organization to have some role but I don't think you can dump it all on the IRB. I think that would be really a mistake because I think what you do end up with then is a bunch of boxes checked off. Again I go back to the only way you're ever going to ultimately deal with these issues is by ensuring interaction between investigators and these groups. I think that while the IRB can serve, you know, kind of a logistical function in making sure certain minimal things are done, I think it's reasonable to focus our efforts on promoting the kind of interaction which I think is probably the only mechanism by which one can ultimately achieve the trust and all that's going to be necessary.

DR. ROYAL: Go ahead, Laura.

DR. ARBOUR: I just wanted to say that in Canada had we not gotten the IRBs involved from the onset that these transitions would not have occurred. The National Council on Ethics in Human Research actually held the first discussion about what was important and as the CIHR developed the guidelines, even before they put them in place, we had two years of education to the IRBs to understand and then build up their capacity. The U.S. has ten times the population so ten times the number of IRBs so it wouldn't be an easy task but I just wanted to comment I don't know that anything would ever change without the IRBs coming up to speed.

DR. ROYAL: Thank you for that, Laura.

CHAIRMAN TEUTSCH: I was just curious if Mike wants to weigh in on this topic of the appropriate role of IRBs in wrestling with this kind of issue.

DR. CAROME: I mean certainly the--just a couple of comments. Some of this research isn't necessarily covered by the regulations. Usually because of the way it's done with de-identified samples it ends up not meeting the definition of human subject and in some cases it's done with existing samples and data and can be done in a way

which is exempt. So for some of this research, which might have--the results of which might have an impact on the community and the populations from which the data and samples were drawn, the IRB wouldn't even have a role under the current regulations. So that's just I think an important thing to be aware about.

For that research which is covered by the regulations it is certainly within the purview of the IRB to consider these issues. Some do. I'm sure the IRBs that are established by the tribes are very much focused on these issues to a great extent and you don't get to do the research with the tribe unless that IRB approves it. University-based IRBs may consider it to a greater or lesser degree today depending upon their knowledge.

We do have a guidance document called *IRB Consideration of the Local Research Context*. And IRBs when reviewing research we recommend that they gain an understanding of various factors related to the context of where the research is going to occur and that includes the subject population in the community. There are lots of ways to get that community-based knowledge. It can come through the investigator, through other resources, through

consultants, through community members that sit on the IRB.

We don't have a lot of guidance, though, that really focuses on specific issues of group harm and how you specifically address that.

DR. ROYAL: Very interesting. That's really what we're talking about, you know.

Mike talked about de-identified data. I mean how do we think about that? Because if we don't de-identify it even if it comes from a group then there are issues and how do we navigate that whole system in terms of how the regulations are written? And that may be some place for us to have something to say about where we think the thinking needs to go.

Marc?

DR. WILLIAMS: So to try and be pragmatic so maybe the way to address this particular issue would be to offer direction to OHRP or other groups that are related to say this issue of group identity within the context of what is currently exempt research and the role of IRBs in terms of addressing these issues appears to be a good subject for additional discussions or scrutiny.

DR. ROYAL: Discussion. I agree. I think

that's great, all right.

Moving on from the IRB.

(Slide.)

Okay. How adequate is the U.S. policies? I think we've talked some about that. The existing policies, whatever they are in terms of groups. And just as you were saying, should we expand--recommend that OHRP's scope be expanded or just that we think about that in terms of IRBs.

As Laura said, I really don't think we can leave the IRBs out because that's the local group that is there to--that the researcher interacts with in terms of accountability.

So I think we've probably taken care of that one.

So the last one is are there additional policies needed relating to--so we talked about the IRBs and how we might make some recommendation about IRBs' role. Are there other policies that we may think of that we might recommend at this level in terms of U.S. policies?

I mean the first two that we talked about, the research that's needed and community engagement in terms of helping us--helping researchers to become more accountable. I mean do that--does that

need to go to this level or that probably is more-- probably some other level. I don't know. Or we let them decide where it goes in terms of how it gets implemented.

Gwen?

MS. DARIEN: It seems to me that the research has to come before the policies are developed. So if we're saying that there is inadequate research and more research has to be done then I think that that precedes policymaking.

DR. ROYAL: Okay. So those are two separate.

David?

DR. DALE: One of the things I think we heard about in Canada is the group forming policy and I think it would be constructive for groups who identify themselves as having an interest to be actively engaged in the discussion about what their group policy would be because for the individual it may often be confusing and you may get ad hoc policy that, in fact, leads to discrimination--reverse discrimination because of the lack of policy within a group. In the same side we shouldn't be making policy that discriminates against group.

DR. ROYAL: That's a good point, David.

You are talking about the process of the policymaking and engaging the groups, and I think that is a very, very important point.

(Slide.)

And our last is the policies of other countries in relation to our policies here. We heard a lot from Laura in terms of what Canada has done. Do we think that is a good framework for us to even start with in thinking about what might happen in the U.S. or do we think that--and the first question there really asks about, for example, tribes in Canada that has members--that have members in the U.S. and regulations that cover those tribes in Canada. Could we just--are those applicable to the groups in the U.S.? That's one separate question.

And then the other is can policies that are developed in other countries really serve as a framework for us in terms of how we think about policies in the U.S.?

Jim?

DR. EVANS: I mean maybe we could just soften it a little. It seems reasonable to me that policies in other countries could inform development of our policy. I think to say extended is probably

impractical. I'm just guessing but I would suspect is a bit impractical given the substrate of different governments and different agencies, et cetera. But I don't see why it can't inform.

DR. ROYAL: Marc?

DR. WILLIAMS: What I think I heard Rebecca say in her discussions is that in many ways for the United States tribal peoples that they are quite a ways down the road relating to these types of things and that there are variations between different tribes' approaches and there's also the international or the acceptance of the U.N. document that's informing how they're thinking about these things. So in some sense one might question as to whether or not they're farther ahead than where consideration or being informed by the Canadian policies would be that helpful.

And then talking with Laura at the break I asked, you know, "Well, are there other policies in Canadian research that address other populations like the Acadians or the Hutterites or something like that?" And at the present time those are not being--those groups are not being treated differently than Canadians as a whole.

So I guess the question would be is if

our--do we have examples of other policies in other countries that address groups that could be potentially relevant to policy development here? And if the answer is “well, we don’t know or we need to look” that would change what we would recommend.

DR. ROYAL: Because there are other countries. Mexico has some policies. Australia has some policies as to the indigenous people in those countries.

Okay.

Anything else on that?

Steve, you had something?

CHAIRMAN TEUTSCH: No, I was just going to say as you move on I think we need to find out if there are any other issues.

DR. ROYAL: Right, that was going to be my next--

(Simultaneous discussion.)

DR. ROYAL: --because this is the last slide so I’m headed there.

Any other issues that we think need to be on the table or need to be in the letter?

CHAIRMAN TEUTSCH: I see Kevin in the back who got started--

DR. ROYAL: Yes, Kevin.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: He's just sitting there quietly. I don't know if he has some perspective that he might want to say and perhaps even how we might want to say it.

DR. FITZGERALD: One thought that came up in all the presentations was this idea of engendering trust and how that is going to be absolutely critical in going forward. Could there be a policy recommendation that at least the processes in place currently for facilitating the inclusion of people from these groups as researchers--so training, developing their careers, supporting the people and moving them on to PI status so that they, themselves, who understand both sides of this, will have a more prominent role. Could we add that as a policy?

DR. ROYAL: I think so. I mean that responds to Laura's--

(Simultaneous discussion.)

DR. ROYAL: --building thing, which I don't know how we forgot that, Symma.

Yes, thank you, Kevin.

Any other thoughts?

That's an excellent point.

CHAIRMAN TEUTSCH: Well, so here is the challenge: We heard a lot of good thoughts here but we don't have too many words on a piece of paper.

DR. ROYAL: I will work with Symma later to write it up.

CHAIRMAN TEUTSCH: Right. But we actually do need to get to agreement on--and what I'm not clear about is if we just have one sort of overarching statement about the importance of this issue and its various aspects, and then some sort of text about what we think needs to happen or if we're going to have actually a concrete set of, you know, you should do A, B, C, D and E that are going to be more specific. I've heard some of both here. Whatever it is, we need to sort of get to it so that we can actually look at it.

So how do you--so I guess I should ask you first, Charmaine, do you sort of just see one overarching statement about the importance and then some text that supports that or do you sort of see that we're going to have actually things to say that is a series of recommendations within each of these? I've heard things about particularly processes and training and capability development and, you know,

policy development that could be pretty specific if we want to actually make those recommendations at that level.

DR. ROYAL: Right. I mean the recommendations would be that these things need to be addressed but I do see us having specific things there just like we outlined in the slides. I would not want to just have a statement that says this is important.

DR. EVANS: I think that you do have a lot on paper.

DR. ROYAL: Yes.

DR. EVANS: I think that like Gwen says, given the discussion that has occurred, I think one can modify many of these into affirmative statements and give the Secretary a very brief set of bullets.

CHAIRMAN TEUTSCH: I agree but then I think--but then what we need to do is actually do that.

DR. EVANS: What a concept.

CHAIRMAN TEUTSCH: What a concept. Unfortunately, Charmaine didn’t have a chance to go through this yesterday sort of like what we did and then have overnight to write them. So I guess the challenge as I see it is to probably over lunch time

or between now and this afternoon--

DR. ROYAL: We can write up.

CHAIRMAN TEUTSCH: --to actually do that conversion, not that we have to get every word exactly right because we can do some copy edits later, but that we get to agreement on what those items are.

DR. EVANS: I guess we can't even have a conference call after this, is that right?

CHAIRMAN TEUTSCH: My understanding is our official business is over as of the end of today. We will have the opportunity--just let me tell you at least as I see the process. Sarah is here and her elbows are sharpened so she can tell me what we can and can't do.

(Laughter.)

Whatever we plan to recommend needs to be taken care of by today; staff is going to be giving you a draft letter, hopefully, that you'll be able to see here later this morning or over lunch you'll have a chance to see sort of what the text might look like so we can begin to see if that's how we want it framed.

After today's meeting they will incorporate the various things that we're hearing

from all of our groups into that letter and probably by the end of the month will send it out to all the committee members who will have a chance to copy edit it. And that's what it means, copy edit. The recommendations will not be subject to substantive change. That's why we've got to get some agreement on what it is.

So, you know, we're talking about engagement of communities. Are we going to call this deliberative process, are we going to have appeals, we've sort of got to get squared away on all of that today at whatever level of specificity we can. Obviously, you know, we very much short-circuited the discussion that we need to have. So that's where we are and that's why I'm a bit anxious as you can see that we actually have something to look at that we can say the committee agreed to.

So that's sort of--you know, to the extent we can convert these I think that will be great but we simply need to get--need to do it.

DR. ROYAL: Barbara?

DR. McGRATH: Can I ask a question? Is it important for--I feel frustrated that we're not able to follow up on some of these because I think this would be a great body to do it. So is there

anything worthwhile to adding in this or maybe in the overarching statement that we hope it gets carried on by some other group, you know, a concrete group, not diffused throughout the entire world?

DR. WALCOFF: Actually I was thinking kind of along the same thing and if we organized it--and I think this is saying pretty much what Gwen said--as sort of key issues for further consideration that have been identified for the work of the task force to date and then some recommended next steps, you know, that are a little more specific. I did want to say as examples but they really are sort of as a recommended next step.

DR. ROYAL: Do you think giving a specific group would be appropriate, Sheila? Like saying SACHRP or just saying some other body. I mean do we need to--

DR. WALCOFF: I think if we can come to an agreement on a recommended body to sort of move it forward to the next step or a combination of entities I think that’s helpful because it’s not really saying that these groups have to take it on. It’s just sort of a suggestion because when you do get something like this that is an area that’s probably relatively unknown to more senior

policymakers it's helpful to say, "well, who do I actually talk to about this now" rather than going back to NIH as sort of a tail chasing exercise. So if we have those groups I think it's useful to identify it but I wouldn't put it in a hard recommendation--you know, in a way that it makes it sound like there are no other groups that could take it on as well. But at least so it gets like carried forward and passing of the baton.

CHAIRMAN TEUTSCH: I like the idea of actually to the extent we can to identify what potential groups are.

Mike, is this something SACHRP could take on? Could the Presidential Commission take some of this on?

DR. CAROME: I can only speak perhaps for SACHRP. I mean I think some of the issues--those related to IRB policies, human subject protections, those are relevant to SACHRP. Some of the things you have on the table here I think are beyond the purview of SACHRP so you'd have to--

CHAIRMAN TEUTSCH: Could you suggest other groups that would be appropriate that already exist?

DR. CAROME: Perhaps the President's Bioethics Commission but I don't speak for them.

CHAIRMAN TEUTSCH: So hearing that it sounds like we can provide those as examples for some of this work but that they are probably not going to be inclusive for all of the work so that we need to find or the Secretary will probably need to find the appropriate mechanisms to do that.

DR. WALCOFF: I really like a leading group, a leading--

CHAIRMAN TEUTSCH: Yes.

DR. WALCOFF: If you give too many then it's sort of--everyone just looks at each other and nobody takes the baton.

CHAIRMAN TEUTSCH: So who might--what might that group be?

DR. WALCOFF: We are not in a renaming exercise of the SACGHS.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: The new and improved.

DR. : Rebranding.

(Simultaneous discussion.)

DR. : Our new banner will be ready when Francis arrives.

DR. : Office of Minority Health was one that someone raised.

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: The institute--there's an NIH Institute on Minority Health is what I heard.

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: I don't know. Do they do--I assume they do the research part of this?

DR. ROYAL: Well, they do--now they're going to be able to fund grants, right?

Vence?

CHAIRMAN TEUTSCH: Do they develop policy and guidance and all of that sort of thing?

DR. ROYAL: I am not sure. They do a lot of policy.

MR. BONHAM: So the National Institute of Minority Health and Health Disparities is the newest institute. It's an institute like the other institutes at NIH and they have an extramural research program and they are developing an intramural program. It's a research institute within the organization of NIH. I guess I would leave it to Dr. Green to add anything else.

DR. GREEN: Listening to this discussion we shouldn't forget about the NIH. We are sitting here. So for some of these topics--I mean for many of these topics that you're leaving remnant issues

that clearly require extensive follow-up, you know, NIH--either at the highest level, like the director, who I guess is coming to see you this afternoon, and he has his own advisory committee. There's an Advisory Committee to the Director and they take up major topics like this. But then sometimes they ask individual institutes or partnership of a couple or even three institutes to grab a topic.

And so, you know, if you're going t make a laundry list of possible groups that are going to take on topics that require follow up you should put, you know, NIH holistically or institutes individually.

CHAIRMAN TEUTSCH: No, I think we would agree that it should be part of it. I guess what we were looking for is a lead agency--a lead organizational entity that would oversee the whole agenda.

DR. GREEN: Which whole agenda? For this topic or for any--I mean I thought--

CHAIRMAN TEUTSCH: All of the issues that Charmaine laid on the table.

DR. GREEN: Yes, but I thought I heard yesterday that--I mean, then yesterday you were talking about whole genome sequencing and all those

issues.

CHAIRMAN TEUTSCH: No, no, no. No, not all those.

DR. GREEN: So I'm assuming for any of these topics you're going to want to have sort of a set of possibilities, right? I thought that was the letter you guys were going to be working on. It wasn't just around this topic but it was--

CHAIRMAN TEUTSCH: Correct. What I'm hearing is as a section of what we're writing regarding the data sharing, who do we think we can recommend that the Secretary should take the lead is what I thought we were getting at. Is there an entity or are we going to provide several?

DR. DALE: Well, I think you've identified the problem. We have been the group to do that and we're going away.

(Laughter.)

