

**PUBLIC CONSULTATION DRAFT REPORT ON GENETICS EDUCATION
AND TRAINING AND DRAFT RECOMMENDATIONS**

DR. McGRATH: Thank you.

We have some tasks to accomplish this time with the task force so I won't delay too much. I'll start off by thanking everyone for giving me the opportunity to present this report. We've been working on it for a couple of years.

Before we launch into it, we are going to hear a presentation by Jana, who is coming up, and has been working on a similar project on the Advisory Committee on Heritable Disorders in Newborns and Children, and is going to share with us their findings.

And then, when she's finished, we will then launch into our report.

Jana?

**BRIEFING ON THE SECRETARY'S ADVISORY COMMITTEE
ON HERITABLE DISORDERS IN NEWBORNS AND
CHILDREN (ACHDNC) EDUCATION SUBCOMMITTEE**

MS. MONACO: Thank you.

(Slide.)

Thank you. Good morning.

It is a pleasure to be here and see some different faces of another committee. It is a pleasure to be here today and to share with you our report as we both feel that we value the need for education and training in genetics, and especially for us in newborn screening.

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Our committee--our subcommittee I should say--is comprised of myself and Dr. Tracy Trotter, who is my co-chair, who is much more colorful presenting, and I wish he was here today, as well as members from other organizations to include ACOG, American Academy of Family Practitioners and American Academy of Pediatrics, Genetic Alliance, and the National Newborn Screening Center, and Genetics Resource Center, and these are some other individuals.

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One of our initiatives is to come up with a newborn screening clearing house and to help facilitate the discussion on that and we're happy to announce that the Genetic Alliance and the National Newborn Screening and Genetics Resource Center with HRSA is going to

serve as that National Newborn Screening Clearing House. Their website is now active. The purpose of this is to increase the awareness of newborn screening and be a good central link and a place for people to go directly to gain information from a professional and a public perspective.

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I won't read each slide for the purpose of time.

These are some other updates of what is going on. You're aware of the Prenatal Family Health History as an important one, which is a three year project to work with family practitioners in the prenatal period to provide a family health history tool to help, again, educate and learn what is behind these genetic issues and newborn screening and to really prepare families.

The American College of Medical Genetics has a great program that is on the horizon and that is their Medical Genetics Summer Scholars Program. And their rationale is that statistics show that about 18,500 medical school graduates each year, out of all of those, only one in 463 enters the field of medical

genetics. Currently there are five states that have one or fewer medical geneticists and six states have less than two. Within the next ten years over 300 medical geneticists are expected to retire. This addresses an important issue that we need more and so they developed this program that will be launched in 2011.

The purpose is to address this workforce issue and to capture students' interest and involving the students by practicing genetics in their work settings, to include clinics, labs, government and regulatory agencies and, hopefully, foster professional memberships and highlight the many diverse employment opportunities that the medical field has. And, hopefully, we'll initiate a stronger interest in getting more geneticists out there in the field.

You have your own educational task force here that you're working on the educational issues as well and again the collaboration of AHRQ subcommittee and your task force here together will be strong in helping to move forward with education and training.

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This is another list of some folks that addressing the issue of education and training and working as partners. Another quote that supports our need for education and training is that out of Pediatrics 2008 "Advances in newborn screening service new challenges to the PCP, both educationally and in the management of affected infants. PCPs require access to information, collaboration with local, state and national partners is essential to optimize the function of the newborn screening system." Because as advanced as it is, it's not going to be as productive as it needs to be if people are not educated and trained.

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These are various partners that we are working with to help enhance this. The focus on the PCP role in newborn screening from all of these perspectives is to really address the response to the initial out of range result, what do the physicians do, how do they do it, how do they handle it; coordinate the complete evaluation to know what are the next steps; provide a medical home and coordinate care and

educate families and healthcare workers from each of their perspectives because everyone plays a role in this very important aspect of newborn screening.

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Our Education and Training Committee serves in an advisory capacity to the current groups involved, both in the PCP and public family education. And it has been very worthwhile to serve in that capacity to help bring everyone together to address this issue, and because we all value the fact that we just need to avoid duplication and enhance that collaboration and we will be more productive.

(Slide.)

In regards to PCP education we were able to participate in the National Institutes of Health Genetics Research Institute in their conference of developing a blueprint for primary-care physician education and genomic education. And with our committee we were able to house a roundtable session on the second day, which included about 30 participants, included the AAFP, the AFP and ACOG, and to really talk and address the issue of what are specific educational

needs and barriers for them from each of their perspectives and what we can do to lift those barriers and enhance the education. A report for publication is being prepared by Alex Kemper.

(Slide.)

And some of the targeted areas are here listed as you can see. Again, from each perspective and how those agencies and organizations can address these issues and together resolve them and provide better education and training because we feel that each organization from the time, from the prenatal time right up until the family practitioner, everybody does really play a role.

(Slide.)

We also address some of the barriers to educating the primary care providers. These are some of the comments that were made that we have to address which is lack of time. Everybody only has so much time in their daily practices to really get in depth into such an issue of genetics. The lack of geneticists to train the primary care providers including especially those that are already in practice, and that is where

we really value the fact of getting those medical students and educating them early on.

Lack of enthusiasm: There is poor genomics and genetics medicine literacy out there that interests people.

Lack of certainty and confidence in this area: It is very easy for people to say, "That is not my specialty, that's not my area of expertise."

And the concerns about relevance to child healthcare and the fact is, as Dr. Trotter always likes to say, that everyone does genetic screening or genetic testing if they took care of a newborn in their practice that day.

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These are some educational interventions that are taking place that we feel will really help move things along and that is to develop educational curriculum for the residency training programs. Again, it is taking steps backward and going to the very beginning of future physicians. Assuring that board certification exams do assess basic literacy and genetics and genomic medicine and having CMEs on the

practical aspects of incorporating the genetics and genomic medicine into primary care as well as promoting the participation in genetics and genomics related educational activities through the maintenance of these board certification processes. And to create a web site that will be a tool for everyone.

