

**Finalization of Draft Report and Recommendations**  
*Facilitator: Cynthia Berry, J.D.*

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DR. TUCKSON: We're going to continue on. I do hope, though, and I just want to make something, and I'm terrified of saying this, because if I open up this doggone door again, I'm going to kill myself, and I want to be very clear, because the committee, I think, has been very clear. If we're not clear on this, talk to me afterwards. Don't say anything now.

We have never, the committee in all of our discussions, we were very clear, but I've had enough people ask me outside, not people from the committee, but people that are in the audience, and I just want to be very clear.

We all recognize that in our Recommendation 7 which we just did, that we are very clear that the government cannot itself create the mechanism around these criteria. We are talking about the government is using its convening authority, its leadership to develop the mechanisms to make this happen.

We have been very clear that we have been, and I mean, exceedingly clear, and I want to continue to be exceedingly clear that we are calling upon the government to use its leadership, its authority, the Secretary of Health, to bring the right people in place to make something happen. Apropos this recommendation.

I think that's a very important thing around that very first point. There are a zillion examples that we have of responsible government leadership that serves to be a catalyst for action. I will give one example, again, which I am personally involved in, which is around electronic medical records.

Levitt, not the HHS Secretary, but the electronic medical records czar, electronic czar, Mike Levitt, I'm blanking on his name. I mean, anyway, the guy in charge of the health information technology, caused there to be a public/private partnership to create a certification criteria for electronic medical records.

Government can't do it, but they can say we need people from this community, this community, this community, all of you all come on into the conference room, and now because you are all in one place at one time, we urge you to take on this charge, this goal, and make it so. Then the private sector or whoever it is that's responsible, goes forth and makes it so. Thank God the government was there to be the sand in the oyster to create the pearl, as it were. Catalytic opportunities.

That's what I think we're trying to get at. So please be comforted, those who are in the audience who are worried that we are somehow ceding to government powers that -- the wording is very clear here. The committee has tried to be very precise. So I just want to make sure that those who are not wrestling with this at the table are as on the same page as those of us who are at the table.

It's a responsible call for government leadership to cause something to happen that might now and well may not happen were it not for the convening power of the Secretary of Health to identify a problem, raise it up in the light of public day as a priority, and then urge the appropriate people to come together to solve the problem. That's what this really is all about. Nothing more, nothing less. So having said that, I hope we're clear. What I don't want is folks in the audience to feel

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like they're going to go, because I'm going to tell you what is going to happen. It will drive poor Sarah and the team crazy.

If folks do not understand that point, they're going to go back out and they're going to talk about it back in government circles. The next thing you know, we're going to wind up trying to answer 5,000 emails about the fact that we are ceding power to the government that it doesn't deserve.

So again, it's responsible leadership to identify a problem and cause the necessary people to come together to be able to solve it. That's what it's all about.

All right. Moving forward. Until Raynard comes, we're going to keep pressing. By the way, the people that raised this in the hallway with me, thank God for you, because it would have been terrible if you had these misconceptions or concerns, not even misconceptions, concerns, and you don't feel like you have a chance to raise them for us to deal with it.

So I'll tell you, your counsel in the hallways and the lunch breaks and the bathroom, I don't care where it is, is just wonderful. So don't stop, because we love you to death. Besides, I don't think any committee gets the kind of loyal folk who hang in there every meeting until the clock finally ticks.

We've got a group of people that pay attention. So thank God for you, because we would not be as good as we are, however good we are, were it not for you, if that makes sense.

Thank you. Moving on.

MS. BERRY: That's my cue. Okay. We're on Recommendation 8. This recommendation pertains to education and training of health care providers.

The addition in red comes from a public comment we received suggesting supporting studies that link education and training tools to improved health outcomes. This particular change doesn't specifically mention health outcomes, but it does say that the Secretary should provide financial support for assessments of the effectiveness of educational and training tools.