And if I could express one other concern, I think the title of the discussion was "Group Risk and Benefits." We need to be sure not to pigeonhole this into a group that's more worried about risk than benefits. And so you need a pretty high level of the organization to assure that. I think because it's a very broad subject. So I think the best we

can do is to recommend to the Secretary that she identify a body who can deal with the risk and benefits of research related to specific groups.

CHAIRMAN TEUTSCH: And what I'm hearing is that there are a number of groups that have interests in all of this but none of which have--

DR. EVANS: I wouldn't list any. Let her figure that out and if it doesn't appear that there is a group--well--

(Laughter.)

CHAIRMAN TEUTSCH: As we talk about the level of leadership that we need, I think one of the things to think about going back to Rebecca's talk is that for native tribes in the U.S. we're really talking about a government--government talking to government. So that requires a really specific--it raises some specific challenges and requires a lot of expertise in how we deal with those issues. It's not just groups. They are not just another group participating in research. I mean there are specific political and legal issues that we need to think about with Native American groups in particular. So I think that is something we need to think about as well.

CHAIRMAN TEUTSCH: So I've two sides of

trying to identify groups or not.

(Simultaneous discussion.)

DR. EVANS: In all seriousness I don't think we have the expertise or the knowledge to identify the best groups. I think that that could even be a bullet that you'll want to identify the appropriate group. I don't think we know enough to do it.

DR. McGRATH: What about Sheila's point to give some suggestions, you know, like list three?

DR. EVANS: I think that--I don't know. I think that's inappropriate because again I think our suggestions are rather hastily put together and rather ill-informed.

DR. WILLIAMS: Although I think there are some that are fairly obvious. I mean I think the IRB issue, that's a SACHRP issue. I think that's pretty straightforward so why not say that? And I think that some of the issues relating to the need for more research around engagement with communities would be a natural for the Institute for Minority, you know. So I think we're not completely ignorant about things and so at least as someone that might hypothetically receive recommendations it seems to me it's easier to act on them if there is some

direction that is reasonable.

DR. EVANS: I don't think that is unreasonable but I would say that any that seem obvious to us would seem obvious to her.

CHAIRMAN TEUTSCH: Sheila?

DR. WALCOFF: I mean maybe the way to kind of split this down the middle is to say, you know, would be a suggestion that these two entities take the next step in working together to identify the appropriate group or groups, entities, institutes, centers across the government that would be able to address these issues appropriately.

I think it does really help to--it doesn't have to be the perfect all encompassing entity or idea. It just helps to have the next step and somebody to assign the next step to.

DR. EVANS: If we know the best next step.

DR. WALCOFF: Well, I don't know that the--I mean it's not that she's going to sit there in her office in the evening and go through the list of all and try to figure it out herself. I mean somebody will advise her on that. So if we can suggest an appropriate--if we suggest a couple of appropriate entities to advise her further on who might--you know, which other entities might be the

appropriate bodies that does sort of give a next directional step when you're in a policy committee and people are getting assignments.

CHAIRMAN TEUTSCH: All right. We'll have some text to look at I guess after lunch. Clearly there's no perfect solution here.

Are there other things that we want to make sure we get on the table so that Charmaine and Symma can crystallize all of this for us?

So, Charmaine and Symma, do you have enough guidance here to craft something for us?

And people will see that again this afternoon.

DR. ROYAL: Yes, you will.

CHAIRMAN TEUTSCH: And it's clearly important issues that we've learned as part of this process and so the sharper we can make those recommendations the better I think.

So let's see where we are here.

So thanks, Charmaine, to you and your group.

You brought us a long way through this entire process.

DR. ROYAL: A great task force. I thank all of you.

CHAIRMAN TEUTSCH: And thanks to all of the speakers for really stimulating talks.

DR. ROYAL: Absolutely.

CHAIRMAN TEUTSCH: I think we can only regret that we're not able to take this as far as it clearly needs to go. Hopefully, this will be an issue that the Secretary does take up and follows through on.

So this is the time in our meeting when we again get a chance to hear from the public and we have--is Jo here?

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: Oh, she's waving. She's behind me. Okay.

Jo Boughman, who is the Executive Vice President of the American Society of Human Genetics, is here to talk to us again.

Welcome.

PUBLIC COMMENT

JO BOUGHMAN, Ph.D.

DR. BOUGHMAN: Thank you.

As Dr. Teutsch just said, my name is Dr. Joann Boughman and I think it's a little bit appropriate even though Ed has left--that leaves Sarah and I who are the two that have not only made

it through the SACGHS but were here during the last Century with the origin of the SACGT.

(Laughter.)

That gives me absolutely no authority to make these statements but it does demonstrate longevity and maybe stubbornness.

(Laughter.)

Today I'm here as the Executive Vice President of the American Society of Human Genetics and, while you all are multi-tasking, on behalf of the leadership and the 8,000 or so members of the American Society of Human Genetics, I would just like to publicly thank and applaud the SACGHS for its work over time on many of the issues that are obviously of great interest to the human genetics community.

I'm not going to list any specific issues. I will simply remind those who can't remember on their own of the amount of time, sometimes years, more than decades, and sustained focus required for achieving some of the goals of this group but many have been accomplished.

With the outstanding leaders and membership of the group you have logged countless hours of study, discussion, concentration and

review.

The products speak for themselves and were reviewed yesterday.

I would also like to reiterate that without the staff none of this would have happened and we, too, applaud and thank the staff for their continuing work.

Yesterday the American College of Medical Genetics and the National Society of Genetic Counselors were mentioned as groups to engage in some of these things. I love both of those organizations and dutifully pay my membership dues each year to both of those but ASHG has also tried to be a good citizen with the challenge and, hopefully, the right kind of determination to gain some consensus opinions out of a very large and diverse portion of our research community.

We have raised our voices when necessary, worked behind the scenes on some of the long-term issues, have had some members appointed and served on this committee, and some of us participating in many of the workgroups over the years.

We believe that without the serious commitment by all of these interested communities, SACGHS could not have accomplished the really hard

work of policy development. But now our communities will need to find another venue for open and important dialogue on difficult policy issues, such as the ones you've been discussing this morning.

But I have to say it will be very difficult to replace this committee's meeting that we knew would come up on a regular basis for us to have rich content, as well as frank discussions. And we're going to have to go home and work hard to figure out how we're going to pick up any slack that is left here.

So, once again, on behalf of the human genetics community in writ broad I would like to thank SACGHS and I personally wish you a great deal of lunch in accomplishing your goals by sundown today.

CHAIRMAN TEUTSCH: Thank you for that. We certainly could use your wishes (sic) in that but thanks also for your generous words and all your support over these years.

Just to go over the agenda, we have no break scheduled this afternoon and we have a lot to do so what I was going to suggest is that we use the next few minutes for Marc to go over the recommendations that we have on comparative

effectiveness and see if we can't bring that to closure yet this morning before we break for lunch.

I don't believe people have that in writing; is that correct?

What we'll have is on the slides; is that right, Marc?

DR. WILLIAMS: As far as I know, yes.

CHAIRMAN TEUTSCH: Yes, I don't recall seeing them in a hard copy.

DR. BILLINGS: So, Steve, what's the format? How do you want to choreograph this afternoon exactly if we're going to have to stop?

CHAIRMAN TEUTSCH: Well, the choreography for this afternoon, to the extent we have choreography as opposed to make it up as we go along, is that you are going to be getting in the next few moments a draft of the letter. So you can look at the basic construct, decide whether that's the way you want to--you know, the basic message.

DR. BILLINGS: Yes.

CHAIRMAN TEUTSCH: And then I would like to go through each of the sets of recommendations on the whole genome sequencing, and I would suggest we do that next after lunch.

DR. : Which I'm not going to be

here.

CHAIRMAN TEUTSCH: Yes, exactly. I just thought this was shorter. We do whole genome sequencing and then we will get to the--well, we have education to do, too, don't we?

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Let's do this: We'll plan to have--after Marc we'll leave a half hour for lunch, come back up here, and we'll go through the education recommendation and training, and then we'll go through the letter, the whole genome sequencing. And what else? What else? We have one more.

DR. WILLIAMS: Sharing, data sharing.

CHAIRMAN TEUTSCH: And the genomic data sharing. But in kind regard to Charmaine and Symma, we'll let that be towards the end so they can have as much time to refine that as they can.

Is that all right?

And here is additional from Sarah.

MS. CARR: Well, just that the draft letter, we have developed the shell of it and then inserted the recommendations that have been developed so far. Marc's and the affordable (sic) genomic data sharing isn't in there yet.

(Simultaneous discussion.)

MS. CARR: But just so you know that that will be coming around and you can look at it but it won't reflect anything you decide right now with regard to Marc's or what you decide later but you'll just see sort of the structure and so forth.

CHAIRMAN TEUTSCH: Okay, Marc.

DISCUSSION OF LETTER FROM SACGHS TO SECRETARY SEBELIUS

FACILITATOR: STEVE TEUTSCH, M.D., M.P.H.

CLINICAL UTILITY AND COMPARATIVE EFFECTIVENESS

MARC WILLIAMS, M.D.

DR. WILLIAMS: Okay.

(Slide.)

I hope this will be quick. I tried to encompass or incorporate the suggestions from yesterday into four bullets. Let me just again read them.

"In order to achieve the goals of health care reform the administration and congress have invested significant resources in comparative effectiveness research. The SACGHS believes that inclusion of family history, genetic and genomic information is critically important to consider if the results of the CER studies are to yield fully

valid information. While some studies incorporate family history, genetic and genomic information, particularly in oncology, there are significant opportunities to include this information in other studies. The SACGHS recommends that the Secretary provide necessary programmatic direction to ensure that…"

And then these are the bullets that you looked at yesterday that reference the specific CER studies where there would be an opportunity to include this information. I'm not going to re-read these different studies.

(Slide.)

"2: The development and use of fully functional electronic health records is another key element to health care reform. Current informatics systems in EHRs are not capable of capturing family history, genetic and genomic information in a coded computable fashion. This deficiency will impede CER studies and post-market data collection for conditions where these data are critical. It will also affect the inclusion of point-of-care educational resources for clinical decision support."

"As such, the Secretary should direct the

Office of the National Coordinator of Health IT to explore options to facilitate the development of EHRs capable of handling family history, genetic and genomic information."

I would add one parenthetical question here, which is in the previous version of this we included some information about some specific projects. I would not want to include this in the recommendation but I would be interested to have the group's perspective on whether we should outline any specific projects such as the PROSPECT studies that Gurvaneet referred to and then the NIH funded project on creation of the genomic enabled electronic health record either in the text of the letter or in an appendix.

"3: The reform of the health care system is dependent on the development of evidence of best practices. While there are some efforts underway to support the development of evidence-based recommendations for genetics and genomics (e.g., EGAPP, GAPPNET and some AHRQ-funded projects, the Secretary should provide resources to expand the development of systematic evidence-based recommendations by HHS-funded centers."

"4: Evidence-based genomics is critically

important in ensuring that CER studies develop and achieve meaningful comparative effectiveness data. As such, the Secretary should recommend that individuals with specific expertise in evidence-based genomics are considered for membership on the PCORI methodology committee."

CHAIRMAN TEUTSCH: Thanks, Marc.

I think Sarah had one other sentence because we didn't get the business on translational research into the first one. Did you want to--

DR. WILLIAMS: Oh, I'm sorry.

CHAIRMAN TEUTSCH: No, it wasn't your fault.

But I would just ask Sarah to read it so people at least see that.

MS. CARR: Okay. This would be a new third sentence. "SACGHS also believes that further research is…"

DR. WILLIAMS: Oh, for 1?

MS. CARR: Yes.

DR. WILLIAMS: Yes. That's correct.

MS. CARR: Okay.

DR. WILLIAMS: Yes.

MS. CARR: "…that further research is needed to ensure the appropriate translation of

genomics into health care."

DR. WILLIAMS: Right.

So that would be after the sentence "of fully valid information." Is that correct, Sarah?

MS. CARR: Yes.

DR. WILLIAMS: Yes. Okay. So that reflects the point that David brought up yesterday.

CHAIRMAN TEUTSCH: Sarah?

MS. CARR: Marc, I apologize for this because I think I caused this to happen. In recommendation 4 it now reads that "the Secretary should ensure" but the Secretary isn't the appointing authority over that committee."

DR. WILLIAMS: Right.

MS. CARR: So I think the wording that Sheila--something more along the lines of recommend that--should recommend that--

DR. WILLIAMS: Okay.

MS. CARR: --appropriate expertise, something like that perhaps.

DR. WILLIAMS: So do you have the version that I sent you because that Sheila's words.

MS. CARR: Yes. But there was--

DR. WILLIAMS: Right.

MS. CARR: I just think rather than say

"should ensure that…"

DR. WILLIAMS: Right.

MS. CARR: "The Secretary should recommend the…"

DR. WILLIAMS: Right. So there is language that you're not seeing that basically more appropriately defines the Secretary's role in the methodology committee, which is basically along the lines that Sheila suggested yesterday of ensuring that a conversation takes place amongst the group to say that this is an important thing.

DR. : (Not at microphone.)

DR. WILLIAMS: Could you use a microphone?

DR. WALCOFF: I think we have a lot to say. I think it's hard to get it much more concise than what Marc and Sarah have put together.

Although, I do think we should--I think instead of saying "ensure" -- I think that's impossible for her to do so just to adjust that a little bit I think is appropriate but, you know, white space and bullets.

(Laughter.)

CHAIRMAN TEUTSCH: Can we take silence as basically concurrence?

So all those in favor of this set of

recommendations the way Marc has laid them out?

(Show of hands.)

All those opposed?

Any abstentions?

Congratulations. Okay. This is great.

Thank you, Marc, for leading us through all of this.

Paul, you look like you're about to jump on me.

DR. BILLINGS: No, I want to say something to you but off line.

CHAIRMAN TEUTSCH: Off line, okay.

So it is now seven after 12:00 by the clock here in the room. Why don't we take a half hour break?

We'll meet back here at about 12:37, I guess, and then we will continue with the discussion of the education and training recommendations which Barbara and staff have carefully reworked.

So again thanks, everybody, for your forbearance on all of this.

I know it's fairly aggressive to get it all done today.

(Whereupon, at 12:07 p.m., a luncheon break was taken.)

A F T E R N O O N S E S S I O N

CHAIRMAN TEUTSCH: I think all of you have the revised draft recommendations on the genetics, education and training session which Barbara and staff have been working diligent on to modify according to our discussions yesterday.

So Barbara is going to lead us through that and, hopefully, help us get to conclusion.

DR. McGRATH: Great, thanks.

CHAIRMAN TEUTSCH: So, Barbara, thanks. Sorry about rushing your lunch. You'll probably hear a few--a little bit of munchies along the way here.

DR. McGRATH: I'm cool with that.

CHAIRMAN TEUTSCH: It's nothing personal.

GENETICS EDUCATION AND TRAINING

BARBARA BURNS MCGRATH, RN, Ph.D.

DR. McGRATH: Great. Okay.

I'll try to be quick and I think this should be pretty straightforward.

(Slide.)

Ideally, if everybody was looking on the page, on page 59 in their books, you could see what we had yesterday and what we have today. The only reason to do that was to see if you think we're

cutting out too much. So if you can do that without spilling your salad on your book or whatever, that would be ideal. But if you can't, we'll just walk through these and you can look at them de novo and think if they just seem to capture our meaning all by themselves.

(Slide.)

So I'm not going to go over the preamble of this because this is basically the background unless--if you have any comments about that, send an email pretty quickly to Symma or myself and we'll change the preamble. But let's talk about particularly the recommendation which is the action item.

(Slide.)

So number 1 had quite a bit more text and we reorganized it, cut and pasted, and cut out a couple of points. We basically cut out--if you're looking at it we cut out items E and F. This is how it reads now: And I'll read it to you.