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Genetics and the Primary Care Training

Institute are working on a learning collaborative that will help prepare physicians with busy primary care practices with experts in genetics and genomics medicine that together they can work and provide that hands-on opportunity to be educated in genetics and newborn screening and at the end, meaning at the end of the year, to share their results and to institute to formally evaluate a project impact.

(Slide.)

Our next steps, as we look on the horizon, are residency training materials through our regional activities, partnership again with our organizations, such as AAP, AAFP, ACOG and the American Board of Pediatrics. And the development of genetics and a

primary care institute and to continue following up with your committee's educational taskforce as we strongly value the need for education and training both on the professional level and the public level. And as technology advances and the awareness and the newborn screening programs continue to develop and progress, the need for this kind of education and training is far more important than ever has been and I think, with the hockey puck analogy, we really have to look ahead to where it's going, especially with the other disorders that are on the horizon that are being addressed and looked at to add to our panel and all our screenable disorders.

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So with that, I thank you for the opportunity to be here again and share our initiatives and work, and look forward to further working with you.

COMMITTEE DISCUSSION

DR. McGRATH: Thank you so much, Jana. Great minds think alike. I think you're finding spring much articulate with ours and it is nice to see that we come up with the same barriers as well as some of the same

solutions so it makes logical sense that we would be able to continue to work together and we will talk more about how to be able to do that.

We have a lot to do in a short period of time and the most important part for me is to have the discretion and receive your comments on our recommendations. But before we launch into that, I want to give a quick overview of this committee.

I actually am familiar with the report as one might assume but last night on the airplane I read it from beginning to end in a nonstop way and came away with a couple of impressions that I hadn't necessarily had before and I wanted to highlight those a little bit for you.

One is the report makes the case that since the very earliest days that there even was a Secretary's Advisory Committee about genetics, education has always risen to the top. Every time we have any priority setting activities, education is there. Whenever we talk about a different topic there is always a nod to this and this has an influence on genetics. So it clearly has been on our landscape

forever.

Over the years much has been written about the challenge of translating findings from the Human Genome Project and other genetics science into something that might be clinically useful. More recent attention is being paid towards looking towards chronic illnesses and how we can apply genetics in dealing with those more common diseases as well. And also the promise of personalized medicine is definitely on the horizon.

A common image that I think all of us are carrying in our heads these days is this continuum. And on one side it might be something like genome science and on the other side it might be something like genomic healthcare, different words, but in between inevitably on that line it's a pretty thick line between the two.

Marc popped up one today and I looked again and that line is fat.

And I think that reflects maybe inadvertently that it's a challenge to do that translation from one to the other. So we are kind of looking at the right-

side of that in this group looking at healthcare but I think if we—but we all sort of know around here that it's a loop, that there are pushes and pulls back and forth, that healthcare pushes science and vice versa. So we do not want to be thinking about healthcare and health professionals sort of in isolation from the science.

There are a few things that are not controversial, I think, and I think overall the whole report is not controversial but two are sort of slam dunks. And one is that I think we all might agree that we are all best served if we have a knowledgeable workforce that understands appropriate use of how to use genetic information.

The other thing is that consumers are participants in this as partners in these endeavors rather than simple recipients of services. So those, I think, are probably shared values, at least for most of us.

What might be a little less obvious is that embedded and batted in this report is this notion, of course, of the translation of science into clinical

utility or application but the report is also about the transformation of thinking, perhaps even in the absence of anything of any on the ground applications. That second idea is often called requiring a paradigm shift. And if we think about the original use of that word, coined by Thomas Kuhn a couple of decades ago, paradigm shifts, we use that a lot. It has been used already a couple of times this morning. They are dramatic and often cause disruptions in science when they happen. They are rare and we do not know if we are in the middle of one or not, but they do cause a big change. So I want to suggest that there may be some change in the subtext of the report that is not necessarily openly stated.

So if we are thinking about paradigm shifts in scientific revolutions, who is part of the scientific revolution and that's the task force group, you have seen these names before. They are really a very interesting group of people. It is a huge group of people. The expertise and richness of knowledge is very deep as well as the staff. We just keep adding and adding staff members to this so it's a big, big

group.

The structure of it we have divided into three work groups and each of those have leadership and healthcare professionals. David Gayle is the chair of that group. He follows Greg Fiero.

The Public Health Provider Group with Joseph Telfa, who actually rotated off the committee a couple of meetings ago and is very involved, which we appreciate, and he is here today to help us answer some of the questions. I appreciate that a lot. And Vince Vanno is the chair of the Consumer Patient Group, and he has hung in there the whole time and provided leadership to that group.

The timeline: We picked this up from the previous group that worked on it in 2004. And we are responding to that report.

We had an international roundtable. We were then tasked with forming a task group, those early meetings, there was a decision about the boundaries and we came away with deciding that this report would cover three groups, Point of care, Healthcare Professionals, Public Health Providers, Consumers and Patients. Those

discussions were long and hard, and it seems like—and that actually the boundaries are tighter than many people suggested, the even larger group that was recommended. We narrowed it down to those three. Those three could also be three different reports and perhaps that is one way to approach it. What we attempted to do was to think about the notion that ideas and people moved through systems. They do not just stay in those three silos. So our intention for combining it into one report is to take a nub and appreciate that integration of services across the landscape and we'll see if we can accomplish that. 2008 and 2009 was where the bulk of the work happened and we reported at this committee each one of those so you've heard this is a lot. At the last meeting we did talk about recommendations and then there was a working session in D.C. held around December where we ironed out the recommendations and then they were heavily massaged by staff after that, and that is what we will be looking at today.