I wanted to also bring us back to the point that Agnes had raised earlier about integrating training health care professionals and making sure that they are able to integrate genetics into their practices. I wanted to get her input, because there may be some tweaks that we might want to make to this recommendation. If it doesn't currently address her point adequately, we may want to make some further changes.

MS. MASNY: I don't know exactly where this would go, but maybe some type of beginning comment that would say something to the effect of since genetic information is being integrated into all aspects of health care and providers act as intermediaries. I don't know if that would sort of do it.

Then the other recommendation that I had made earlier was that where we are giving the examples, so that about midway down the paragraph, where it says, "HHS agencies to work collaboratively with state, federal, and private organizations to support the development, cataloging, and dissemination of case studies, practice models and genetic competencies (as proposed by NCHPEG)."

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MS. BERRY: This sort of is a regurgitation of a recommendation that we made in 2004. That language that you have, was that what we said in 2004? Or are you adding something new?

MS. MASNY: No, that is what I was adding new.

MS. BERRY: Right. But this part of the recommendation, that simply says back in 2004, this is what we said. So it's kind of regurgitating what we said. We can't change what we said, so can we put it someplace else?

MS. MASNY: Yes. Okay. Specifically to look at the genetic competencies for all health care providers as recommended by NCHPEG.

MS. BERRY: So should we add another separate standalone bullet? The first part is kind of an introductory, saying what we recommended before. The blue change talks about supporting studies into the effectiveness of training tools.

Should we amend that, or do you think we should add a separate part to the recommendation that addresses your suggestion?

MS. MASNY: I think you could go as a separate bullet.

DR. WILLARD: Well, one point is the genetic competencies are put forward by several groups, not just NCHPEG. I'm not sure, again, if I'd single out --

MS. MASNY: Could we say, "such as" NCHPEG, and name the other organizations?

DR. WILLARD: But there could be a dozen organizations. We're getting dangerously close to where we've been.

MS. MASNY: Where we've been before, okay.

DR. WILLARD: The blue end, or red, depending on whether you are looking at the screen or the printed page, the wording of that is ambiguous to me, and maybe it's purposely so on your part.

Effectiveness is not clear whether it refers to effectiveness in training, or clinical effectiveness because of that training.

The public comment certainly by referring to health outcomes, made me believe it was the second, and not the former. So if you meant it to be related to clinical outcomes, I'd probably say something like, "provide financial support to assess the clinical impact of educational and training tools."

DR. WINN-DEEN: You know, I think we could add something about the competencies at the end of the sentence for education and training of health providers in genetics and genomics to a level of accepted competency.

MS. MASNY: For all health care providers.

DR. WILLARD: If push came to shove, wouldn't you rather assess it against clinical impact than you would against some stated list of genetic competencies, right? I mean, if you're relating it to outcomes, you're relating it to outcomes, which is a much more direct measure.

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MS. BERRY: I sometimes think when we make amendments, we create these monstrous sentences. We should break it up, I think, into two parts.

The first part is funding studies to link education and training to improve outcomes, period. Then we can address the point about clinical competencies in some way. So I think there is probably a more direct, easy way to address that point by just creating a separate sentence. So I think I would add a period and get rid of the rest of that, all that.

DR. LEONARD: Maybe it can be added up at the first sentence. I'm not sure what is not said by the first sentence. We're asking for support of ongoing training, continued education of health providers in genetics and genomics. I mean, maybe you could add, "to achieve genetic competency," but I don't know that that adds anything to what we're already stating.

MS. BERRY: Right.

DR. McCABE: I would argue that you could add something as another sentence here that would be in essence saying that health providers who are utilizing or who are giving genetic or providing genetic services should meet an adequate level of competency, or something like that.

So that all of it leads down to the fact that there needs to be some, certainly all physicians at least can bill for genetic services, but they need to meet some level of competency. The way you get them there is through all the stuff up until then, because we don't hold them accountable.

DR. WINN-DEEN: I think Agnes' point is that at some point, we're going to stop thinking about physicians as providing genetic services, and that it's just integrated into the normal practice of medicine. So I don't want to create an exceptionalism view of this.