"Innovative approaches that coordinate the efforts of entities involved in health professional education and training are required to address these gaps." This refers to what the preamble says. "Therefore, HHS should convene a task force of

stakeholders to identify."

Four things: "Outcomes-based education and training guidelines and models; best practices for enhancing and expanding the content needed to prepare health care professionals for personalized genomic health care; mechanisms to assure the incorporation of up-to-date genetic content into standards, certification, accreditation and continuing education activities; and funding sources for developing and promoting genetics education for relevant health care professionals."

We questioned a little bit the use of the word "best practices" in B if you have a thought about that. And before the above "convening a task force of stakeholders" we took out all the examples of stakeholders. Those were in there more--earlier to sort of give an idea that we are looking for people who aren't usually at the table--I keep using that expression--but pulling together groups who don't often sit at one place. So I don't know if it was an okay idea to take that example out or whether we'll just leave it out. Those are the two questions we had yesterday.

Any thoughts on recommendation number 1?

DR. WILLIAMS: Well, at the risk of being

repetitive, despite my best efforts it seems like we keep extracting things related to education based within electronic health records. I just quickly scanned through the other recommendations and I don't see that.

I guess I would like to, you know, continue to support the idea that our electronic health records are going to have to have the capabilities to provide point of care education for providers. So I'd really like to see something in this draft recommendation about that.

DR. McGRATH: I think that some of that language got put into the family history one. Yes. It is in family history. I don't know if we want to say it twice; just a question.

Oh, maybe that did cut. I'm sorry. I'm looking at a--I can't scroll forward but--well, let's put it in here.

CHAIRMAN TEUTSCH: So where would you put it? Like under C as one of the items in C?

DR. WILLIAMS: Yes. That is what I would think, "Standards certification, accreditation, electronic health records and continuing education activities." I think that would be--that would probably be the best place to lump it.

DR. McGRATH: So just the word “electronic health records.”

DR. WILLIAMS: I think its fine because in the text of the report we explain what we’re really talking about.

DR. McGRATH: Right.

DR. WILLIAMS: So I think that that’s fine.

DR. McGRATH: Okay.

DR. WILLIAMS: You do have it specifically in relation to recommendation 6 but I think it shouldn’t be linked just to family history.

DR. McGRATH: Okay.

Feel good?

CHAIRMAN TEUTSCH: Anything else on this one?

After lunch we usually have--you know, you get that--

DR. McGRATH: I know. We’ve been so kind of hyper I’m thinking--

(Laughter.)

DR. McGRATH: But people are definitely chewing. All right.

Are you comfortable with me not--that other question was the stakeholders. Did we lose

some richness by taking out examples of stakeholders? We're trying not to have the same old recommendations, the same old language.

DR. DALE: I think it's the right language. It avoids leaving anybody out.

DR. McGRATH: Okay. All right, okay.

Any other comments?

All right, so shall we move on to 2?

(Slide.)

This again is the preamble for 2 which we won't look at carefully but here's the recommendation:

"HHS and its public health agencies should: Assess the public health workforce to determine the number of public health providers with responsibilities in genetics and genomics and to ascertain current trends and future education and training needs; and B to identify and engage exemplary public health genomic programs to identify critical workforce information not captured in the assessment."

And then there is a C and I'll just do that.

(Slide.)

"C. Using the results of these assessments

and to address identified gaps, HHS should:

Support development of skills and competencies in genetics and genomics that specifically address the identified needs; based on these skills and competencies, fund the development and implementation of accessible educational programs and continuing education in genetics and genomics for the public health workforce; and promote leadership development in the field."

I have a question about that very last bullet "promote leadership development in the field" where they've got "field" like it's just floating. And then I'll go back to these other ones. This is, of course, the whole one on the public health workforce.

MS. BACH: Under A, I think it's a little more than just determining the number of public health providers. Could we at least add like the number and type?

DR. McGRATH: That makes sense. Okay.

Does B make sense to you? Do you know what its saying? "Identify and engage exemplary…" and I don't know about the word "engage" but "…exemplary public health genomic program to identify critical workforce…"

Do you know what that means?

CHAIRMAN TEUTSCH: I wonder--we don't really discuss that in the body of the report, do we? It might benefit in the report if we added a paragraph about what these are.

DR. McGRATH: Oh, you mean examples of programs.

CHAIRMAN TEUTSCH: In the text. Right, because I wonder if this--I don't recall seeing that in the body of the text.

DR. McGRATH: We don't use that language but that's a good point to use that very word. These are examples of exemplary or these are some exemplary public health genomic programs. So they can refer the same--

CHAIRMAN TEUTSCH: Exactly.

DR. McGRATH: Got it.

CHAIRMAN TEUTSCH: Unless there's more specific ways to specify what these are.

DR. McGRATH: Okay.

(Slide.)

And C? This is the whole competencies thing but we, of course, kept in the word "skills." So develop them and then fund them. And then what do we think about the third bullet?

CHAIRMAN TEUTSCH: Do we indicate somewhere that there's a need for that? I mean, I think there is.

DR. McGRATH: There is. And I remembered a conversation where I was told there was but I'm going to propose now that that gets--it seems like there might be more context if we put it back in the text. That when we're discussing the whole field of public health that one of the problems is that there is a paucity of leadership moving up the ranks. That seems to fit here.

CHAIRMAN TEUTSCH: One thing you could do is put it in the first sub-bullet under C. "Support development of skills, competency and leadership in genetics."

DR. McGRATH: Oh. "Development of leadership."

CHAIRMAN TEUTSCH: "Skills, competencies and leadership skills." Or "and leadership." Something like that.

DR. McGRATH: Capabilities or leaders.

CHAIRMAN TEUTSCH: Something like that.

DR. McGRATH: Okay. It makes sense to me.

CHAIRMAN TEUTSCH: Yes, and leaders. You could do it that way.

DR. McGRATH: Okay. You guys have never been this easy before.

(Slide.)

Number 3. That's the preamble.

(Slide.)

And the recommendation. "To increase services and access to care in underserved communities, HHS should: A. Support research to identify effective educational models for health care professionals and public health providers in underserved communities; B. Identify and support programs to increase the diversity and genetic competencies of the health care workforce serving underserved communities."

(Slide.)

"C. Incentivize organizations and ensure that consumers and representatives of rural minority and underserved communities participate in a process of developing education and training models and materials to assure that they are culturally and linguistically appropriate and tailored to the unique needs of these diverse communities."

Perhaps in combining two we've got a lot of "ands" but at any rate if you look at--that's what we did is we combined a couple of the

recommendations and threw them all together.

So let me go back to the first part of it.

(Slide.)

Number A. I have to admit as I read it over this morning I have lost the meaning of A. I'm not sure what a model--what kind of models we're talking about here. I don't know if it got lost in all the translations or--I couldn't explain what "A" means at this point. If somebody else can help me maybe we can get more language.

Gwen?

MS. DARIEN: Aren't we looking at existing models?

DR. McGRATH: What kind of models?

MS. DARIEN: Existing. I think that's to support research to identify existing models.

DR. McGRATH: Well, what--can somebody give me an example of a model that's going to affect professionals working in underserved communities? Is it--

MS. DARIEN: Well, I think the idea was not to--

DR. McGRATH: --cultural competency or what is it?

MS. DARIEN: Yes, I think it was the--the

idea was not to reinvent something if it already exists. So a lot of times in--I mean, in my experience in groups people say we have to develop these materials or we have to develop this--we have to develop this curricula and it already exists.

DR. McGRATH: Right. But is there a curriculum that health professionals working--

MS. DARIEN: I don't know.

DR. McGRATH: That's my question and suddenly I was drawing a blank on it.

DR. DALE: An example in our area is the public health model in Alaska where we have centralization of teaching and physician assistants and nurse practitioners--

DR. McGRATH: Oh, okay.

DR. DALE: --villages and communities in public health-based studies.

DR. McGRATH: All right.

(Simultaneous discussion.)

DR. McGRATH: So it's models of using more distant things and WAMI programs and things like that.

DR. DALE: That's right. You have to figure out how to communicate across distance.

DR. WILLIAMS: And Hawaii has also done

some work relating to that. So I think there are existing--

DR. McGRATH: Okay. Great.

DR. WILLIAMS: But putting the word “existing” in there would be--

DR. McGRATH: Got it.

DR. DALE: Yes.

CHAIRMAN TEUTSCH: Something else you might do is just to get rid of “support research.”

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Because to the extent they are existing it’s a matter of identifying them.

DR. DALE: Yes, identify; right.

DR. McGRATH: So you are saying “support effective--existing effective.”

CHAIRMAN TEUTSCH: No, no, just “identify effective educational model.”

DR. McGRATH: Oh. “Identify.”

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Existing--effective or existing, whatever you want to say.

DR. McGRATH: Yes. Okay. Done.

All right. In B we took out our examples.

And then any comments on B?

(Slide.)

"C." Our big long sentence.

CHAIRMAN TEUTSCH: I wonder if we can tease this into its pieces so it would be easier to--

DR. McGRATH: Go back to 2?

CHAIRMAN TEUTSCH: Well--so we can wrap our heads around it a little bit easier. There seems to be a bunch of concepts in here.

DR. McGRATH: Yes. It's the idea that these programs should happen and that they should be informed by the community.

MS. DARIEN: I think that you can flip the sentence around.

DR. McGRATH: Okay.

MS. DARIEN: So if you start out "To assure that…to ensure culturally and linguistically appropriate programs tailored to the unique needs of diverse communities, incentivize the organizations and ensure that…" I mean, that wasn't the most elegant way to say it but I think that--I have to look at it a little bit. But I think if you flip it doesn't it work better?

CHAIRMAN TEUTSCH: Or you could just say "provide incentives to ensure that…" It gets at least that simpler.

MS. DARIEN: Yes, “provide incentives to ensure that culturally and linguistically…”

CHAIRMAN TEUTSCH: “To ensure that…”

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Then you’ve got two basic points, right? The first one is about the consumers and representatives--

DR. McGRATH: Right.

CHAIRMAN TEUTSCH: --blah, blah, blah. And the second one is “assure that they have culturally and linguistically appropriate materials.”

DR. McGRATH: “Incentivize…” and then you could have a colon and have the two points.

CHAIRMAN TEUTSCH: That might be just as a way to simplify it. Or “provide incentives to…”

DR. WILLIAMS: I’m not absolutely certain that those are two bullets because I think what we have is participants and a product. The participants and the products are intimately linked because we want the participants to participate in developing the product. So I think if we put two bullets it seems to imply that there is something for the participants and there is something for the products but they are not naturally linked. I mean,

I know it’s a bit wordy but I still think that it conveys the meaning adequately.

DR. DALE: How about two sentences, one bullet?

CHAIRMAN TEUTSCH: What is that? Read it to us, David. What is it going to say if you wrote it in two sentences?

DR. DALE: I think you had it. The incentivizing organization is sentence one and then assuring that they are culturally and linguistically appropriate.

DR. McGRATH: You are going back to what you have printed on 59 or whatever page it is now?

DR. DALE: But Gwen suggested reversing the order.

DR. McGRATH: But keeping them separate.

DR. DALE: I don’t think that we’ll change the outcome if we’ve got the two. We just need, as Marc suggested, two ideas there.

DR. WILLIAMS: I mean, if you wanted to make it slightly more simple, what you could do is to basically put a colon after “are” and then, bullet, “culturally and linguistically appropriate,” bullet “tailored to the unique needs of these diverse communities.” You eliminate one

"and."

DR. McGRATH: Would it also help to put in parentheses? "To incentivize organizations and ensure adequate or appropriate representation (rural minority and underserved)" Or something like that?

DR. WILLIAMS: I think that increases rather than decreases complexity.

DR. McGRATH: Okay. So you've got a colon after "are." Comma. Okay.

DR. WILLIAMS: I'm not wedded to that. I'm just saying that--

DR. McGRATH: Yes.

DR. WILLIAMS: --I hear the need for bullets and so that's how I would bullet it.

DR. DALE: Or you could put the period after the word "material" and then "these programs should be culturally and linguistically appropriate and tailored to the unique needs of these…"

DR. WILLIAMS: I think that's better.

DR. McGRATH: Yes, actually I like that. Thank you.

CHAIRMAN TEUTSCH: So what I'm hearing here is--just getting the grammar here correct and understandable but are there any conceptual issues here with this?

So if we take David's advice we can still--I understand we can do a little bit of copy edit offline but the--I'm hearing we're good with this. Okay.

DR. McGRATH: Okay. Great.

(Slide.)

Preamble of 4. This is consumer education.

(Slide.)

And here is the recommendation: "HHS should support…" Oh, we've flipped this. If you're looking at it, this is written as recommendation 5 in your book but we've flipped the order.

"HHS should support research and public-private collaborations to identify methods that are effective for translating genetics knowledge into information that consumers and patients can use to make health decisions. Specifically, HHS should:

"A. Support multidisciplinary research that identifies effective methods of patient and consumer communication;

"B. Based on this research and to reach diverse people and communities, HHS should develop educational programs that use a wide array of media and community-based learning and provide culturally

and linguistically appropriate materials, and--

(Slide.)

"--in collaboration with the Department of Education and the National Science Foundation, support the incorporation of genetics and genomics into K-12 education."

(Slide.)

So this one--and we eliminated on your hardcopy version, on page 61, eliminated bullet D or item D, and combined a couple into the parenthetical comment.

DR. WILLIAMS: So the only suggestion I would make again, which is more of a language one, is I think we could compress that introductory paragraph because we're being redundant when we say "should support research" and then we say "support research."

DR. McGRATH: Yes.

DR. WILLIAMS: And so what we could say is "SACGHS believes it important to identify methods that are effective…" blah, blah, blah. "Specifically, HHS should…" and then bullets.

DR. McGRATH: Wait. It is important to what?

DR. WILLIAMS: So it is important to blah-

blah.

DR. McGRATH: Well--

(Laughter.)

DR. WILLIAMS: It is important to identify methods that are effective. So in other words you basically replace the first part of “should support” and just say “SACGHS believes it is important to identify methods” and then continue from there.

DR. McGRATH: And can we throw back in that public-private collaboration? That was pretty important to this--to get away just from the--

DR. WILLIAMS: Well, the--okay. I see what you’re saying. So it’s probably not worth--because it doesn’t fit in the bulleted statement.

DR. McGRATH: Well, I think I can throw that phrase back in. “That are based on private-public collaborations and are effective.” Something like that?

CHAIRMAN TEUTSCH: I think it probably will help because research in public-private collaborations aren’t really parallel kind of construction.

DR. : Right.

DR. McGRATH: If we want to try to capture the points from the task force it was the idea to

break out of the box of having all research done by public institutions or wherever, that there's too many silos of people doing separate sorts of things. Like private professional organizations do their own research and NIH does its but they don't often get together and come up with novel approaches together. So that was the intent behind it.

CHAIRMAN TEUTSCH: I guess I have a question because the second sentence is to identify methods that are effective for translating genetics knowledge. And later on we talk mostly about various communication strategies. Are there other methods besides communication that we're talking about here? If not, we can just say communication and that will simplify it. But I didn't know if you were thinking of multiple--

DR. McGRATH: I think this one was focusing on communication. I think.

CHAIRMAN TEUTSCH: To identify effective communication strategies or techniques or models, whatever, for translating genetic knowledge.

DR. McGRATH: Vence, does that work for you?

MR. BONHAM: I think that works.

DR. McGRATH: Do you have a thought about

the public-private? Is that important to keep in?

MR. BONHAM: Well, I don't know if the text in the report actually supports, you know, identifying it there in specifically the recommendation. If it does then I would suggest keep it. But if not, it could go.