The final report will have an executive summary and recommendations. The draft one that you

see here does not. It does have the ordinary background and scope which is the literature and then the three working groups have their own sections on their literature as well as the data that they collected. We have a freestanding survey of federal activities which was intended to follow up on what has happened since the previous 2004 report and then conclusions and recommendations. Our data gathering activities included a review of all of the literature concerning those three groups that we mentioned and then each workgroup conducted their own original research. They each paid and administered, created and administered surveys. And then the Patient and Consumer Group also did some interviews. Each of the work groups functioned within each of those leaders—I'm sorry—they had people working with them. It wasn't just the three names you saw up there and we should—next time I'll show those people but within those workgroups they were the ones to decide what data gathering activities were to be done so they had a lot of autonomy though we coordinated a lot.

Before we talk about the discussions I'm

going to highlight what we are trying to accomplish here today and where you all come involved. We do have a couple of discussion questions that we're going to ask at the end of them.

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And one is do the findings follow from the literature review and survey? Do the draft recommendations target the issues and concerns identified in this report? Meaning specifically, are these recommendations specific enough? We have always talked about that we want them to be actionable. Do they rely on the appropriate degree on the public sector, the private-sector and the public-private partnership? Are we targeting it to the right places? And, overall, is this report ready for primetime?

When we go through it, you will see that the recommendations are fairly dense and we will talk about whether we think that perhaps the message gets lost in its denseness or it is required so we get our point request and there is a couple of decision points about how to phrase these.

I have talked about this report in the past

as kind of an unruly teenager, partly because it is so big and we have taken on such a big task. Not to kill a metaphor but I will do it one more and then I promise no more metaphors but right now it feels like it's a young adult. It is feeling quite confident that it is ready to enter the real world and that it can handle any criticism that may come its way because how hard can that be, and perhaps sort of optimistic that good intentions do lead to good outcomes. So part of the question that we're asking everybody here is, is it really ready for prime time? So that will be at the end of the session.

CHAIRMAN TEUTSCH: So we are trying to turn it into a cynical, older adult? Is that the idea?

DR. McGRATH: That is why I'm going to stop at the young adult and not keep wearing this poor metaphor out.

Findings generally: We came through both data points, review of the literature and the original data that we collected, and came up with the couple broad conclusions. One is that the integration of genetics into healthcare is limited by inadequate or

ineffective genetics education. There is just not enough. There needs to be more education. The need for clinical services has increased but the workforce is insufficient. We need more numbers and healthcare professional organizations report about competing priorities. These are legitimate concerns that this is not a primary concern or obligation they have, and where do they put it in this list of very important other tasks that they do.

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The current public health force is not well-prepared to receive and assimilate genetic and genomic information in to public health and there are a number of barriers to that because the public health workforce is uniquely diverse because it covers such a range of population health issues and consumers prefer to obtain genetic information from the providers but they also turn to the media.

A couple needs were identified through themselves and through other advocates: The need to understand the concept of multiple risk factors. This is in contrast to a very deterministic view of

genetics. Understand the role of the environment and the complexity of that, a need for various tools that are understandable to evaluate the veracity of the information, and then, of course, concerns about direct to consumer genetic testing. Most consumers view the government as a trusted source for information and so we have an obligation to follow through with that.

(Slide.)

There are seven recommendations so it is not a million. I went back and forth trying to decide what to do with this and I am going to read them in case some people cannot see the screen or don't have them. I actually find them easier to follow in the book on page 110 in Tab 5, and that's sort of where I'll be following. So I will read through all of them first and pretty rapidly, and then we will discuss them. There are a few that you will see require very concrete decisions, others will be spoken to if you have comments about that. Okay. Here we go.

(Slide.)

Each recommendation is prefaced by what you might call a preamble or a preface, and that's just to

give it the context.

So for recommendation number one the preface is a significant body of literature from the United States and abroad highlights the inadequate genetic education of healthcare professionals as a significant factor limiting the integration of genetics into healthcare. Genetics content is often minimal in health professional educational programs and focuses primarily on single gene disorders and is not associated with long-term knowledge retention for clinical application. Innovative approaches that coordinate the efforts of entities controlling health professional education and training will be required to remedy the situation. These entities include but are not limited to healthcare professional organizations, educational institutions, specialty certification boards and academic accrediting organizations.

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So there are two options of recommendations that follow this preamble. We will need to choose between one of the two or combine them or throw them out entirely.

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The first one is HHS should form a multidisciplinary public-private advisory panel to identify and promote innovative approaches to genetics and genomics education and training in a context of healthcare. The key words in this one is "is to form a panel."

This proposed advisory panel should be composed of representatives from HHS agencies and other federal departments, for example, the VA and DOD, with established programs in genetic/genomic professional education as well as representatives of health professional organizations engaged in genetics and genomics accreditation certification and continuing education efforts. This body will:

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A: Identify successful education and training guidelines and models that are outcomes based, identify where it works.

2: Identify current funding streams for developing and promoting genetic/genomics education, as well as gaps in funding. So this is all about funding.

3: Recommend mechanisms for expanding and enhancing the content needed to prepare healthcare professionals for personalized genomic healthcare. This is about what content needs to be included.

4: Recommend how evolving standards, certification, accreditation and continuing education activities might incorporate genomic content. That is about the whole world of certification.

And, five, publish findings and recommendations and develop a plan to monitor outcomes of its work.

(Slide.)

Option B is HHS should convene a workshop to identify --the rest is the same. So the keyword there is to "convene a workshop." The purposes are just the same as the ones I just read and the choice is between forming a panel and convening a workshop. So think about that.

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At the end of that there is a recommendation connected to this to act on a recommendation from a previous SACGHS report, The Oversight Report. And this

relates to the notion of decision-making tools—

DR. : (Not at microphone.)

DR. McGRATH: I knew there was a word missing there.

DR. : Clinical decision support.

DR. McGRATH: Clinical decision support, and how that plays into the education needs of health professionals. We can decide whether we think it should be part of the recommendation or stand as part of the preamble or whatever but that is the choice. Okay.

(Slide.)

Recommendation two: Consistent findings—this is the preamble. Consistent findings in the literature and SACGHS surveys indicate that healthcare professionals and public health providers serving underserved and underrepresented groups and populations face significant challenges. Additionally, these communities have specific needs and their involvement in the development of effective education models is imperative. This is about health disparities.