What we want to do is we want to just see genetics and education rolled out in such a way that it's integral to the competency in all phases of medical practice. I think that is what Agnes was trying to get to.

DR. McCABE: I agree, but I think what we're trying to say is that because I see it now, that people are providing genetic services, but they don't really have the resources to provide that. The information is erroneous.

So saying that people should get educated is a good thing, but then I think they need to be held accountable at some point as well.

DR. WINN-DEEN: And I think that was the point of saying that they need to come to some competency level in their knowledge of genetics as it relates to their particular whatever it is they do in the practice of medicine, whether they're a nurse practitioner, a physician, whatever allied health professional.

DR. EVANS: I don't know how much editorializing or justification we want to do, but in relation to Agnes' first sentence, it might be worth putting something in there about the fact that yes, genetics is permeating medicine, and providers are acting as intermediaries, and they also consistently say that they are not prepared or do not have sufficient training.

I don't know if we want to justify what we're saying in those terms, but certainly that's a heard comment among providers.

DR. LEONARD: And it's documented in the literature, too.

MS. BERRY: The word keeps popping in my head that we should try to emphasize somewhere the point that these educational and training tools, and we're not just talking about professionals in training, in residency, or in schools, but actually ongoing training for providers who are in practice, and that these tools should also in addition to ultimately leading to improved outcomes, facilitate the integration of genetics and genomics in the practice of medicine, nursing, or whatever.

So if we can maybe get those two thoughts. So there are two goals, really. One is to assess the clinical impact, i.e. improve outcomes, but before you can even get there, I think the threshold is these tools have to enable docs, nurses, and counselors and everybody else to integrate genetics into their practice areas.

DR. SHEKAR: I think that I would be remiss as ex officio from HRSA if I didn't mention the concept of diverse populations being served, particularly with a 10-year lag time of research to patient bedside, particularly important with regard to genetics and genomics that we have the opportunity that all populations ultimately through these tools get served.

So somehow if the concept of across diverse populations or multiple populations could be employed somewhere within those paragraphs, it would I believe strengthen that comment.

DR. TUCKSON: I'm going to also sort of break, Cindy, one of my little rules as chairman and just sort of raise a question. I hate to bring things back, but I just for the first time sort of read in a different way this first sentence.

Since providers act as intermediaries between health plans and plan members, it sort of leaped out at me that it's a little strange. I don't think that we view the role of the health professional as an intermediary between the essential dyad in health care, it was between health plans and the members.

Somehow or another, the health professional is an intermediary, and thank you very much for helping out. I sort of see the essential dyad as being more the professional and the patient.

MS. BERRY: I think what's meant there, and Suzanne reminded me, I think in a sense the gatekeeper function of the provider. In other words, the provider determines when a test is ordered. It doesn't have to do with the health provider is some sort of interpreter or insignificant middle man role, but mainly as it deals with access issues, it is the provider and the health plan kind of determining what a patient would have access to.

DR. EVANS: But I think like Reed says, that's not at all the primary way we see ourselves when we are dealing with patients. That's a secondary onerous task.

MS. BERRY: I don't think it adds an enormous amount anyway. What was the reason for that language to be in there? I mean, I know what was meant by it. But if we remove it, are we losing some critical thought that someone had?

DR. McCABE: I think you could stick the access back in there. You can get rid of intermediary and make it clear that providers have an important role in ensuring access, or a critical role in ensuring access.

DR. LEONARD: I think given what the end of that sentence says, that, "There is a need to support the ongoing training and continued education of health providers in genetic and genomics," we need to point out I think as Dr. Evans said, is that they are insufficiently trained at the current time. The way that is looking now is that genetic information is being integrated, and the providers are going to do this.

So it doesn't really follow that we need all this education and training without stating that providers, a majority of providers are inadequately trained currently, or something to that effect.