Is there a significant enough--

DR. McGRATH: The only text that's in there is people are saying there should be more of it. There's no data saying it's better but they're just talking about it being a limitation of the educational program that they are not integrated.

MR. BONHAM: I think it's a judgment of the committee.

DR. McGRATH: Okay. All right.

DR. DALE: Is it public-private collaborations and research or is it research and public-private collaborations? The word "research" is the parallel to collaboration, isn't it?

MR. BONHAM: If I were to make a recommendation I would delete it.

DR. : You would what?

MR. BONHAM: I would take out the "public-private collaboration" out of the recommendation.

DR. McGRATH: Okay.

CHAIRMAN TEUTSCH: You could really simplify it then. Say HHS should support or should identify methods--I guess communication methods for translating genetic knowledge into useful information for consumers and patients.

DR. DALE: Right.

MS. DARIEN: But even simplify it further and say "HHS should support research to identify effective communication methods for translating" and make it even simpler.

CHAIRMAN TEUTSCH: Well, you have got research--yes.

DR. McGRATH: The one on the table--let me just read it for everybody.

"HHS should identify communication strategies for translating genetic knowledge into information…" blah, blah, blah.

DR. DALE: Right.

CHAIRMAN TEUTSCH: Effective strategies, right.

DR. McGRATH: You want "effective." Okay.

CHAIRMAN TEUTSCH: yes.

DR. McGRATH: That's another word.

(Laughter.)

CHAIRMAN TEUTSCH: What did you say?

MS. DARIEN: (Not at microphone.)

(Laughter.)

DR. McGRATH: It would be good to identify them, though, really. Okay.

So that's the preamble.

"A" I happen to be very proud of. Any problems with A? Did we get too pithy?

All right.

And "B" is the only time we really bring in that idea of sort of not just internet but different things.

And then "C"--well, I'll stop here.

Any on and "A" and "B"?

All right.

(Slide.)

And then "C" is we just flipped the--a way to highlight the two organizations. Okay.

It sounds like we're all right on 4.

DR. : Yes.

DR. McGRATH: Okay. Great.

(Slide.)

5 now. If you're looking at your thing it's written up as Recommendation 4. This is the preamble.

(Slide.)

And here is the recommendation: "HHS should create and maintain a state-of-the-art internet portal to facilitate access to comprehensive, accessible and trustworthy web-based genetic information and resources for consumers." And that stands on its own. So very brief. We spent quite a little bit of time yesterday around 6:30 trying to come up with the right word. "State-of-the-art" is what won the little discussion we had.

Does this capture what we wanted? It's really very much decreased from the original text.

CHAIRMAN TEUTSCH: Did we lose the other media that we wanted in there or not?

DR. McGRATH: This one didn't--never had the additional media.

CHAIRMAN TEUTSCH: Never had it in this one?

DR. McGRATH: The last one just did and then there will be more later, more coming.

Okay. I'm going to take that as agreement. Okay.

(Slide.)

Recommendation 6. This is the recommendation that has no preamble and this is the

one about family history that is still pretty long. See what you think.

"Because family history tools are a potentially powerful asset for consumers and health care professionals to use in risk assessment and health promotion, HHS should: A. Support efforts to validate family history tools for risk assessment and health promotion; B. Support efforts to educate health care professionals, public health providers and consumers about the importance of family health history; C. Promote research on how consumers use family history to make health care decisions."

(Slide.)

And "D. Assess the effects of gathering family histories within diverse cultures and communities and among individuals whose family histories are unavailable; E. Support use of family history in clinical care through development of point-of-care educational materials and clinical decision support tools in electronic health records that utilize coded and computable family history, genetic, and genomic information; and F. Promote the embedding of educational materials in family history collection tools and personal health records directed to consumers and ensure access for all by

providing these tools in various formats."

So, if you recall yesterday, we had them divided by the three study groups--work groups and now we've blended them more and there's actually not less bullets.

DR. WILLIAMS: I think these are really good. The only question I would have is under "D" why would we specifically articulate "among individuals whose family histories are unavailable"?

DR. McGRATH: I was hoping somebody would ask that question. Because there's an emerging body of literature of people feeling disenfranchised and quite nervous. Refugee communities, adoptees, people like that who--they are getting the messages on the posters, get your family history, come in to clinics, and feel since they don't have--they don't know their family history, don't have a family history--that they should get genetic tests to cover up for that. So it's an issue. It's an emerging issue and I think that population is just going to grow in the United States with migration of people and things. So I think it's worth calling--myself--calling attention to it as an unanticipated consequence of the marketing for family history.

DR. WILLIAMS: So maybe I might propose

just to make it clearer because since the “and” refers to effects of gathering, which doesn’t seem-- obviously it didn’t make sense to me. If we were to change that to “as well as the potential for stigmatization of individuals whose family histories are unavailable.” Maybe “stigmatization” isn’t the right word but it at least then embeds the concept of what you’re worried about as exclusion or--

DR. McGRATH: I see what you are saying. And I don’t want to put words--

DR. WILLIAMS: That presupposes.

DR. McGRATH: Yes. Some people may feel benefitted by not having a family history because they don’t have diseases that they know of. So I don’t want to presuppose but just the general effects of it. Maybe it’s promoting. “Assess the effects of promoting family histories.”

CHAIRMAN TEUTSCH: Let me ask sort of a broader question about this one because this is really about family history in general. It’s not just about education.

DR. McGRATH: Right. And this is where we left it yesterday is that does it even fit? It really reflects the context within which this report was written, which was family history was huge and a

lot of educational efforts for all three groups are kind of going through the portal of family history thinking that's the entry point. And once we educate providers and consumers about family history the other things follow. So that--but I'm willing to--

CHAIRMAN TEUTSCH: Well, I'll be specific. So if you look at "A" which we need. We need valid tools. That is not really an educational issue primarily. So to me that belongs in the general discussion of the family history issues but probably isn't central to the educational side.

DR. McGRATH: Got it.

CHAIRMAN TEUTSCH: The second one is.

The third one. "C" probably is.

I would say "D" is also not primarily an educational issue. It's a use issue. It's an ethical issue. It's all kinds of things but it's not an educational one.

And "E" because it has the point of care sort of education is probably germane.

So I think you could get rid of "A" and "D" actually and at least it would be more on point with the educational.

DR. McGRATH: The only--

CHAIRMAN TEUTSCH: But, you know--

DR. McGRATH: The only--I'll just counter for a second and see if I (sic) agree with what I say. We include a fair amount about the importance of establishing clinical utility for genetic tests and various things--if we're going to educate health care professionals they first need to be convinced of the usefulness of this technology in their practice. So we've included support for the research on clinical utility in previous ones and this would seem to be quite parallel to that. But I don't--

CHAIRMAN TEUTSCH: You could say the same thing about all the tests that would need to be found valid and have utility before they go into educational material because see then that's a general issue.

DR. McGRATH: Yes.

CHAIRMAN TEUTSCH: And the problem, of course, is most of the stuff on family history--while we think it's central--the evidence base is pretty skimpy as we found from the last--from the NIH conference--was it last year? So I--

DR. McGRATH: Okay. I agree. I'm with you.

Now the only thing about--that I don't like about taking out "D" is a lot of--or at least the part I listen to--a lot in the conference was that we really don't know enough about family history with diverse communities, that it is an issue that may have different effects in different communities. If we take out "D" we don't have anything in there about the whole notion of health disparities and all of that. Maybe I could include some language in "C." "Promote research on how consumers use family history to make health care decisions…" Sorry to keep tripping "…and their use within diverse cultures and communities" or something like that or "disparate groups" or something like that?

DR. WILLIAMS: So maybe the question there is how much in the text of the report is this covered and is it necessary to be as specific in the recommendation. I don't remember from the report about that.

I think I would agree with Steve's point and also maybe to extend that to expand "C" to say "promote research on how consumers use family history to make health care decisions" and incorporate that into educational materials,

consumer educational materials so that it does all tie back to the education point.

CHAIRMAN TEUTSCH: So, Barbara, I know we're having a postprandial response here but why don't you help us. Tell us what you think these are now.

DR. McGRATH: Of this--

CHAIRMAN TEUTSCH: Walking through. So--

DR. McGRATH: Okay. So "A" is--

CHAIRMAN TEUTSCH: --what do you think--

DR. McGRATH: --gone.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: We'll take a vote at the end. I just want to make sure we're all together about what's here.

DR. McGRATH: You mean on 6? Just for these 6?

CHAIRMAN TEUTSCH: Yes, on 6.

DR. McGRATH: Oh, on 6. Okay. Yes.

So we've taken--we've gotten rid of "A". I don't have a computer here to do it. But anyway--so "A" is no longer there.

"D" is the same.

"C" just has a phrase. "…and incorporate" this or it "…into consumer educational

materials.”

DR. : (Not at microphone.)

DR. McGRATH: Maybe I don’t need--I don’t know but I could have. Sorry, I didn’t know.

“D” is gone with some sadness to me.

(Laughter.)

Just the notion of diverse cultures and communities I like. You know, we go back to the idea we were tasked with bringing health disparity issues throughout everything and if we keep saying it’s in the text, and if it’s not in the recommendations or executive summary it’s one more thing that gets put to the back of the bus.

MR. BONHAM: So is it reframing “D” to focus on education related to diverse cultures and communities related to family history--is that the appropriate way to make sure that there’s focus on diverse communities--

DR. McGRATH: Yes.

MR. BONHAM: --but making sure that it’s linked directly back to education.

DR. McGRATH: That’s exactly it. That’s the problem.

MR. BONHAM: That maybe is what is needed to happen.

CHAIRMAN TEUTSCH: Could I make a suggestion then, Barbara?

DR. McGRATH: Yes.

CHAIRMAN TEUTSCH: If that's what we want to do, in "C" if we'd simply add this. "Promote research on how consumers and diverse communities…"

DR. McGRATH: Yes, that's what I originally was--

CHAIRMAN TEUTSCH: And then "use family history to make health care decisions and then incorporate it into the educational materials."

DR. McGRATH: I'm happy with it.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: So we would not lose the --

(Simultaneous discussion.)

DR. McGRATH: I'm happy with that.

Thank you.

I'm not going to go until I am happy here.

(Laughter.)

CHAIRMAN TEUTSCH: Worry not, we won't let you go.

DR. McGRATH: I think "E" and "F" stay the same. So we've got whatever it is. Five with the new addition of "C". Okay. All right.

(Slide.)

And now the last thing which was just some of the language is in the cover letter, not as a recommendation, and it's basically to ask the Secretary to work with agencies to see that these things get implemented and monitored and followed up in five years.

DR. WILLIAMS: We just need to make sure it's AHRQ.

CHAIRMAN TEUTSCH: Our copy editor hopefully will pick that up.

DR. McGRATH: I can't even say A-H-Q-R (sic). It doesn't quite work, does it?

CHAIRMAN TEUTSCH: It's sort of--

DR. McGRATH: Yes. All right.

So what's the next step?

Do we take a vote? What do we do now?

CHAIRMAN TEUTSCH: All right. This is great, Barbara. Don't leave.

DR. McGRATH: No, I'm just looking.

CHAIRMAN TEUTSCH: So we need just a vote now on these recommendations so that we can finalize this report.

All in favor of accepting the recommendations as presented?

(Show of hands.)

DR. : (Not at microphone.)

DR. McGRATH: Charmaine, you know you can raise your hand.

CHAIRMAN TEUTSCH: This is a part of trust.

(Laughter.)

Okay. All those opposed?

DR. McGRATH: Do we have a quorum?

CHAIRMAN TEUTSCH: All those abstained?

So we have unanimity.

Barbara, congratulations.

DR. McGRATH: Thank you all.

CHAIRMAN TEUTSCH: Thank you very much for leading this.

DR. McGRATH: Thank you, everybody.

(Laughter.)

CHAIRMAN TEUTSCH: And thanks, everybody. I think we have a much tighter set of recommendations that are really--

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: --to this report. So thanks to everyone.

Since I know that my colleagues to my right are still refining a couple of things, can we turn to

the whole genome sequencing work and see--Charis and Paul, I know you guys have been working on it.

Apparently we don't have an electronic version that's easily accessible so Allison is handing out a hard copy.

You're on.

DR. ENG: I'm on? Okay.

CHAIRMAN TEUTSCH: Yes.

IMPLICATIONS OF AFFORDABLE WHOLE-GENOME SEQUENCING

CHARIS ENG, M.D., PH.D.

SACGHS

DR. ENG: I'll read it. Okay.

Now, as you recall, our great chairman made the recommendation that we have a short preamble followed by the concerns in a quick "recommendation."

So "Next generation sequencing methods have brought the clinical use of whole-genome sequence data to reality. Although these technologies provide exciting, even paradigm-shifting, opportunity in advancing health care, several challenges will need to be addressed. These challenges include:

"Limited information about clinical validity for many genotype-phenotype associations,

which impedes the interpretation of variants revealed through whole-genome sequencing;

"A coverage and reimbursement paradigm that is ill-suited for WGS testing; it does not adequately cover or reimburse informatics costs or the cognitive services required to interpret WGS data;

"Timely and appropriate reassessment of WGS data, as research reveals new findings; a clear understanding of who will be responsible for communicating new data in 'real time' to the patient;

"Limited workforce that can skillfully communicate findings from WGS testing, including variants of unknown significance, off-target results, and findings of a potentially sensitive nature."

CHAIRMAN TEUTSCH: We're getting some feedback from something. I don't know if we're getting it from the phone.

If anyone is on the phone, would you please mute your line?

Thank you.

All right.

DR. ENG: So then the final sentence says

"SACGHS urges the Secretary to convene a group of experts and interested parties to explore fully topics that arise from the rapidly decreasing costs and increasing power of whole-genome sequencing. In doing so, HHS can follow advances in WGS technologies and the adoption of these technologies for clinical use. Communication and coordination between HHS agencies will be essential for the successful integration of whole-genome sequencing into health care."

DR. WILLIAMS: So I have one minor suggestion to the bullet list and two bullets to consider adding.

On the third bullet I just think it should be "communicating new data in real time to patients and providers" because I think in most cases the communication goes from the laboratory to the provider.

The two bullets I would add--one would be related to a lack of a definition of what is adequate analytic validity or reliability for whole-genome sequencing. In other words, the definition of what is appropriate accuracy. You know, 10^{-6}, 10^{-9} errors per sequence run, something to that effect. Obviously that is not wordsmithed at all. Yes,

"acceptable" or "a threshold" or something like that, "definition of."

And then the other bullet relates to the points that I think Liz brought out yesterday, which would be analogous to the coverage and reimbursement paradigm, which would be "a regulatory paradigm that is ill-suited for whole-genome sequence testing." And then if we want to add anything to that.

DR. : Say that again.

DR. WILLIAMS: So I'm adding one bullet on the analytic validity or defining the appropriate or adequate level of accuracy and then I'm adding a second bullet which is "a regulatory paradigm that is ill-suited for whole-genome sequence testing."

DR. FERREIRA-GONZALEZ: On the analytical validity we also don't have the tools or the materials to be able to determine that.

DR. WILLIAMS: Do--yes.

DR. FERREIRA-GONZALEZ: So I would add that.

DR. ENG: So then I'm hearing "lack of a special definition" as well as "tools for evaluating the analytic validity and reliability for whole-genome sequencing." And the second one is "a regulatory paradigm that is inadequate for whole-

genome sequencing."

CHAIRMAN TEUTSCH: I have a question on the third bullet.

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: Pardon?

DR. : Third on the paper?

CHAIRMAN TEUTSCH: Third on this paper that is "Timely and appropriate reassessment of whole-genome sequence data as research findings become apparent." But isn't there are some steps in here about then how that information--how that information is going to be made available, as well as how it's going to be communicated?

DR. FERREIRA-GONZALEZ: Where it's going to be stored?