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So the recommendation is HHS should promote the development and implementation of innovative genetic and genomic education and training models for healthcare professionals and public healthcare providers serving underserved and underrepresented groups and populations.

Specifically, HHS should--one or A? This time it's A--target research funding, the key word is funding, to identify effective educational models for healthcare professionals and public health providers in underserved communities; so funding to identify models.

B: Identify and support programs to increase the diversity of the healthcare workforce in general and the genetic specific workforce. This has to do with workforce diversity.

And, C, ensure that consumers and representatives of rural, minority and disadvantaged communities participate in the process of developing education and training models to assure that they are culturally and linguistically appropriate and tailored to the unique needs of these diverse communities. This is community engagement.

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Draft Recommendation 3: The background is the inherent diversity of the public health workforce makes it difficult to target educational efforts to improve genetic and genomic knowledge across the workforce. A systematic effort that evaluates the composition of the public health workforce with current job responsibilities related to genetics and genomics and identify future needs has not been done. This has to do about serving the public health workforce, that group that is so diverse.

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Specifically, tapping the expertise of its agencies with relevant missions in public-health, HRSA, CDC, HIS and NIH, HHS should assess the workforce to determine the number of public health providers with responsibilities in genetics and genomics to ascertain current trends to sort of look forward to the public health workforce and see where we are now and where we might need to go. I'm sorry, I missed a sentence. And future needs...that's the future part ...to identify education and training needs to promote leadership

development in the field. Based on this assessment, HHS should support and encourage the incorporation of relevant genetic/genomic core competencies and the knowledge base of federal and nonfederal public health providers and specific competencies in those whose responsibilities require genetic knowledge. The key here is the core competencies, it should be based on those.

B: Fund educational programs based on these competencies that promote genetic and genomic knowledge, recognize the potential impact of affordable genomic analysis and incorporate the concept of environmental interactions in risk assessment for population based genetics.

They competencies should be based on these trends that we're seeing. Okay. That's about public task force.

(Slide.)

Recommendation Number four: Consumers have consistently expressed the desire for genetic information that is comprehensive, accessible and trustworthy. And again, this is the second

recommendation that we have two options that we should decide on today.

The first one is that HHS should endorse and ensure sufficient funding for existing government resources such as those developed by NIH and CDC to provide comprehensive, accessible, trustworthy genetic web based information for consumers. These resources should include scientifically validated information and also links to credible information regarding the topics such as genetic contribution to health and disease, gene environment interactions, genetic testing and legal protections against genetic discrimination. To reach a broad range of communities these resources should also include links to information that are not web based, such as television and radio programs and print materials, and they should--the availability of these resources should be promoted using a wide range of strategies from collaborating with developers of internet search engines to working with community leaders at local level, mechanisms to alert interested persons to adapt and new information.

The key here is the notion of working with

existing government resources. We might think about things like the genetic home reference here, also various agencies have their own that each one is unique. NHGRI, CDC, NCI, as well as the rare diseases websites might be thought of those as the models we are talking about here.

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The other option, Option B, is that HHS should endorse and ensure sufficient funding for a web based information resource center that builds on existing government resources. The rest is the same.

The difference between these two choices is the first one is to work with existing resources. The second recommendation is recommending that the Secretary facilitate the development of a new freestanding web based information resource perhaps that fills in the gaps that the other ones don't and is developed with what we know now.

The rest of the recommendation is the same.

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Recommendation five: The background is with the vast increase in scientific knowledge stemming from

genetic and genomic research and new technologies and the increase in direct to consumer genetic services, consumers of all literacy levels are challenged to understand and use this information to make appropriate health decisions.

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The recommendation is HHS should support research that identifies the methods that are effective for translating genetic and genomic knowledge into information that consumers and patients can use to make health decisions. HHS should also support research that identifies effective methods of patient communication. Based on this research and to reach diverse people and community needs, HHS should develop educational programs that use a wide array of media, television, radio, print and mobile phones, and provide for translation of materials into locally predominate languages. HHS should then support the dissemination of these programs.

As part of this dissemination, the Secretary of HHS should work with other relevant departments and agencies such as the Department of Education, National

Science Foundation, to integrate effective educational programs into science and/or health education initiatives.

This is recommending that there be research to identify models or the best methods for patient and consumer education, patient and consumer communication strategies and then the best ways to disseminate these programs.

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Recommendation Number 6: The background is about family health tools were developed as one means for individuals and families to gain health literacy and take a more active role in preventing and managing disease, particularly inherited conditions. These tools are a powerful asset for consumers and healthcare professionals to use in risk assessment and health promotion but EHRs must be capable of accepting the information provided by the consumer oriented tools, and you might think of my family health portrait as a consumer oriented tool, otherwise the value of family histories are diminished or omitted as a factor in risk assessment.

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The recommendation is that HHS should support continued efforts to educate healthcare professionals, public health providers and consumers about the importance of family health history. Specifically for health professionals, HHS should support the use of family history in clinical care through development of clinical decision support tools and mechanisms to integrate pedigrees into electronic health records. Clearly we're talking here about the tools and the EHRs. For public health providers, HHS should promote research identifying the role of family history in public health. How does family history fit into population health?

(Slide.)

And for consumers, HHS should promote research on how consumers use family history to make healthcare decisions. For example, things like lifestyle changes. They should assess the effects of gathering family histories within diverse cultures and communities and among individuals where family histories are unavailable, perhaps among refugee

groups; expand public health awareness programs and patient information materials on the importance of sharing family history information to primary-care providers. This is education again. And promote the embedding of educational materials in family history collection tools directed to consumers and ensure access for all by providing these tools in various formats, using those as another educational venue for consumers.

(Slide.)

And the final recommendation, number 7:

Given the reality that healthcare professionals and the professional societies representing them are likely to invest significant resources in education and training and content areas for which services are only partially or not at all reimbursable, a critical step in promoting increased knowledge of genetics and genomics among healthcare professionals is ensuring reimbursement for time spent in direct patient care that delivers genetic and genomic services. We are here calling attention to the notion of time.