DR. TUCKSON: I'm going to need to do one short process check and trust in the attention span of the committee. It is 4:00 exactly. Raynard Kington is here. I need to just suspend for just a moment what we're doing, and also because I have to step out for 10 seconds also simultaneously.

### CONTINUATION OF DISCUSSION

MS. BERRY: How about this? Agnes, we're going to need your help. I'll just read it out loud, but you can follow along. "Since genetic information has the potential to be integrated into all areas of health care and providers have an important role in ensuring appropriate access to genetic tests and services, there is a critical need to support the ongoing training and continued education of health providers in genetics and genomics."

Then it goes on to reaffirm the recommendations that we made to the Secretary in 2004, recommendations which included blah, blah, blah. Then we still haven't fixed this last part. But let's take that first paragraph. Does that capture what people are getting at? We have to fix the second one, but I want to make sure the first one is okay. The second part. This gets to the studies.

DR. McCABE: Well, we haven't done, Cindy, in the first part, and maybe there needs to be a separate one so that we don't get too many run on sentences. But we do need to acknowledge the diverse population somewhere.

MS. BERRY: Should we have that in the part about ensuring appropriate access to genetic tests and services? We want to add to everyone or to --

DR. FITZGERALD: (Inaudible.)

MS. BERRY: Not just for them, but for everyone. Okay. Diverse populations. Does that do it? All right. So here is the question. I almost think we don't need to have this second sentence.

DR. WILLARD: You almost have it. You can combine those two. Just say, "These tools should enable health providers to meet standards of genetic competency and to thereby integrate genetics into their respective practice areas."

MS. BERRY: Yes.

DR. WILLARD: To thereby.

MS. BERRY: And then get rid of this last -- competencies or competency? Singular, or plural?

PARTICIPANT: Cies.

PARTICIPANT: Plural standards, you have singular competency, yes.

DR. McCABE: The term of art in regulatory medicine is competencies.

DR. WILLARD: Right, but then you don't need standards.

DR. LEONARD: Yes, you don't need standards at all.

DR. WILLARD: Or to meet a standard of genetic competencies. They can't be the same.

MS. BERRY: I'll take that standards out, right? Do you want to take "standards" out? I liked it better, just "meet genetic competencies," don't you think?

DR. WILLARD: That's fine.

DR. EVANS: There certainly could be different standards for different levels of providers, right?

MS. MASNY: Thank God Reed's not here for him to bring up something from the past.

MS. BERRY: I won't tell. Go ahead.

MS. MASNY: No, just what we recommend as one of the tools to help with education and training was only one of the aspects in that 2004 report. It makes it sound like including, just maybe to say one of the training mechanisms. Remember we had all the suggestions for integrating genetic information into credentialing exams. What could be done for ongoing education to get training of faculty.

This was one of the recommendations that was made based on the survey that we did with the health professional organizations. They said that the providers needed these tools of cases to see how it was actually applying to their practice. But that was just one aspect of what we were looking at with the education recommendations.

MS. BERRY: So do you want to emphasize that?

MS. MASNY: Well, it makes it sound like when you say "which included," it makes it sound like that that was the complete list.

MS. BERRY: Included is like it sort of included these things, but there were more.

MS. MASNY: Okay. All right.

MS. BERRY: Ed?

DR. McCABE: We should discuss this, but I would say "meet adequate genetic competencies." That's usually, there is some level that is set as inadequacy. To meet genetic competencies, I think we should specify a level.

I would say, "And thereby to integrate genetics effectively into their respective practice areas."

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MS. BERRY: Does "adequate" sound good enough? Or does it sound like we just want a bunch of mediocre providers?

MS. AU: Can you put, "Established genetic competencies?" I mean, adequate, who's adequate?

PARTICIPANT: But some of them haven't been established for every --

DR. McCABE: I think it needs something more than, to say "meet genetic competencies," that seems too vague. "Establish" is better.