CHAIRMAN TEUTSCH: Well, who--how is this going to be done in a practical way?

DR. FERREIRA-GONZALEZ: We don't know that. Well, we can--you can do the whole-genome sequencing and have it in my--while competing--in my underground laboratory but that doesn't mean that, you know, I can have access to that. So there are all these whole things--where the DOT is going to be located. Who and how--you know, how accessible it's going to be. Who has access to it

or what tools we're going to use to reassess.

CHAIRMAN TEUTSCH: So you have all of those sort of data management issues but you also then have--somehow we're going to have to combine that--which is what I think you're getting at, which is the information about what the heck it means. Right? And who is going to--how is that going to get managed in a way that then it can be transmitted to clinicians and patients who have got to use it.

DR. WILLIAMS: Right. So we may be able to solve that if we look at "responsible for reevaluating, interpreting and communicating new data." That would kind of capture, I think, the points that you were raising.

Now, again I don't know that we need to be comprehensive in these explanatory bullets because obviously the whole point of convening the group is to flesh out all of these different issues but that would be a relatively parsimonious way to do that.

So "responsible for reevaluating, interpreting and communicating."

DR. ENG: So I also had so "a clear understanding of who will be responsible for accessing, reevaluating and communicating the new data…" blah, blah, blah.

DR. DALE: (Not at microphone.)

CHAIRMAN TEUTSCH: That's the data management issue.

(Simultaneous discussion.)

DR. ENG: So the first part of that bullet I added "timely and appropriate reassessment and data management" or let's say "data management and timely and appropriate reassessment of WGS data."

DR. DALE: (Not at microphone.)

DR. ENG: Yes.

DR. DALE: (Not at microphone.)

DR. WILLIAMS: So it could be--you could use "communicating these findings in the real time" which would be a little bit more inclusive because you're right it's not just the data that's communicated.

DR. DALE: Right. That's my point. Thanks.

DR. FERREIRA-GONZALEZ: Because the new data is the genotype/phenotype correlation. I mean, the genotype doesn't change but this new data is the genotype/phenotype correlation.

DR. ENG: Right.

CHAIRMAN TEUTSCH: Right, but it's--

(Simultaneous discussion.)

DR. ENG: It's the clinical outcome and interpretation.

CHAIRMAN TEUTSCH: It's the interpretation of that, how big is that magnitude.

So are there other major issues that we should capture here in addition to this and what Charis and Paul have added--have put here?

DR. FERREIRA-GONZALEZ: What's an off target result?

CHAIRMAN TEUTSCH: Can you speak a little louder?

DR. FERREIRA-GONZALEZ: Yes. I don't know what--I mean, I know what a "variant of unknown clinical significance" but what's an "off-target result"?

CHAIRMAN TEUTSCH: You're talking about false-positive?

DR. ENG: Yes, false-positive.

DR. FOMOUS: The way it was explained--I'm trying to think of what speaker we heard at our last meeting I think.

DR. :

DR. FOMOUS: No, I think at our last meeting where it's a--so you have done whole-genome sequencing for a clinical purpose but you're finding

other variants of significance but they weren't the ones you were originally looking for.

CHAIRMAN TEUTSCH: Oh, that's different. That's different.

DR. FOMOUS: Yes. So it's just--

CHAIRMAN TEUTSCH: That's an incidental positive finding.

DR. ENG: It's an incidental finding.

CHAIRMAN TEUTSCH: That's very different from false-positive.

DR. FOMOUS: Yes, very different.

CHAIRMAN TEUTSCH: But they are both--

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: They are--positive incidental findings is one thing and false positive--

(Simultaneous discussion.)

DR. FERREIRA-GONZALEZ: We talked about all these massing of data on these incidental findings.

DR. WILLIAMS: So let's change it to "incidental."

DR. ENG: I think "incidental" will be clearer.

(Simultaneous discussion.)

DR. : Do you want to capture false-positive? Is that--

DR. ENG: I think--

DR. WILLIAMS: But that's going to come out--

DR. FERREIRA-GONZALEZ: That's part of the quality control.

(Simultaneous discussion.)

DR. FERREIRA-GONZALEZ: I think the incidental is more relevant.

DR. WILLIAMS: Yes.

DR. ENG: Yes. Thank you.

CHAIRMAN TEUTSCH: Do you want to get--I think to make the point that this can be paradigm shifting, do we want to say that they also--in addition to shifting the paradigm, we actually have not really a good clue at the moment as to what the economic impacts are--economic and financial impacts are on the health care system.

DR. ENG: Should that be a bullet?

CHAIRMAN TEUTSCH: No, I would probably just put it here.

DR. ENG: Okay.

CHAIRMAN TEUTSCH: When you talk about paradigm--

DR. ENG: Okay.

CHAIRMAN TEUTSCH: Your preference. I think you can put it in either place, as a bullet or up in the preamble.

DR. ENG: Let's put it at the bullet. "Inadequate knowledge about the economic impact on health care."

CHAIRMAN TEUTSCH: On the health care--

DR. ENG: On the health care system.

CHAIRMAN TEUTSCH: Do you have any comments on the actual--I mean, that's all preamble.

DR. FERREIRA-GONZALEZ: The preamble--yes, we heard several challenges but is there any way to say that these are some of the challenges that we have identified and that there are going to be a lot more?

CHAIRMAN TEUTSCH: Well, maybe if we could just--instead of saying "several challenges," say "There are many challenges, some of these include--some of these challenges are…" because I think we all realize this is a partial list.

DR. FERREIRA-GONZALEZ: Yes, as more and more individuals and laboratories start doing it, a lot more questions are going to arise.

CHAIRMAN TEUTSCH: Right.

DR. ENG: Right.

DR. DALE: (Not at microphone.)

CHAIRMAN TEUTSCH: Microphone?

DR. DALE: (Not at microphone.)

CHAIRMAN TEUTSCH: Microphone.

DR. DALE: "Next generation sequencing methods…" That's jargon.

MS. DARIEN: I don't think that's so jargony (sic) because there has been so much coverage in the press about it. So I think that it--you know, it is something--it is a word that people use. I mean, I'm very sensitive to jargon and these things but I don't think it's that jargony. Does anybody else?

(Simultaneous discussion.)

DR. FERREIRA-GONZALEZ: It is used in peer review literature and books and--

DR. DALE: Well, for general communication I'd say "DNA sequencing methods." That's a more--but anyway it doesn't matter. If it's okay it's okay.

DR. ENG: We want "new and novel" in there because we don't want people to think, oh, it's the same old--

DR. DALE: Say "New DNA sequencing method

or new sequencing methods." But anyway--

DR. ENG: What if we go "Next generation sequence in parenthesis one way or the other so that those in the know will say "Ah, NGS."

(Laughter.)

CHAIRMAN TEUTSCH: Other issues here with the first two slides?

Let's look at the slides. That shows you my paradigm. I'm still back in-let's look at the actual recommendation on the second page and see if that's what we want to say.

Dr. Randhawa?

DR. RANDHAWA: In the second sentence here I think what the committee is trying to get at is not just following advances but verifying the outcomes of these technologies, both economic and health outcomes, and that sense is what I'm missing here. It seems to be just passively following the advances and its adoption and not the point of verifying the outcomes is not in here.

DR. ENG: So "in doing so HHS can follow advances to clarify health and economic outcomes."

MS. DARIEN: The other thing I might do in this first sentence is rather than just saying "topics" which sounds really bland and vague, I

might use some other words like “impact, challenges, knowledge.” And I would put “to fully explore.”

But do you think that it should be--I mean, impact, challenges, knowledge? I mean, something--oh.

DR. WILLIAMS: We use challenges in the laundry list and in the preamble so I think that it would be appropriate to reflect challenges. “To fully explore the articulated challenges or challenges or whatever.”

CHAIRMAN TEUTSCH: So a way to be more specific because we’ve talked about a set of laboratory challenges, health outcome challenges, and then health system impacts; right?

MS. DARIEN: Right.

CHAIRMAN TEUTSCH: So we could actually be a little bit more specific and we need to look at all those different levels.

MS. DARIEN: Could we say “health and societal?” Is that specific enough or is that not quite--

CHAIRMAN TEUTSCH: I think we need the laboratory piece. We need the laboratory because there’s a whole set of--

MS. DARIEN: So “science, health and

societal" maybe. I don't know.

DR. FERREIRA-GONZALEZ: Not only the challenges but also the opportunities.

(Simultaneous discussion.)

DR. WILLIAMS: Yes. I think that again the risk we have in terms of expanding the recommendation is that we end up then being redundant to the list of things that we have listed previously to kind of set up the recommendations. So I don't know that--I think it is important. I think that some of the changes that were proposed that bring in the idea that it's going to be important to look at the outcomes and that we should fully explore challenges and opportunities or opportunities and challenges would be important but I wouldn't really want to keep creating lists.

DR. WALCOFF: I actually--I was going to also suggest that--just in terms of trying to make it really more concise and shorter--to move the points about the decreasing costs and increasing power. I think that's more of a preamble overarching type of a statement.

CHAIRMAN TEUTSCH: (Not at microphone.)

(Simultaneous discussion.)

DR. WALCOFF: Okay. Sorry about. I was

actually trying to redraft as we were all talking but I think you can be more direct. I mean, instead of just saying, you know, we want a group to just keep looking at these--I mean, isn't that the purpose of looking at both opportunities, challenges, the topics that are arising? I mean, it's really to help shape and drive policy around whole-genome sequencing that will improve outcomes and you are trying to get the economic issues in there. I mean, I think how we would say it is support further innovation or something along an economic line. It really is to benefit outcomes and to support further innovation in this area but doing it in an appropriate balanced way.

CHAIRMAN TEUTSCH: A word like "value" or "efficiency."

DR. WALCOFF: Right. I think even just being more straightforward because I think when you start saying "explore" or "discuss" it just becomes another meeting rather than an action oriented objective.

DR. ENG: So I think I'm hearing "SACGHS urges the Secretary to convene a group of experts and interested parties to address challenges--to fully address challenges and opportunities that

arise from the incorporation of whole-genome sequencing into clinical care so that it will inform policies to improve health outcomes and enhance further innovation."

DR. TEZAK: I would say maybe you want to put just "to improve health outcomes" because if you add "innovation" then you're kind of giving one side.

DR. ENG: Okay. How about "to drive policy for optimal delivery of value-based health care." I know I sound like Michael, sorry, but I do like him.

(Laughter.)

DR. ENG: "Value-based delivery of health care" is what we're talking about.

CHAIRMAN TEUTSCH: We can either talk value or we can talk about efficiency.

Janice, you were going to say something?

MS. BACH: I was just concerned that the word "group of experts" might not sound quite strong enough. It sounds a little casual to me like it could just be a one time thing, get people together.

CHAIRMAN TEUTSCH: We just heard about "groupiness" (sic).

(Laughter.)

MS. BACH: So I don't know if there's some stronger--

DR. ENG: Convene a standing body.

MS. BACH: Yes, a standing or something--

(Simultaneous discussion.)

MS. BACH: --ongoing steering committee or something there that it's going to be continuous and not just--

DR. ENG: You mean like unlike us?

(Simultaneous discussion.)

MS. BACH: Well, that's the problem. I don't know what we're really allowed to say but I think --

DR. : Stakeholder.

(Simultaneous discussion.)

DR. : An advisory committee.

DR. : That's what I was trying to get at.

DR. WALCOFF: Yes, just to make it more--a little Washington speak there. Stakeholder.

DR. ENG: Okay.

CHAIRMAN TEUTSCH: And I would think--I would say we talk about health outcomes and efficiency of the health care system, and then you've got the economics and values piece in there.

Charis, I know it's hard to lead this discussion and take notes at the same time but why don't you try and re-read what--tell us what we said.

DR. ENG: Unless she's got everything.

DR. : No.

DR. ENG: Okay.

(Laughter.)

DR. : I've just got pieces of it.

DR. ENG: Okay. "SACGHS urges the Secretary to convene an ongoing body of experts and stakeholders to fully address the challenges and opportunities that arises or that will arise from the incorporation of whole-genome sequencing into clinical care to inform health care policy and inform policy to improve health outcomes as efficiencies. In doing so, HHS can follow advances in WGS technologies to clarify health and economic outcomes and the adoption of these technologies for clinical use. Communication…"

DR. : It's a little redundant.

DR. ENG: It is a bit redundant. "Communication and coordination…" blah, blah, blah.

DR. : You don't need it twice. Just one way or another.

DR. ENG: Okay. Do you prefer that in--do we say that in the first sentence or do you like Gurvaneet's idea in the second sentence? Okay.

DR. : Gurvaneet is always right.

(Laughter.)

DR. DALE: I have a suggestion.

(Simultaneous discussion.)

DR. : They need to hear that in Rockville.

DR. ENG: We like Gurvaneet. Great ideas. David?

DR. DALE: I have a suggestion. "SACGHS urges the Secretary to monitor and develop policies" is the action. "Monitor and develop policies arising from…" yes. "To convene a group of experts and stakeholders to monitor and develop policies arising from the rapidly decreasing cost and increasing power of whole-genome sequencing." I would stop there. I think the rest kind of dilutes the message. That's all that you're asking to do is just to basically reconvene this committee.

(Laughter.)

DR. ENG: No, we don't say that.

(Laughter.)

DR. DALE: Or something like it.

(Simultaneous discussion.)

DR. DALE: I said, “SACGHS urges the Secretary.”

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Barbara?

DR. McGRATH: Mimicking what David just said I was just going to take out that last sentence because it didn’t seem like a recommendation. It seemed like background information.

DR. DALE: Yes.

DR. : (Not at microphone.)

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Okay. Let’s hear it one more time with feeling.

DR. DALE: I said, “SACGHS urges the Secretary to convene experts and stakeholders on a regular basis to monitor and develop policies arising from the rapidly decreasing cost and increasing power of whole genome sequencing.”

DR. : (Not at microphone.)

DR. WILLIAMS: As I listened to that I think the verb “arising” isn’t the right--it’s more resulting from as opposed to arising. I don’t know. Not seeing it, it’s a little bit hard to react to but that didn’t--those clauses didn’t strike me as

being joined well by “arising.”

DR. FOMOUS: Or we could say “arising from the challenges of declining cost and increasing power.”

DR. FERREIRA-GONZALEZ: And opportunities. Don’t leave the “opportunities” out.

DR. : Yes.

(Simultaneous discussion.)

DR. FERREIRA-GONZALEZ: You’ve got to make it positive.

DR. ENG: That’s right. And let’s flip it, opportunities and challenges.

DR. ENG: Yes.

DR. WALCOFF: I have one more try.

CHAIRMAN TEUTSCH: Go for it.

DR. WALCOFF: I don’t have “arise” in there though but “convene experts and stakeholders to advise policymakers on the efficient adoption and clinical use of whole-genome sequencing technologies to improve health outcomes.”

CHAIRMAN TEUTSCH: Do you have that nicely written down so we can copy that?

DR. WALCOFF: I sort of do.

CHAIRMAN TEUTSCH: Okay. Read it one more time.

DR. WALCOFF: "Convene--" I left out "a group of" but "convene experts and stakeholders to advise policymakers on the efficient adoption and clinical use of whole-genome sequencing technologies to improve health outcomes."

DR. WILLIAMS: is that an alternative to David's?

CHAIRMAN TEUTSCH: Yes. That's a friendly amendment.

DR. WALCOFF: You might be able to merge it but I was writing when you were talking so I need to get all of it.

DR. : (Not at microphone.)

DR. WALCOFF: Because I feel like this is sort of at the end that we've described all of these and it's important to create policy around this.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: All right. Read it one more time and then let's see if we can get a vote.

DR. : Cathy, do you have it all?

CHAIRMAN TEUTSCH: Do you have it?

DR. : She has it now.