Specifically, in order to increase incentives

and encourage investment by public and private organizations in education, training in genetics and genomics and to increase the willingness of healthcare professionals to participate in educational programs the secretary should: (a) ensure reimbursement for healthcare professional time spent in direct patient care delivering genetic and genomic services, such as interpreting of tests and collecting family history; ensure the reimbursement for all members of interdisciplinary teams and for distance consultation and telemedicine; and (c) act on the recommendation of the previous report on coverage and reimbursement that specifically called out to genetic counselors and reimbursement.

(Slide.)

Good reading, huh? Okay.

The next steps are what we're doing right now, review these and get some feedback and make a decision if this puppy is ready for prime time. If it is, it will go out for public comment. We will analyze those and report back in June with a final report. If it gets accepted at that point it will go to the

Secretary in August.

So, I know we need to talk about one and four so maybe I'll just--since I have an urgency to settle that issue, I have the mike open so I will open that up first going back to recommendation one and again the issues.

Two proposals presented by the task force are (a) forming a multidisciplinary panel meant to be filled with maybe not your usual players looking at cutting edge ways of thinking about education and translation, and that panel would have whatever authority the secretary gives it. Another one is to form a workshop which is often considered to be a single one time day long or couple daylong event that would come out with some things at the end of it. And we can open it up to any combination of that.

I think that Mara was first and then Paul.

Thank you.

MS. ASPINALL: Well, I think you clarified it at the end. The idea is a workshop is a one-time event, a panel is an ongoing event.

DR. McGRATH: It tends to be, yes.

MS. ASPINALL: And this may be—I don't know if it's slicing it too thin but the idea would be potentially combining the two and the idea of starting with a workshop to kick off the issues to then better inform a potential panel going phone.

DR. McGRATH: I imagine a risk with that would be if the workshop decides that getting it done in a day is enough then you wouldn't have that richness of a panel but that's certainly—you know, if the recommendation is simply for a workshop, you could end with a workshop. That might be the risk of doing it that way. But the idea of blending the two, there is some good reason for that.

MS. ASPINALL: Did the committee have a recommendation or was this--did the Committee have a preference?

DR. McGRATH: I think there wasn't 100 percent consensus. The benefit of the panel is that it could be in greater depth. The benefit of the workshop is that it might be something that the Secretary actually does, whereas, a panel may be not one more panel.

MS. ASPINALL: I'm going to say I would go with the combined idea. Start with a workshop so it actually happens with the possibility of forming a panel thereafter and we get the best of both worlds.

DR. McGRATH: The best of both.

MS. ASPINALL: I think is practical.

DR. McGRATH: Yes, I agree.

DR. WISE: So I want to also endorse the notion of doing both and, in particular, to assess--and this may have already occurred in part of your deliberations and I may just be unaware of it but to assess the role that the private sector plays in providing education. There has been a lot of focus, of course, on marketing and the negative aspects potentially of the private sector materials linked to marketing. But there is also an enormous amount of education material produced by the private-sector which is, in fact, a substantial part of educational activities now and it needs to be thought about. And, in fact, I would strongly encourage it being a topic and representatives of the activities being included in any ongoing panel or review.

The other point I just wanted to make was one of personal experience, which is at a community hospital that I am involved with we are trying to improve genetics' education for the medical providers at the hospital. And CME rules are actually interfering with our ability to get more genetics into the curriculum because of rules about priorities, establishing priorities of the hospital based on needs of the clientele. The fact is that genetics is not viewed as a need at this point so some attention to those issues, I think, is also important.

DR. McGRATH: Just really quickly, yes. The whole notion of the perceived need is a definite barrier to education and should not be taken lightly. It shouldn't be dismissed. I think you're right. The idea of using new educational models as part of this number one recommendation, get out of the old tired way of doing textbook learning and try to think about what new technologies and just in time learning work.

Thank you.

Gwen?

MS. DARIEN: This may be a naive question,

and I'm sorry I stepped out for just one second but if we say that we want to do a combination of a workshop and a panel we cannot say that the workshop is going to decide that there needs to be a panel. Then there's no reason to do a workshop. Is that correct?

DR. McGRATH: I think that's correct. I would imagine we'll get advice from staff on the wording but I would imagine part of it would be hope that the workshop would address the following issues, and one of them would be the need for a long panel or something, a multidisciplinary panel or something.

DR. WILLIAMS: This is just to facilitate this then what I would recommend then that what we do is, given what I've heard, is to take Option B and essentially add an F to that, which is that part of the charge to the workshop would be to determine the need for and develop the—determine the need and, if necessary, develop the charge for our panel to move forward with the issues identified by the workshop.

DR. McGRATH: Perfect. Yes, I agree. That makes total sense

And, Joseph?

CHAIRMAN TEUTSCH: You need a mike. Just come to the table, Joseph.

DR. TELFA: Okay. Thank you very much.

No, actually, Dr. Williams beat me to the point that I was going to make.

We had a discussion actually as part of our task force on this issue of the combined, too. And we were pushing in the direction, you know, of the workshop allowing for the charge to be developed.

The challenge again, as Dr. McGrath said, was we wanted to look for something that was a low-cost/no-cast opportunity that we thought would be done.

DR. McGRATH: Okay. I like our solution. I think we will go with it. Done.

DR. EVANS: I just wanted to—on a different note, one of the things I worry about is the people who are uninitiated in this will read it and see training and education all in terms of residency and medical school, et cetera. And I know we say "in the context of clinical care." I'm just wondering, if this isn't wordsmithing too much at this point, to say something like "and integrated with clinical care" because I

think the only way we're ever going to educate the body of physicians out there is to integrate it with clinical care with just in time types of things.

DR. McGRATH: Right. I think it is good to add that where we have it in our heads but not on paper. Great.

Mara?

MS. ASPINALL: I completely agree with Jim's comment and what Paul had said. I was wondering if we—again it may be awkward at this point but, you know, this is in many ways process and philosophical but I'm intrigued by the area of domestic violence, which has been a very important and key area for physicians to be the gatekeepers to recognize domestic violence.

My understanding is that after a workshop of sorts and a panel, I believe, convened by the AMA but I'm not sure, it was a recommendation that it became a required piece of CME education in the 47 or 48 states that have CME. It is probably premature to recommend that but my understanding of that process on domestic violence from start to finish happened in about five years and now by state it differs somewhat in terms of

what the actual educational component is.

But to Jim and Paul's point, as a required piece of CME, which it now is, it absolutely integrates its and keeping something as broad and its very relevant to what we talked about this morning of the affordable genome, which is putting a piece on genetics and genomics as a required piece of CME. I recognize that adding that in and of itself may be too much to put into the report as it stands now but I would ask the committee to think about it and/or bring it up as a panel discussion.

I personally have written several--a couple of articles on this exact issue and in small groups of physician associations they were quite intrigued with that because it would put some rigor and national view so that we would get in all communities a requirement so it wouldn't be because one state physician association was interested. Those state physicians get more information than others and there are some areas of the country from a relative point of view with fewer academic centers, potentially that's one logic, that have less focused energy on this issue.

DR. McGRATH: I think domestic violence is a terrific example because it is not only, as you mentioned, raising to the top in terms of CME and other continuing education for other health providers but is also making it into a required part of the medical chart in many healthcare practices. So it is translating from learning in that--in your conference in Hawaii when you are sitting and learning about continuing education for your field to--your clinic having it be similar to a vital sign, that it is a question that needs to be asked of all women by a certain age. So it is that translation thing that we're talking about of clinical education and just in time education.

It would be great if we kind of keep moving in that direction. So that's a good point. Thanks.

(Slide.)

Okay. Number 4: Recommendation 4 is the other one where we just couldn't decide so we decided to let you all help us with this. And this is the idea of community--of consumer resources. The data from the survey, the literature and the interviews highlighted

the fact that consumers simply have too much information out there. They don't know what's credible. There are specific sites for one thing. If they need something else, they have to go to another site, and pretty soon they're sort of very frustrated by it. A lot of those sites were developed a number of years ago and some of them are sort of looking dated.

And coupled with this is the very strong message that we heard is that consumers trust the government as a clearing house and a gatekeeper for information. So what do we do with that information? What do we do with that data that we gathered? Is there something that—a recommendation around that?

And as you see, there is two. One is to take—you know, don't throw the baby out with the bathwater. There are existing resources, maybe work with those. The other is to develop or ask for the development of one that may be unique, that might be a little more forward-looking.

So those were our choices. Any thoughts on those?

Again, this is going to the Secretary of HHS,

which I think is very important to remember.

DR. : I think that there is a real opportunity for a one-stop shopping site, if you will, that would be a novel resource. The thing, of course, that always is incumbent on it is execution. We just need to—that's the more pragmatic perspective, which is it's all well and good to say we're going to do it but if we don't do a good job of it then it's really not going to be helpful.

And I think it's also one philosophically can't try and do everything. It has to be cognizant of the other resources that are out there and direct people to those resources as appropriate but, you know, be sort of the place where people can go to have, you know, a one-stop place where it can facilitate navigation and deal with some of the frustration. It is somewhat interesting that the study results show that the public does, in fact, trust the government. There is not a lot of empiric evidence to support that point but be that as it may that is what they said.

COMMITTEE DISCUSSION

DR. McGRATH: Gwen, and then Muin?

MS. DARIEN: Well, I think that—I mean, if you look at it, people go--the two places that people go that I know for cancer are cancer.gov or cancer.org. So it's either ACS or the NCI. But I think there is a compromise here which is to develop a new portal within an existing system so you end up on the CDC site or the HHS site but there is actually a portal that you can-- that has its own name, that has its own URL so that you can go in either way so you get everything together.

I think people are constantly trying to replicate what is out there and better it without saying, well, this—we're now picking the best of what is out there and integrating it into that place. So I do think there's actually a middle ground there.

DR. : And I think I was saying that but you said it much better. The idea of the portal-- and you can look at this as some of these newer search engines that are coming out where they are really trying to understand what it is exactly that you're looking for. So rather than, you know, going to cancer.gov and saying I can't find what I need here, I need to go somewhere else, where they could go in and

there could be some methodology by which they say, well, you know what, based on what you've told us, here is the best resource for what it is you're trying to find, so the content doesn't have to be extensive but some of the thought process about how to interact with the consumer might be quite novel.

DR. McGRATH: Muin, and then—

DR. KHOURY: So part of the challenge here is, of course, communicating to a wide variety of audiences, including the providers, including the consumers, and traditionally it has been tough because even within the government—I mean there are all these resources, I mean, NCI, cancer.gov and others, and I think the consumer is really bombarded with a wide array of so-called information but there is—I mean it is hard to know what works and what doesn't work.

So as an experiment what we're doing with GAPNET right now is to try to develop this genomic applications and practice and prevention knowledge base so we are partnering with NIH, NCI and others to develop this sort of what you call information resource that actually has—is a virtual link but also has what

are called the state nuggets or topic briefs that actually capture what we know and what we don't know very quickly.

And for those of you who watch the *Federal Register*, we just put out an RFA yesterday or the day before called "Calling for the creation of a Genomic Knowledge Synthesis Center" that could, hopefully meet some of the needs of what you're trying to do here.

This Knowledge Synthesis Center will work with EGAP, will work with GAPNET. It can't be all things to all people but it is going to try to distill through a process of systematic reviews as well as quick topic briefs for particular applications, what we actually know and don't know and whether there are evidence-based guidelines out there that can lead the consumer to the right decision making process.

So I mean I, of course—I mean we've been thinking about these things for years and I welcome the opportunity to work with other agencies to see how best implement an information resource that is both centralized but actually virtually, it can link to other information resources because you can't have one

site that fits the demands of everybody.