CHAIRMAN TEUTSCH: Okay. Go for it.

Cathy?

DR. FOMOUS: "SACGHS urges the Secretary

to convene experts and stakeholders to advise policymakers on the efficient adoption and clinical use of whole-genome sequencing technologies to improve health outcomes."

CHAIRMAN TEUTSCH: The two concepts that we probably want to say is "regularly convene" so it suggests that it is ongoing and I don't know if you want to say "health outcomes and health care-- efficiency of the health care system" or you want to just leave that out about the efficiency of the health care system.

DR. WALCOFF: I think I had--well, I guess I--

(Simultaneous discussion.)

DR. WALCOFF: "Efficient adoption."

CHAIRMAN TEUTSCH: "Efficient adoption."

DR. WALCOFF: Right, "and improved health outcomes."

CHAIRMAN TEUTSCH: Okay.

Any other modifications to this?

All those in favor?

(Show of hands.)

All those opposed?

Any abstentions?

We have unanimity.

DR. BILLINGS: So, Steve, just since we've just voted on the topic that I was remaining here for I just wanted to thank my colleagues for their votes and their work on this topic. It has been a pleasure serving with you.

And I just wanted to say for the record, Steve, what I said to you before, which is that I actually--along with the whole-genome sequencing topic--I believe that there are several other topics of unfinished business here at SACGHS and that while our mandate may have been technically fulfilled or our charter questions maybe have been technically fulfilled I think the topic area that we've been considering is not. And that I would certainly like to see our communications both with Dr. Collins and with the Secretary reflect the fact that we--these areas remain worthy of investment by a group like ours and with the intelligence and dedication of a group like ours.

So I just wanted to say that for the record, Steve.

And thank you all.

CHAIRMAN TEUTSCH: Good. Well, thank you.

Thanks to both of you for leading us through what has I think been a very stimulating

discussion of these issues and helping us get this focused as well.

DR. WALCOFF: And I think of the many things this committee considered I feel like you were at the leading edge of this and folks are going to look back and say you were at the leading edge of this. So you guys did a really good job.

DR. ENG: Thank you.

DR. BILLINGS: Thank you.

DR. FOMOUS: Steve?

CHAIRMAN TEUTSCH: Yes?

DR. FOMOUS: I don’t mean to beat this language into the ground but I just wanted to ask one thing.

(Simultaneous discussion.)

DR. FOMOUS: We talk about convening experts and stakeholders, and I think that implies that the stakeholders aren’t experts

DR. WALCOFF: I know. I would have normally just said “stakeholders.”

DR. FOMOUS: So could we go with this: “And convene experts from appropriate stakeholder groups?”

MS. DARIEN: I think we should just put “stakeholders” because “stakeholders” is all

encompassing.

DR. FOMOUS: Okay. And leave out "experts."

MS. DARIEN: Yes.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: They mean different things, right? I mean, not all experts are stakeholders and not all stakeholders are experts.

DR. FOMOUS: But it implies that the stakeholders aren't expert.

CHAIRMAN TEUTSCH: No, I don't think so. I think--but it does have a lot to do with how you want this group constituted. Is it a group that is supposed to really look at--bring all of those different constituencies together or is it a group that is supposed to have real--you know, more of a scientific kind of expertise?

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Pardon?

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: It's not discipline because that sounds academic. I think what you're saying is people from the industry, from health care, academia, all these different--

MS. DARIEN: So I--

CHAIRMAN TEUTSCH: That's what I hear when I hear "stakeholders."

MS. DARIEN: --I will cede to the idea that we can put "experts" and "stakeholders" but I will just say that I find everybody to be--I think "experts" are also "stakeholders." So I think it's fine if it leads to the result that we want but I just want to say I think that "stakeholders" includes "experts." So that's my point of view.

CHAIRMAN TEUTSCH: Just for sake--why don't we just leave "experts and stakeholders" in here since we seem to be of a different--okay.

Again, thank you.

So I have not seen this because they have been working on it. So here is what began as a shell of our letter to the Secretary.

It has now grown some pieces, most of which I haven't read so I can't tell you exactly what's here but I think there are a few things.

One is we have to look at the basic structure of this to make sure that it's what we want to say.

The second thing is that for each of the sections that we've been specifically talking about, the whole-genome sequencing, the data sharing, what

will finally be in here is what we've decided and this has been a work in progress so it's not necessarily accurate. I don't know if the clinical utility one matches exactly what you said either but it needs to be what we discussed this morning.

So why don't you take a couple of minutes just to look through the document. And, in particular, look at the introductory paragraph and the last parts of the paper, particularly the part on guiding principles which we believe to be sort of a framework for these issues going forward. And the guiding principles were pooled by staff from our prior reports paraphrased. They don't necessarily-- they are not word-for-word. And see if those are the kinds of things that we think should be guiding the working in HHS going forward.

I'll give you a couple of minutes to read through this and then we can go through specifics.

(Pause.)

Sarah reminded me there's something here that you've actually not seen. There's a section before the guiding principles on public health implications of genomics. That's a topic that was on our priority list but we never got to. So, take a look at that as well. It's not really a set of

recommendations. So if you could look at that see if we want to include that a well. That would be good.

(Pause.)

I know most of you are still reading but let's talk about how we might approach this. So I'd first like to get a sense of is this the right structure and then we can go through some of the content in the different sections that we haven't already discussed.

I see many of you with pens and pencils out. Since most of what's in here is going to--you know, we're not going to go through word-by-word and get it word crafted this afternoon and these are not the--other than the recommendations where I do think we have to be--you know, things are going to be closed today. We can do copy edits, rephrasing of some of these things as far as the text goes. So your suggestions will be welcome and I think we need to make sure that we have the content roughly correct.

So let's start with just the overall structure of the document.

Barbara?

DR. McGRATH: I'm just going to quote back

to what you were saying yesterday, the KISS idea. It wasn't clear to me that we thought these three issues were the highest priority in the way it was written so I don't' know if that phrase needs to be there or the font different or somehow--it looks like just one long document of about four pages rather than you were saying that we want three issues highlighted.

CHAIRMAN TEUTSCH: Gwen?

MS. DARIEN: So I think the--I mean, I guess this relates to somewhat to what Barbara was saying but I think that in the beginning what's missing for me is just the explicit notion that we are--these are things that are left undone that we urge the Secretary to complete. As opposed to being the three most important issues they are really the three major unfinished issues.

So I think without seeing that it makes them seem as if they are the three most important.

CHAIRMAN TEUTSCH: I think this is what Paul wanted--was getting at as he left.

MS. DARIEN: Right.

CHAIRMAN TEUTSCH: That while we think we've made great strides there is unfinished important work.

MS. DARIEN: Right.

CHAIRMAN TEUTSCH: And I think you're right. We haven't prioritized them specifically but these are things that we've--

MS. DARIEN: Right. And I would--I mean, I would even go more than--farther than important. I might even say critical. I mean,--

CHAIRMAN TEUTSCH: Sheila?

DR. WALCOFF: I was just thinking also in terms of structure if you just really focused on just the first page. I think that we do need to state upfront that the committee--the charter is sun-setting because there are a lot of Secretary advisory committees and I think it's just a nice way to start saying, you know--you might could have it like on here and say why are they going away. So sun-setting--it's an honor to serve but I think that language is important to thank her and the department.

And then I would actually--the second paragraph, I think that's more kind of summarizing at the end because if we really want to get out the point that there are some critical issues that are still require consideration, development, further action. I think that really needs to be the next

thing. Here are some--here are some key critical issues that work remains to be done on, you know, under your purview--under the Department of Health and Human Services.

And then I think I might even move--you know, if we can--I don't know how long--the guiding principles are long. If we had maybe some of the key guiding principles include… And then go into the background on each one sort as the second piece. And then even wrap it up and conclude with "during its tenure," and then "thank you again."

CHAIRMAN TEUTSCH: Okay.

David?

DR. DALE: Well, somewhere in the front here I would put what we focused on at our--what we discussed at our last meeting. Particularly the education piece. That's big in terms of where this is all going. There's a huge disconnect, as I see it, between NIH level research and the nation's health.

CHAIRMAN TEUTSCH: We have the--we actually have a report going to the Secretary on education.

DR. DALE: But I would mention it here.

CHAIRMAN TEUTSCH: I mean, we could

mention it here as one of the reports we've done but that will go with a separate cover letter as one of our reports.

DR. DALE: Well, anyway I think it deserves to be mentioned here as one of our last acts. I just worry that the letter is so long that I'm not sure who is going to read all this.

DR. WILLIAMS: Well, it's the last gasp. I mean, this is our chance to get it out there, right? And, you know, compared to one of our typical reports or even to the executive summary of our typical reports it's not that long.

I think these are issues that we all feel, you know, very strongly about.

Now, it may be that there are some reorganization of the way we say this that is important but I think we've been pretty efficient in terms of saying here are the three issues that are sort of--that we didn't get to finish and here is what we've learned, and here is what you need to know about this.

I think in some ways the guiding principles, I think, are a way to summarize, in fact, all of the reports that we've done to say these are the things that are recurring over and

over and over again.

So you've heard me rail on before about the idea that we can somehow compress complex issues into one page and assume everybody is going to understand it. At some point somebody has to do the dirty work and read some of this stuff and act on it.

DR. DALE: I agree, Marc. I just was-- maybe we can do it with the font or the type or the underlining or something to be sure we get the message across because I agree with you. I just mentioned the education piece as coming right at the end of our work but I don't want it to be neglected. As an advisory group to the NIH that's really not an education organization so it hangs out there.

DR. WILLIAMS: Well, we're advisory to the Secretary.

DR. DALE: That's right. That's why that's so important.

DR. WILLIAMS: Yes.

DR. WALCOFF: Maybe it even flows if we-- you know, if we just mention the sunset and then the honor it is to serve, and then we can actually say "during our final meeting in October we finalized this report." And then lead right into "in

addition, there are these three key areas of work that was on--you know, that the committee ongoing that we were not able to complete during our tenure that we think are--we think is important work and here in more of the body of this letter are some of the key things and recommendations that we were able to convey to you at this point during that work." And then kind of sum it all up with all the work that the committee has done and the guiding principles. Because I think that that's important. You don't want the last big piece of work to get lost in the shuffle.

CHAIRMAN TEUTSCH: Gwen?

MS. DARIEN: I just have a point of--I actually have a clarifying question.

So in the second paragraph we talk about "during our tenure the committee produced reports, letters and commentaries…" and then the last sentence in that paragraph is "we believe that these reports, which contain more than 60 recommendations, provide a roadmap…"

So we go from the full work to just what the reports provide or is it supposed to be everything that provides a roadmap? So it just is--it isn't clear to me where--how that flows.

CHAIRMAN TEUTSCH: So I think you can help us with words here. So we can say that--so that we do indicate that the--

MS. DARIEN: Right.

CHAIRMAN TEUTSCH: --our reports along with including the 60 recommendations or something.

MS. DARIEN: Right.

CHAIRMAN TEUTSCH: So we can work on that.

MS. DARIEN: "We believe that our work provides a roadmap to help the nation realize the benefits of genetics and genomics while avoiding potential harms and pitfalls."

CHAIRMAN TEUTSCH: Right.

DR. WILLIAMS: And then I guess the question would be is tense. Should that be a past tense sentence?

MS. DARIEN: Provides.

CHAIRMAN TEUTSCH: Provides.

MS. DARIEN: Provides a roadmap.

CHAIRMAN TEUTSCH: So, Sheila, would you do this sort of with the second paragraph at the very end and followed by--or have it stated and then follow with the guiding principles? Which comes first? Do you want to conclude with the guiding principles or do you want to conclude with this

paragraph?

DR. WALCOFF: Sometimes you have to kind of see it to see how it stakes out.

CHAIRMAN TEUTSCH: I know.

DR. WALCOFF: But I think--I don't know that I have a strong preference for that. I think that--I do think this sort of summarizes everything in this final paragraph but at the same time I mean, you could use it as an intro to the guiding principles too.

CHAIRMAN TEUTSCH: Exactly. It goes--works either way.

DR. WALCOFF: Right, really I think it does. And, you know, I think as long as the guiding principles are also highlighted. So that just leaves you with a small closing, which I think also is fine.

CHAIRMAN TEUTSCH: So, I mean, I got--I think I hear agreement that we want to have a fairly short beginning so that we can really focus on these outstanding issues. And then we will go through this and then, depending on how this looks, either the guiding principles and this summary of the work over our tenure or vice versa.

Is everybody okay with that?

All right, so let's go into what's on page 4 and 5. Let's start on page 5 actually.

Look--as I said, the staff have gone through our prior work and tried to pick out statements, conclusions that sort of go beyond those immediate reports in terms of a set of principles we think can guide future--the future thinking of the Department. It's a long list. It's all paraphrased. It's not the words from the reports directly.

So please look at that list and, if this is the kind of thing we want to say, are these the right things to say? Are there missing pieces? Are there pieces that need to go away?

Marc?

DR. WILLIAMS: I would, unfortunately, add a couple of things.

DR. WALCOFF: I thought maybe you'd say we've got to get this down to three.

DR. WILLIAMS: No. No, I'm not. I'm sorry. It can't be gotten down to three. There's no way.

DR. : Thirty maybe.

DR. WILLIAMS: So you're going to have to deal with ten bullets, Madame Secretary.

In bullet 5 when we're talking about "disparities and equity and fairness" the one thing that I didn't see in the guiding principles was the work that was done relating to coverage and reimbursement.

So I hesitated to add a second sentence but something to say "existing coverage and reimbursement mechanisms also create barriers to access and equity." Something to that effect that because that has been a major area of focus that has come back again and again.

And then I would suggest that we probably need an additional bullet. Something to the effect of generation of evidence about utility of genetic testing is foundational to translation into improved health outcomes.

I looked through these and I just don't think we're explicit enough about the evidence piece. Even though one of the three areas relates specifically to clinical utility and comparative effectiveness research I think if there has been any guiding principle at least over the last three or four years it is this idea of what evidence do we have that this is really improving health.

CHAIRMAN TEUTSCH: Barbara, I've scribbled

down some notes. I hope this--I should ask. Is somebody on the staff getting these thoughts down? I just want to make sure.

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: Pardon?

I mean, I'm trying to take some notes.

Is somebody writing them down? They always do.

DR. DALE: Marc, could you do that with number--what's bullet point 8? "Integration in the health care systems..." That is that they should be based on evidence.

DR. WILLIAMS: Yes. So you could say something to the effect "to integrate genetics and genomics fully into…" Well, this is focused more on sort of information systems but I think you could probably modify the language and say maybe something to the effect of "to successfully translate genetics and genomics fully into health care delivery"

DR. DALE: Right.

DR. WILLIAMS: "Evidence of the utility of testing is foundational and information systems are needed to accommodate and share genetic information responsibly."

DR. DALE: Exactly. I like that.

Something--those are the places--those flow together well.

DR. WILLIAMS: Yes. That way--

DR. : (Not at microphone.)

DR. WILLIAMS: Yeah, right. Okay.

"To translate genetics and genomics fully into health care delivery requires the generation of evidence."

DR. : (Not at microphone.)

DR. WILLIAMS: "Requires evidence of benefit and information systems that can accommodate and share genetic information responsibly."

And then just the last sentences that are already there.

DR. DALE: And where in this list does this payment go?

DR. WILLIAMS: I had suggested that under the fifth bullet, which is relating to access, equity and fairness. But whether that's the appropriate place for it I don't know. I just--as I looked at them, there seemed to be more affinity with that because the focus of the coverage and reimbursement report was really focused on the idea that this is creating significant barriers to--

DR. DALE: Well, I like that because

payment should be equitable and fair, too, just like care should be equitable and fair.

DR. : (Not at microphone.)