DR. McGRATH: Thank you.

DR. : I am speaking up in favor of trying to augment the existing resources. Kind of like remodeling an old house but it's a good thing to do.

And, in particular, there is so much material that has been developed that can be adapted for different audiences. And I have been a participant in the past in health literacy issues where you try to look at how do people learn and how do you get to their level, and I think adapting existing materials like gene clinics, for instance, is a way to get there in a far shorter time with far less work and cost.

DR. McGRATH: Right.

DR. : So I want to go back to the consumers and where they get the information. And I think what we need to keep in mind is that this Wayne Gretzky analogy and where the puck is going, and you know we're saying we need to educate people, we need to educate people at the higher levels, but what's happening is—you know, my son goes to middle school and in middle schools in science they are now having

expression microarrays, playing genetic counselors, that may be an anomaly but that may be coming all over the country. So these kids who are middle schoolers, who are 12 years old, are learning this stuff.

So maybe we need—when we are looking at stakeholders, maybe we—and the workshops, maybe we should include somebody, middle schools, some—not middle school kids but, you know—

DR. McGRATH: Educators.

DR. : Education.

DR. McGRATH: Right.

DR. WILLIAMS: Well, I think, you know, that is a really good point. One of the other recommendations, not the one that we're currently looking at, specifically indicates the need to connect with the Department of Education and say—because you're absolutely right. If we begin it from day one in the education then we will have a genetically knowledgeable public and workforce but it will 20 years from now.

DR. : And, you know, genetics is right now hot apparently if they're teaching them at the middle school. So it's a good opportunity but who

knows where it's going to go.

DR. McGRATH: Sylvia, and then Gwen.

DR. AU: So I think this portal is like the congressionally mandated Newborn Screening Clearing House from the Newborn Screening Saves Lives Act that Jana talked about where it links you to existing resources, and I think one of the things that we're doing in helping develop the clearing house is a filtering system so that people that come in, you know, will say I am a parent living and had my baby in Hawaii, and so that filters the results so that Hawaii specific materials would come up at the top first for newborn screening.

So I think maybe something like I am a primary care physician and I'm looking for information about whole genome sequencing because all my patients are having it and bringing the results to me, and then being able to have some of those results coming so just some filtering like that.

DR. McGRATH: I think that speaks to Marc's idea of the search engines that can be more specific, yes, and that would be the portal.

Gwen?

MS. DARIEN: I think the one—just to build on the issue of what kids are getting in school, I think that it's important to remember—I mean, we did talk about collaborating with the Department of Education but it has to go through your entire education because how many of us got A's in algebra and can't help teenagers do their algebra homework? I mean, you know—so if—

(Laughter.)

DR. : (Not at microphone.)

MS. DARIEN: Well, I'll raise my hand but it is—I think it is really important that it's not just a very isolated thing and that it actually goes through a longer lifespan of education.

DR. McGRATH: Right. Okay.

What I hear is a notion of a portal that would have some of the decision-making capabilities in it to help the person be more specific with the exception of David's comment of a recommendation to revise what's existing.

If we go with the portal method, the idea--

and, of course it would have links to those existing ones and maybe there could be an input to improve those or update them or whatever. The way the recommendation is written, is it actionable to the Secretary of HHS? Can we picture what she might do in response to this if we are saying we would like a new portal developed that has all these features?

DR. : Yes?

DR. McGRATH: Yes. Okay.

DR. : (Not at microphone.)

DR. McGRATH: David, and then Joseph, and then maybe Sara.

DR. DALE: Were I the Secretary I'd immediately ask what do we already have?

DR. McGRATH: Uh-huh. I think you're right. Joseph?

DR. TELFA: Yes, as usual. I was going to say similarly but what I was going to rec-I think one of the things that we had a lot of discussion around was to take advantage of existing resources.

What I heard actually was not a new portal but an add-on ornament or a site dif-you know,

modification of a site where one already exists and all you would add would be just one more add on that would allow you to do this. So it is not the creation of a new one but just, you know, the add-on and use existing resources. That would be something that--and part of what we were trying to get at, which would be actionable and you could use would be something that could be slightly modified out of what's already in existence.

DR. McGRATH: Okay.

Marc?

DR. WILLIAMS: So if we look at the evidence that was generated I think that you can make the case based on the studies that were done to say that, yes, we know there are a lot of existing resources out there but they are clearly not meeting the need because we're hearing from the public that they're saying, you know, this isn't doing it. So some of that is incumbent on what David is saying about we need to modify those existing resources.

But I think it also argues for the fact that, you know, it's not just those resources are perhaps not

designed as best as they could but the people are having difficulty getting to them. And I think that the—I think David's idea is very compatible with the idea of having sort of a one-stop shop that would help to direct queries to appropriate resources.

I really think that those working together to improve the existing resources and to have, if you will, a service layer on top of that that really helps get people to the right part—I mean in the electronic health record environment this is exactly the issue that we deal with all the time.

We have all of this information that's in our electronic data warehouse and people want to get at the information, and if they are just turned loose in there they will never find it. So you create service layers in there to say, well, what are you really looking for. I'm looking for this laboratory result. They can enter it in plain language and they go directly to where they need and it saves a lot of time.

I think it is a very elegant approach.

DR. McGRATH: So a one-stop shop to me means a unique portal. Okay.

DR. WILLIAMS: Yes.

DR. McGRATH: Yes, okay. Just to clarify that.

And, Vince, I'm just going to ask if you have anything to add because this is-

DR. : (Not at microphone.)

DR. McGRATH: I don't think it's on.

Sorry about that.

DR. : I echo Dr. Williams' comments. Some of the comments that we received from the interviews was this issue of we have a lot of resources that are great resources, that have great data but the people don't know where to go, and identify some kind of a resource that then can lead to other resources. So that was the whole perspective about a portal-development of a portal versus just enhancing the current resources.

So my comments just echo Dr. Williams.

DR. McGRATH: I am feeling a consensus without having hands raised that suggests that maybe because it's a little bolder, a new thing, is to suggest the development of this new portal. We risk it

being dismissed as too ambitious but I'm sort of feeling the tone in the room for that. Should I be corrected on that?

We will get public comment as well and we can revisit this again.

So let's go with the portal for now because it's actually something new and we'll get comment on that and see where we go with it. Okay.

Those are my two pressing agendas. I of course have questions on the others more generally. Are they too wordy? Are they clear? But I'd like to open it if there are specific recommendations that we would like to talk about, and we do have—we are doing all right. We've got about another half hour, I think.

CHAIRMAN TEUTSCH: Yes. And, also, if there are recommendations that should be included that aren't.

DR. McGRATH: Yes, absolutely.

Scott?

I don't think you get lunch early just because we do not talk, though.

(Laughter.)

DR. : I will start.

DR. McGRATH: Thank you.

DR. : Which is I thought it was a great report so that we may still get to lunch early but I thought it was quite comprehensive and I thought that the recommendations, as well as the report itself, was actually remarkably easy to read and flow through and did not feel terribly—you know, sort of appropriately technical. I'm not quite sure it was the best page turner but it was good and it really got to the substance of the issues without, for the most part, diving in too deep. So I am happy with the recommendations as they stand.

DR. McGRATH: Great. Okay.

So now two—

DR. WILLIAMS: It would have been a better page turner but Salinger died before we were able to take full advantage of him.

DR. : That's right. He wouldn't write for 30 years but he made an exception for our report.

(Laughter.)

DR. : (Not at microphone.)

DR. McGRATH: Yeah, I talked to him on the phone about it.

(Laughter.)

Sylvia?

DR. AU: I'm sorry if I missed it. Are there recommendations in priorities? We never voted on this. Okay.

DR. McGRATH: Do you think that they should be? I mean that's kind of sometimes there, sometimes not.

DR. AU: I just don't know what the--like does the Secretary take Recommendation 1 as the most important? I am a logical person so I would--like for me when I get a report, I think of Recommendation 1 as the highest priority and Recommendation 10 would be the lowest priority. So that's how I think but, you know--

DR. McGRATH: Uh-huh.

DR. AU: --that's me.

DR. WILLIAMS: You know, that's a good point. It's certainly something to be considered, particularly as we get the public input and see what is really

resonating with the people that--part of our process in June would be, I think--before June would be to rethink the priorities of the recommendations.

DR. McGRATH: So I just missed the middle.

Do you think we should try today to--

DR. WILLIAMS: No.

DR. McGRATH: Oh, after. Got it. Okay.

DR. WILLIAMS: No, let the public weigh in.

DR. McGRATH: Okay.

Andrea, did you have a--

DR. FERREIRA-GONZALEZ: Yes, I think we need to wait to prioritize.

DR. McGRATH: Okay.

DR. FERREIRA-GONZALEZ: I just wanted to move Recommendation 7 up. That's all.

DR. McGRATH: Okay.

(Laughter.)

DR. McGRATH: Let me ask that question.

There are two places in here that reference to previous reports as recommendations. There's--I don't know if it's more about style or philosophical difference. One would be to leave in those free-standing

recommendations to acted upon or not or the other one is to put that text either in the preamble or somewhere in the Executive Summary that there are relevant reports that came out of SACGHS that relate to this and part of our overall recommendations the Secretary gets on those.

What do we think is a better approach to take? Leave them as recommendations or take them out or put them in the text?

DR. : Cathy, can you move one slide back because that's the one that's not represented in the actual hand out.

(Slide.)

DR. McGRATH: Right.

DR. : So that's the oversight report and the other one is the coverage and reimbursement report are the two reports.

DR. McGRATH: Yes.

DR. : Okay.

DR. McGRATH: Are people familiar with this one? Okay. Some people are—

DR. : We know that you are.

DR. McGRATH: If you aren't, Kathy has the text if you want it. Just pop up a hand and we'll read it. It looks like people are okay with it. All right. Good enough.

So that's the question on the table.

David?

DR. DALE: When I picked up the report again I looked for the recommendations and I had to turn back to page whatever to find them so I would put them in the front. I think that readers will like that and then they can see why did you say that?

DR. McGRATH: Yes, there will be in the big—the Executive Summary is the very first page. It's not here in this draft.

DR. DALE: Right.

DR. McGRATH: But it will be and that is like a page of background and then the recommendations. Exactly.

What about keeping these references to previous reports as recommendations? What do we think?

Sylvia is kind of nodding leaving them as kind of separate.

DR. : It's consistent with what we're doing.

DR. McGRATH: Okay. And it's consistent with other reports. Okay. Done. I'm just checking off the decisions.

So you can see that there are seven reports. We would try to be fairly equal on ones that address the needs for the healthcare providers, which are clinical providers, public health providers, their educational needs. We tried to address the need of just to consumers. We tried to address the needs for seeing that education tries to help eliminate health disparities. That's one of the major missions of SACGHS and we brought it in for that reason. And we are highlighting family history because that is an easy portal for Education.

Did we cover what you would think, you know, if you had to take away your big messages?

Okay.

Well, I don't—

DR. : I think you've done great.

DR. McGRATH: I'm just going to say we don't

need to beat this horse to death, do we?

DR. WILLIAMS: No, let's not.

DR. McGRATH: Just an--there is plenty of editing to be done. Please send your comments to Cathy either as changes or whatever issue--the method. We have a couple weeks to make it just a little prettier. It will go out to public comment pretty--you know, with the content basically as we see it and then we will revisit this in June.

CHAIRMAN TEUTSCH: All right. So you will not see this again.

We will get your edits. We'll get any changes that you think really need to be here but I'm hearing the consensus.

DR. McGRATH: Yes.

CHAIRMAN TEUTSCH: And so we will let the committee do the final adjustments and we'll get it out and, hopefully, we will be in good shape to review in June and get it finalized. So I think this consensus is testimony to the fine work that you and your colleagues have done on this. So many thanks. Great. And we can move it forward.