DR. TEZAK: Yes, just one. In bullet 3 you have safety twice. Instead have “utility and potential use.” So I don’t know whether you wanted to have “validity, utility and safety” or what--

CHAIRMAN TEUTSCH: You are right. “Potential uses” is redundant, right?

DR. TEZAK: And “safety.”

CHAIRMAN TEUTSCH: Right, “utility and safety.”

Yes, Barbara?

DR. McGRATH: The very last one, “Genetic exceptionalism.” I wonder if that really adds anything in here or if it is such a--if the Secretary and staff who aren’t in genetics understand what we’re trying to say in that one.

CHAIRMAN TEUTSCH: So this is the whole issue of mainstreaming of genomics and genetics.

DR. McGRATH: So maybe if that’s what we mean we just say it’s time to integrate it but I’m not sure.

DR. WILLIAMS: We could paraphrase the Sun Microsystems CEO and say, “Genetic exceptionalism is

dead; deal with it."

(Laughter.)

DR. : Of course, then Microsystems is no more.

(Laughter.)

CHAIRMAN TEUTSCH: Because this has been one of those issues that has been percolating for quite a while, and actually we got into it--it's not totally dead as we heard from our data sharing discussions and other kinds--it's not totally dead but it is clearly not central to the main issue of how do we integrate this into the broader health care system.

So--and I know that this--it has been one of the things that has been underlying a lot of our work. We're not dealing with rare Mendelian disorders and things like that specifically. So are we--how do we want to say this or do we not want to say it at all?

DR. : (Not at microphone.)

(Simultaneous discussion.)

DR. WALCOFF: I think it could be stated in a shorter way maybe at the top as kind of an overarching--maybe at the top of the guiding principles section. It's kind of an overarching

thing. Genetic information is medical information.

CHAIRMAN TEUTSCH: To be treated like medical--any other type of medical information--

DR. WALCOFF: Right.

CHAIRMAN TEUTSCH: --rather than as an exception.

DR. DALE: At present that's a goal, isn't it? It's not a reality.

DR. WALCOFF: I think we should say "it is our view."

CHAIRMAN TEUTSCH: That it should be?

DR. DALE: It should be but we don't even have it in the medical record yet; right?

DR. FERREIRA-GONZALEZ: We don't have it in the medical record not because it's an exception.

It's because--

(Simultaneous discussion and laughter.)

DR. WALCOFF: (Not at microphone.)

DR. FERREIRA-GONZALEZ: Yes. I think--yes.

I mean, people are starting to--I mean, understand this, that there's no genetic difference. I mean, the information is different.

So I think we need to reiterate that this is our view and they should be taken--

CHAIRMAN TEUTSCH: So would someone please tell me what the words would look like? Do you want to use the word “exceptionalism” or should we just indicate that genetic information is--

MS. DARIEN: Can we just--

CHAIRMAN TEUTSCH: --part of the mainstream.

MS. DARIEN: Can we just--yes. Can we just say the idea that genetic information is inherently unique and--can we start the sentence there or is that not going to work?

MS. CARR: “It is not inherently.”

CHAIRMAN TEUTSCH: “It is not inherent--“

DR. McGRATH: See that’s the problem. I’m not sure as a committee we all agree on this. These are guiding principles and I have--I know it has been an undercurrent but I’m not sure we all agree with the notion of genetic exceptionalism.

DR. FERREIRA-GONZALEZ: We have a statement in the--

CHAIRMAN TEUTSCH: Use your mike.

(Simultaneous discussion.)

DR. FERREIRA-GONZALEZ: So the oversight report states that, you know, we consider genetic information to be exceptional.

DR. McGRATH: To be exceptional or to not--

(Simultaneous discussion.)

DR. McGRATH: Okay. Because you're shaking your head, okay.

(Simultaneous discussion.)

DR. McGRATH: Okay.

DR. FERREIRA-GONZALEZ: So that's what--it's in the report, the oversight report.

DR. McGRATH: Okay. Well, I just was listening yesterday and you do get a sense that there are some differences so it's such a loaded word I would much rather--because it's a black and white word. "Exceptionalism" to me is. I would much rather nuance it down a little bit so that it might be a little more inclusive because I'm not sure everybody at this table would say there's no difference but maybe I'm wrong.

MS. DARIEN: So what about making it into a positive sentence? "Genetic information--the integration of genetics information…" I didn't do that correctly--all right.

(Laughter.)

DR. ENG: How about "understanding that genetics information is no different than mainstream

medical information will facilitate the integration of genetics…" blah, blah, blah?

CHAIRMAN TEUTSCH: Andrea, do you remember how we said it in the oversight report? I mean, you got the gist right but I don't remember exactly how we phrased it.

DR. : We can go back to that.

CHAIRMAN TEUTSCH: Maybe we can go back to that and capture it because I think that's--

DR. FERREIRA-GONZALEZ: We spent a fair amount of time on exactly how we were wording that.

CHAIRMAN TEUTSCH: Yes, there were a few bombs in that report, right, and that was one of them.

(Laughter.)

DR. WALCOFF: I was really going to try to get this out while Marc was out of the room but he quickly returned and I was going to say I do think as we go over these there is some repetitiveness in terms of the principles and maybe--you know, I just went through and circled some really to key highlight words and there might be a way to--without taking away anything from any of the guiding principles--just make them a little less repetitive and highlight some of these key words. Like, you

know, public access and the public being actively engaged, the issue of “oversight, the importance of health professional education and training, and some of the words that sort of fit around each one I think because they were each drawn from various reports that we’ve done I think do reiterate some of the same concepts over and over.

So there might be a way to--in fear of using the word--condense this but to--

DR. : Streamline it.

DR. WALCOFF: --streamline it in the way that we get those key points across but doesn’t lose anything from what we’re saying.

CHAIRMAN TEUTSCH: So since I don’t think we’re going to be able to do it here in real time, for those of you who see redundancies, if you could identify them and, hopefully, staff can work with us to do that. If you can provide us those comments, you know, by email or leave your hard copies here then hopefully we can do that.

I’d like to go on because I’m sensitive to the fact that we expect Dr. Collins here at 3:00 and haven’t heard otherwise.

There’s a fairly general statement here about public health implications of genomics. And

just as a reminder it was one of our priority topics which we never really got very far with. It would have been one of the next things on our plate. So there are two questions.

Do we want to include it here as a signpost even though it is probably not one of the things we want to identify on the first page? And, if we do, does it say what we want?

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: I'm looking at the bottom of page 4.

MS. BACH: Well, I think it should be included somewhere as somebody coming from public health but the first paragraph is kind of repetitive, the first couple sentences.

CHAIRMAN TEUTSCH: Okay. That's one vote for at least inclusion.

MS. DARIEN: Yes, I think it should be included and I think it should be--I think there should be a transition just like there is between the first--the intro and the three topic areas. I think we should say "while there are a number of--there are three major topics or areas of consideration that have been left unfinished, there is one significant area that we have not even begun

to address and it's--you know, we urge the Secretary to address it."

CHAIRMAN TEUTSCH: Are folks generally okay with doing that here?

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: So if we do, rather than try to wordsmith it here, Janice, because you're pretty close to this, if you--would you mind going through this and provide us some of your thoughts about how it can be cleaned up? I mean, you will all have a chance to see all of this one more time.

What I'd really like to now because I think we've gone through the bulk of this--we've got the clinical utility material in here. There is the text that you have not seen before that-- Marc, they don't think they saw your text--your whole text. They only saw the recommendations, right?

DR. WILLIAMS: Correct, they didn't see the text of the letter.

CHAIRMAN TEUTSCH: So I would just ask you please to read through that. And if you have suggestions, provide them.

The material that we talked about with the whole-genome sequencing is going to be added because

obviously we just did that.

And I think that leaves us o try to pull the pieces together, Charmaine, on the data sharing, right? And those--some of the words are in here but I understand there's a bullet point at least not here.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: So, why don't--I have not read what you did. So can you walk us through how you converted our discussion this morning into--not so much how. I don't want to hear about the how. What you did. What was done here?

(Slide.)

GENOMIC DATA SHARING

CHARMAINE ROYAL, Ph.D.

DR. ROYAL: Well, we kept it very simple. We just put the bullet points from our discussion this morning, the points that we had up on the slides that we went through. And rather than put the sub-bullet points as well, we just left--we didn't put any--that additional information because we just thought we would--we needed to keep it short so we did. So any thoughts on that would be welcome.

There is one bullet point that we forgot

to add in terms of tribal governments and thought it necessary to have a specific bullet on that because there is an Executive Order that requires consultation with tribal governments on issues that might affect them. We're suggesting that that needs to be applied in the area of genomic research and data sharing. So, that that's bullet point that's up there and that we're going to add.

DR. WILLIAMS: So, Charmaine, the only thing I would note there that makes this different from the other bullet points is that it actually has a recommendation in it. So the question is does this need to move into the recommendation language as opposed to being a bullet point?

DR. ROYAL: Okay. That's a good point because we don't really have any recommendations here.

CHAIRMAN TEUTSCH: Well, you have a recommendation at the very end where it says "the committee recommends the Secretary identify mechanisms to address the issues."

DR. ROYAL: Okay. We do. I forgot that.

So you're saying we should put it there?

DR. WILLIAMS: Yes. So you could just basically add a sentence that says "in addition to

the advisory committee's--" you know, that you include a sentence that says that "this federal order does…" that could be listed as a bullet but there is this Executive Order. And then one of the recommendations be that--you know, exactly what you have written there would then move as a sentence into the recommendation paragraph.

DR. ROYAL: Okay.

DR. WALCOFF: At the risk of being radical again, that just made me think that maybe we should--actually I think, David, you said this too--pull the recommendation up and like say "recommendation" italicized or something right under the title of the topic area that we're talking about and then go into the discussion.

DR. ROYAL: Okay.

CHAIRMAN TEUTSCH: Do you think that works? So for parallel structure we would want to do that--

DR. WALCOFF: For all of them.

CHAIRMAN TEUTSCH: --for all of these?

(Simultaneous discussion.)

DR. WALCOFF: I mean, how many recommendations--

CHAIRMAN TEUTSCH: Right.

DR. WALCOFF: I guess--

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: There's one or two--

DR. WALCOFF: --one and two.

CHAIRMAN TEUTSCH: --main sections, right?

DR. WALCOFF: Yes, I think it was just one or two that works. If it is any longer it doesn't really work because it gets out of order.

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: Go ahead, Marc.

DR. WILLIAMS: Sorry.

DR. ROYAL: I wonder about that.

DR. WILLIAMS: Yes. So for the genetic data sharing and the whole-genome sequencing there is basically one or now in the case of data sharing two recommendations but for the CER and CU we have four. So it may make more sense to keep that one organized as is and then--I don't know.

CHAIRMAN TEUTSCH: From a formatting point of view I think we've got--

(Simultaneous discussion.)

CHAIRMAN TEUTSCH: --present them the same but I also think we need to have these recommendations sand out.

DR. WALCOFF: Right. So I think--

CHAIRMAN TEUTSCH: So it needs to be formatted in a way--

DR. WALCOFF: Right, I think consistent formatting and if we--we can still italicize them if we leave them at the end because I think you're right it doesn't work. And I think if you don't pull them all to the front they might get lost even if they are italicized because the eye will just automatically look to what it has seen the last few times.

CHAIRMAN TEUTSCH: So, Charmaine, why don't you walk us through the issues that you identified here and make sure that everybody is happy with those?

DR. ROYAL: Okay, all right. So I don't know if you got to read the preamble there but basically we just gave a little background on what we've been doing and then talking about us focusing in on group--indigenous, racial and ethnic groups, and then highlighting the issues that have come to the fore in terms of those that need most attention.

And then we--the first one is the importance of considering cultural perspectives in the design of genomic studies, including groups

expectations and motivations for participating. Again we didn't want to just leave it as thinking about the risks but also wanting to hear about groups' thoughts about the benefits to them in participating.

So I don't know if anyone has any comments on that again.

CHAIRMAN TEUTSCH: (Not at microphone.)

DR. ROYAL: What's that?

CHAIRMAN TEUTSCH: (Not at microphone.)

DR. ROYAL: Oh, just go through all the bullets?

CHAIRMAN TEUTSCH: (Not at microphone.)

DR. ROYAL: Right, and then the need for guidance. And that brings up the point that Jim made in terms of needing to be some way of making this important to the researchers and keep it--holding them accountable in terms of how--of engaging communities. So guidance in that arena would be helpful.

Greater incorporation of data that already exists on groups' participation in genomics research and where there are gaps. Where there is no data then needing to make sure that we have data so we really understand what groups are thinking about

these issues. And then the issue of the IRBs. We put there the IRBs or other bodies, not just limiting it to the IRBs but considering the role of the IRBs in addressing these issues. Again, as Mike pointed out, there are limitations in terms of what IRBs do with regard to groups and that might be something that--

DR. : (Not at microphone.)

DR. ROYAL: Okay. Symma was just saying in that bullet we should have benefits as well, the role of IRBs and other oversight bodies in addressing potential group harms and benefits.

But I guess since we're addressing it there we're probably talking more about the harms, right? But I guess we think about that.

And addressing potential group harms and ensuring that they are carefully considered in the design. So we're kind of leaving it open that if there is any thought that there might be another group apart from the IRBs that would be considered as well.

And then questions about existing policies in the U.S. that might be applied to these issues and in reading that I'm wondering; the adequacy and effectiveness of U.S. policies to protect--okay. I

mean, I'm wondering there now if we should say something about policy development but the next one says "applicability of policies from other countries." I'm just wondering if that bullet point, "the adequacy and effectiveness…" Well, I guess it's a question to be addressed; to look at it to see how adequate it is. So that probably inherently implies that if they are inadequate then we need to develop new ones.

So we may not need to state that explicitly. I'm not sure.

I don't know if there are any thoughts on that, the adequacy and effectiveness of U.S. policies to protect groups in genomics research and data sharing, and the applicability.

I was actually thinking that we would put this bullet above the Executive Order right after that bullet but then we'll consider what Marc was saying in terms of highlighting it as a recommendation and we'll see how we--what we want to do with that.

And then the last one, the applicability of policies from other countries for us to think about other models that might inform what we do here.

DR. : (Not at microphone.)

DR. ROYAL: Any thoughts on any of that? I know I went through it pretty quickly.

MS. BACH: Just on the second bullet if we could maybe clarify that it's guidance for the researchers' best practices.

DR. ROYAL: Okay.

MS. BACH: Because I'm not sure just reading it--you're not sure who the guidance is for and it was specifically--

DR. ROYAL: For researchers.

MS. BACH: --so that the researchers are more aware of that.

DR. ROYAL: Right.

Any other ideas?

I mean, we surely could have written a whole lot more on this.

Gurvaneet?

DR. RANDHAWA: Just in the interest of streamlining I was wondering if the second to last bullet which addresses the adequacy and effectiveness of U.S. policies that would be the place where the Executive Order can be put in and we can make a reference there instead of making that a separate recommendation.

DR. ROYAL: Right. And that's why I was saying that we were thinking of putting it right there--thanks, Gurvaneet--as opposed to making it a separate recommendation.

CHAIRMAN TEUTSCH: So we won't have the second part of your statement up here is what you're saying, right?

MS. CARR: I think if you put it in the list of bullets--and I'm not arguing one way or the other but if you do that then you--unlike what you've said here--you're simply saying--making it a question.

DR. ROYAL: You think about it.

MS. CARR: Is this a question--is this Executive Order relevant to genomic data sharing policy development.

DR. ROYAL: And I'm wondering if that's what we want to do as opposed to saying the Executive Order exists so we need to make sure that--

MS. CARR: Right, because you haven't really--I don't think anyone has actually looked at the Executive Order. Not that you have thoughts about it but just how it would relate.

DR. ROYAL: Yes, that's a good--

DR. WILLIAMS: So then it would be more related to exploring whether this executive order is relevant to. I mean, that's what you're really trying to say as opposed to the language, right.

DR. ROYAL: Okay.

So, yes, we would just--that's a good idea. We'll put it in the bullet.

So we'll take that second sentence out and just modify the first.

And then we went on to suggest other agencies that might be considered to take this on. We have the President's Commission on Bioethics and SACHRP and then we went on to just say other federal agencies such as OHRP and NIH. I don't know if we need to be any more specific than that or if folks have other ideas of how we might want to frame that.

Any thoughts or any questions or does that seem adequate?

CHAIRMAN TEUTSCH: I think we've worn them down. What do you think, Charmaine?

DR. ROYAL: It seems so. It seems so, Steve, yes.

CHAIRMAN TEUTSCH: So any additional thoughts on this?

Charmaine and Symma, thanks so much for

bringing some order to all of this. I think it's a big help.

So let's take a vote on what basically is the recommendation primarily but the work we just discussed on data sharing.

So all in favor of what--

DR. WILLIAMS: Steve?

CHAIRMAN TEUTSCH: Yes.

DR. WILLIAMS: I'm sorry, a point of--

CHAIRMAN TEUTSCH: I almost got--

DR. WILLIAMS: This is a point of order in the sense that--do we--I mean, I think we approved the letter when we had a quorum but I'm not sure we still have a quorum.

CHAIRMAN TEUTSCH: We still have a quorum.

DR. WILLIAMS: We do. Okay, great.

CHAIRMAN TEUTSCH: We need nine people. We have them. We locked the doors.

So, all in favor of the statements that were just made regarding data sharing?

(Show of hands.)

Charmaine presumably.

(Laughter.)

All right. Any opposed?

Abstentions?

So we're unanimous. That's great.

Charmaine, thank you very much.

(Applause.)

So that's great. The other thing that's--we need--so now you've seen the whole package for this letter and what it's going to basically look like. Obviously you'll have a chance for some wordsmithing but I'd like to get approval for us to send this letter forward pending the copy edits that we have. The recommendations that are in those sections on data sharing, utility and whole-genome sequencing are not going to change substantively.

So with the sort of reformatting that we discussed earlier moving some of the accomplishments to the end primarily and the kind of work we did on the guiding principles, how many folks are in favor of moving this letter forward?

(Show of hands.)

Any opposed?

Abstentions?

We got it. Okay.

So--

DR. : (Not at microphone.)

CHAIRMAN TEUTSCH: No, we're not going to leave. Nobody leave.

(Laughter.)

But because we've had such good behavior on our parts and we've been worn down, why don't we go ahead and take say a ten minute break before Francis joins us. And, hopefully, we'll be good to go by then and refreshed.

So thank you, everyone, for really I think a job well done.

(Applause.)

Please nobody leave.

(Whereupon, at 2:45 p.m., a brief break was taken.)

CHAIRMAN TEUTSCH: Folks, if we could reconvene.

We'll be concluding the meeting today with a special privilege. It's really a delight to have Dr. Francis Collins here. As all of you know, he was instrumental in the creation of SACGHS. He has been an ex officio member. We've capitalized on all of his knowledge and wisdom for many things.

So, it's terrific to have you here in your--I guess you weren't here for--in your capacity as NIH Director. Obviously it is a bittersweet occasion for us as we sunset this committee but we really appreciate your willingness to come and share

your thoughts with us.

So I'll turn it over to you.

PRESENTATION OF CERTIFICATES OF APPRECIATION

FRANCIS COLLINS, M.D., PH.D.

DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. COLLINS: Well, it is a bittersweet occasion because I have such affection for the topics that you have been working on and such affection for many of you as people who I know and admire as colleagues. And certainly a great sense of accomplishment that this SACGHS has achieved ought to be something that you embrace and take to heart.

We are at a point, I think, where with difficult budgets and complexities everywhere the Department as a whole has had to take stock of where exactly resources can continue to go. I will tell you there were some organizational structures that went away because they weren't doing anything. Well, that's not this one.

There were a few that basically were considered to have succeeded at the task put in front of them so sufficiently well that it would be appropriate to extend congratulations and thanks, and to invite you to spend a little bit more of your

time on other things, which I'm sure in other ways might be somewhat welcome. Some of the people on the committee have already taken that invitation I see and moved on to the airport to begin that new part of their lives, and that's okay.

(Laughter.)

Well, I am here to bring you greetings from Secretary Sebelius and to thank you on her behalf for your service to the Department of Health and Human Services. Some of you have been on this committee for some time and certainly the committee since its formation in 2002 has taken on a very substantial number of topics.

As I come here today I think back even to some of the predecessors of this group, the SACGT, the Secretary's Advisory Committee on Genetic Testing, and before that the Task Force on Genetic Testing, which was its predecessor. So we've been kind of at this for quite a long number of years, about 15 exactly, deliberating on these various issues. And I would say making really substantial progress in clarifying both where the most important points were that needed attention and then making recommendations about what to do.

And this is not a group that has been

satisfied with simply deliberating. You have made recommendations; a lot of them. And that is exactly what the intention was when your charge was given.

But I think the other thing that has happened is that genetics has--which we all hoped it would--moved more into the mainstream and the exceptionalism that people were unhappy about in some ways for genetics is now less prominent than it was even though, of course, the issues are not all solved as you well know.

But over the course of these eight years I think you've really worked diligently to fulfill your purpose and to address those specific topics that were outlined in your charter. You've made these wide-ranging recommendations, more than 60 of them. We counted them, and they cover a lot of territory from genetic research, genetic test development, and patient access to genetic tests, genetic technologies and how they're being used in employment, in insurance and other settings. You used fact finding, analysis, public consultation, sometimes extensively so, as investigational methods. And I think much to your credit you approached all of this with open minds about what actually the right path might be and not coming to

this with an already preset notion of what the recommendations ought to be.

And that I think leaves us then with a really remarkable record of accomplishment that--and a set of guiding principles that will help the nation realize the benefits and the pitfalls of genetics and genomics as we're going forward.

So through all of this I think you've played a key role in setting the stage for how genetics and genomics will find their way into health care in our new environment, which we're all looking forward to seeing coming into its full fleshed form. And I think the recommendations that you've made will be particularly useful as we see that happen.

So let me give you some examples of how I think your work has already come to fruition because again my goal here is really to congratulate you and thank you for what you have contributed, and it's not hard to find ways to point to that.

A prime example, the FDA's decision to move forward with regulation of laboratory developed tests. How many years have we been talking about that as a need in order to be sure there was enough oversight that the public would, in fact, be

confident that laboratory developed tests had appropriate standards of clinical validity.

And right along with that CMS's plan to update the requirements for proficiency testing of non-waived laboratory tests. Another area this group has commented on repeatedly and it has taken a long time to see action and now that action is happening.

Along with that here at NIH the decision we made to implement your recommendation--and I had something to do with that recommendation when I was the NIH liaison to this group--about having a registry that would provide transparency of genetic testing information through a comprehensive database that would provide consumers with the chance to find out what really is the data behind tests and not have to depend upon somebody who is marketing that test to them to be the only source of information.

Other achievements: Through the Medicare Evidence Development and Coverage Advisory Committee we are now seeing CMS begin to evaluate coverage of genetic testing for diagnosis and screening, and to guide cancer treatment. Something this committee felt very much needed to happen.

In your 2007 report on the policy issues

associated with undertaking a new large U.S. population cohort study of genes, environment and disease you called on the Secretary to assess public willingness to participate in such studies. And NIH responded by funding additional studies to assess those public opinions and we are still very much contemplating what the possibilities might be there. Somewhat sobered, I guess, by the current budget circumstances in terms of tackling something on that scale but still hopefully that by some means, perhaps by tapping into existing organizational structures, we could still mount a new multi-disease large scale prospective cohort.

In 2006, the Federal Trade Commission responded to the concerns you expressed here about the risks associated with direct-to-consumer marketing and published a consumer alert; *At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription*. And the FTC activated by that interaction continues to pay some attention to this issue which had really not been on their radar before.

And, of course, last and certainly not least, this committee played a critical role in the enactment in 2008 of the Genetic Information

Nondiscrimination Act. You wrote letters encouraging the Administration to support the legislation and you gathered evidence for the need for federal action in a series of public hearings that really documented the impact of public fears of discrimination on medical decision making. And those were highly valuable, including the videos that were made of those gatherings.

So you have a lot you can point to here as far as achievements.

More to be done of course but again with the set of recommendations that you have put forward I think genetics is in a much stronger place to see the remaining issues dealt with.

I know that there is no easy time to stop any project, whether that’s in the lab or whether that’s in the operations of a policy group like this, and certainly we have caught you a bit in the middle in terms of the questions about the affordable genome and what it might mean.

And my apologies to Paul Billings, who is not here, and to Charis Eng who is, that we kind of revved up this engine. I know you already had gotten into some pretty interesting territory and I do hope that that will be captured in a way that it

can be pushed forward in some other format because clearly this is a coming technology that is coming pretty soon. There are many issues about that that probably deserve more attention than they've gotten so far.

I'm glad that you were able at this meeting, I think, to complete what you were doing on genetic education. Unless you're going to tell me you had a meltdown I guess you will have that document and its recommendations to put forward as another important contribution. And that will be appreciated and well received.

There again that's a topic that we've talked about in various settings for quite a long time. The urgency of improving genetic literacy amongst health care professionals and the public grows by the day and you have a new set of suggestions about how to do that and particularly how to do that with sensitivity to diverse communities that I think are very important to pay attention to.

So it really is interesting to reflect back over those years and to say thank you to the current members, the past members who have spent their time around these tables, and to the liaison

members who have faithfully also made their time available to come and be part of the deliberations.

It was an honor for me to serve as one of those liaisons for the first six years of SACGHS. I don't think I missed a meeting during that time and I can remember many of those conversations as having been particularly enriching in terms of the prospect and perspectives brought both by members of the committee and others that came before this group to tell their stories and to appeal for action of various sorts.

Since I came to the position of NIH Director a little more than a year ago I have been honored to transmit the reports that you have sent along during that time during the Secretary.

So I really would like once again to express appreciation to each one of you. And at this point to represent that by actually presenting each of you who are finishing your time here with a Secretary's Certificate of Appreciation.

So perhaps I could ask each of you to come up one at a time to receive this if you're still here.

So in alphabetical order I guess.

Janice Bach.

Congratulations.

MS. BACH: Thank you very much.

DR. COLLINS: Thank you.

David Dale.

DR. DALE: Thank you.

DR. COLLINS: Thank you so much for being here.

Maybe I better make sure I didn't get these--are these in the right order? Did anybody scramble them? I haven't sort of looked to see what's inside.

Gwen Darien?

MS. DARIEN: Thank you.

DR. COLLINS: Thank you, Gwen. Thanks for all you've done here.

And Charis Eng?

DR. ENG: Thank you.

DR. COLLINS: Thank you, my friend.

Andrea Ferreira-Gonzalez.

DR. FERREIRA-GONZALEZ: Thank you.

DR. COLLINS: Thank you so much.

Charmaine Royal?

DR. ROYAL: Thank you.

DR. COLLINS: Thanks for all you've done. You've been with this effort for a long time in a

very wonderful way.

Sheila Walcoff?

DR. WALCOFF: Thank you.

DR. COLLINS: Thanks, Sheila. I'm glad you got to be part of this.

DR. WALCOFF: Me too. You've really inspired me. We will keep working.

DR. COLLINS: Keep working.

And Marc Williams.

DR. WILLIAMS: Thank you.

DR. COLLINS: Thanks, Marc.

And I do want to mention the service of other members, Laura Aspinall, Paul Billings, Rochelle Dreyfuss, Jim Evans, Barbara Burns McGrath, Sam Nussbaum and Paul Wise. We will mail their certificates to them.

But now to Steve: Steve, I would like to express a special thank you to you for your leadership of this committee. Not an easy job and you have stepped into the shoes of some other outstanding chairs who came before but you've been wonderful exemplifying all the qualities of a great leader. You have clarity. You have fairness and you have appropriate management of sometimes a rowdy and unruly group--well, not so bad.

(Laughter.)

And during your tenure I would say this committee has been extremely productive with the reports you've put out on oversight of genetic testing, pharmacogenomics, direct-to-consumer genetic testing, gene patents and licensing, genetics education and training, all of those. It's quite a record of accomplishment.

So on behalf of the Secretary thank you very much for your leadership.

CHAIRMAN TEUTSCH: Thank you such.

(Applause.)

DR. COLLINS: I think there's a certificate here, too, unless I've gotten them mixed up. No, that's yours as well.

CHAIRMAN TEUTSCH: Thank you so much.

DR. COLLINS: And you might open that up in front of everybody when you get back to your chair because it's kind of interesting.

(Laughter.)

It won't explode I promise.

CHAIRMAN TEUTSCH: (Not at microphone.)

DR. COLLINS: We would have never got it on to the campus that way.

So I really want to thank really all of

you but especially Steve for his focus and graciousness.

So without, I think, further slipping into maudlin territory, I mostly wanted to be here this afternoon to have a chance to just recognize what this group has done.

I also want to recognize Sarah Carr for her remarkable dedication to this effort.

(Applause.)

Sarah, we're going to have to figure out something for you to do.

(Laughter.)

And don't worry. Let's see. Do you want to work on stem cells, Guatemala or what will it be here?

(Laughter.)

We do have lots of hot items.

So I think really the way in which the advisory committee and staff have worked together has also been wonderful to see. I've certainly occasionally seen committees where there was not such a good synthesis between the capabilities and it has been terrific to see both how you all have been able to function independently but also to take advantage of really capable staff work on behalf of

Sarah and others on her team.

Well, so I don't know if we should sing *Auld Lang Syne*. No, we better not do that.

(Laughter.)

I simply would like to say one more time, on behalf of the Secretary and all of us at NIH, for your service we thank you; for fulfilling your charge we thank you; for giving us such a strong and lasting foundation on which to build we especially thank you.

Thank you all.

(Applause.)

CONCLUDING REMARKS

STEVEN TEUTSCH, M.D., M.P.H.

CHAIRMAN TEUTSCH: Thank you, Dr. Collins.

That is much appreciated and as a token of our work you not only will be getting the education report but another letter to the Secretary, which is virtually completed.

I think all of us do take a great deal of pride in the work of this committee and all that it has done. It has been at least for me an extraordinarily uplifting experience to work with an incredible array of people who have an enormous amount of expertise and humanity who really brought

their whole selves to the tasks. When asked to step up, everyone did.

And that's certainly true of the committee, our ex officios who were here regularly and provided us not only the input from their organizations but also of course their own expertise and participation in all of our activities. And without them the job couldn't be done.

And finally to our incredible staff, Sarah and all of them, I think have--you know that you keep us going. You do all the hard work behind the scenes. You make these meetings productive and you bring the work to fruition.

So it has been a terrific ride and Dr. Francis Collins has certainly captured a lot of the work that we've done over these years.

We know there's unfinished business ahead of us and that's in the letter too so that we trust that the good graces of the government will find ways to make sure that that work does go forward. I know many of the members of this committee would welcome the opportunity to serve.

Again, many, many thanks to all of you for making this a wonderful organization and for all the success to which you've contributed so thanks again.

(Applause.)

Sarah, any final business?

MS. CARR: No.

DR. COLLINS: She has never said that before.

CHAIRMAN TEUTSCH: No, but she didn’t mean it either because actually you’re going to be getting--any of your edits in the next couple of weeks and then you’ll get the penultimate draft for your final comments so that we can get it into the Secretary.

Everyone, safe travels.

Again, many thanks.

(Whereupon, at 3:20 p.m., the proceedings were concluded.)