DR. TURNER: The word "tools" to me doesn't seem -- education and training programs, maybe. Tools are a part of the program. "Tools" seems to be a very particular subset of what we mean. It's like a checklist or an exam. Those are the tools, but it's the larger training programs and educational programs that we want support for.

MS. BERRY: Would you still call it a program if you're talking to a doc who has been in practice for 20 years and you are providing him with some kind of CME? Is that a program still?

DR. TURNER: A short course.

DR. WILLARD: Or just call it "genetic education and training."

MS. BERRY: Yes. Right. So get rid of "tools." Just say, "Impact of genetic education and training."

DR. TURNER: Because it asks the question then, what are these tools. We don't define those or describe them.

MS. BERRY: Okay. How's that?

DR. LEONARD: In the second sentence, you need to change "these tools."

MS. BERRY: Right. This training should enable health providers? Or education? This training or education?

DR. McCABE: I would go "education" rather than "training." Training is the old fashioned way.

MS. BERRY: Or "these efforts." Okay. Any other changes?

Agnes?

MS. MASNY: Again, coming back to that initial paragraph, do you think that we should say, though, that SACGHS recommendations, I'm not reading it off the screen there, regarding the education and training of health professionals, so it's a reference back to that original document that we sent?

Because as was just reminded to us when the awards were given out, there actually were resolutions that we came up with. So there is a specific document on that, just as a reference point.



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MS. BERRY: I think maybe "the Secretary" should go up here. "SACGHS reaffirms the recommendations it made to the Secretary in 2004 regarding." Does that do it?

Muin?

DR. KHOURY: Can you scroll down a little bit? Just come down a bit more. I want to show you, okay. The selected division suggested by public comment recommends supporting studies that link education and training tools to improved health outcomes.

This is a document about coverage and reimbursement. It is not a document about general education and training in genetics. Of course they go hand in hand. I'm feeling that we may have lost something in the translation, because we are talking here about making a set of recommendations to HHS about coverage and reimbursement of genetic tests and services that should be evidence-based, and that should follow all the other recommendations.

Somehow this Recommendation 8 has evolved into sort of a catch all stuff of some sort. I'd like us to go back and rethink a little bit why we have Recommendation 8 to begin with, and what are we trying to do to answer the public comments about linking the training of the health providers with improved health outcomes?

At the end of the day, you want to show that coverage and reimbursement of appropriate genetic services can lead to improved health outcomes among patients and the population. You'd like to link those things together.

I thought what the task force responded to, and somehow this paragraph has become something else.

MS. BERRY: Well, to answer the first part of your question, this recommendation, again, it's hard for us because we're taking them in isolation. It's hard to see the context. But where it fits in is in the report under provider education and training. That was mentioned as a key component to coverage and reimbursement, insofar as if a provider is not properly trained in the area of genetics, they don't know what they don't know, and they won't necessarily provide their patients with access to these services because they won't necessarily order them, or they won't know that the patient needs them.

It is also addressed in that section, the fact that a lot of health plans have physicians and other providers making coverage decisions. If they don't have a good knowledge base of genetics, they won't necessarily make appropriate coverage decisions. So this is where in the report this recommendation fits.

So it is in a provider education and training section. It's not a major part of the report, so we don't really go off onto too big of a tangent in the report, but it is identified as an issue that pertains to coverage and reimbursement.

Now, you asked about the commenters health outcomes point. That may be something that we need to think about.

DR. KHOURY: Yes, and I think that's something we may need to think about. Why are we training health providers in the new genomics era so that they can provide the evidence-based services to improve health outcomes.

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If we're asking the Secretary to provide financial support for the assessment of that link between education and health outcomes, I think we are focusing on the first part, but we're not focusing on the second part.

If you can do outcomes research that considers as part of the analysis the level of training of the health care providers in genetics and genomics and how that might be related to changes in the outcomes of patients and populations. So just see whether or not the committee can somehow pick up the theme of linking all of that stuff with improved health outcomes. That's what I thought we were responding to.

Maybe it requires a creative way of putting improved health outcomes in this paragraph somehow.

MS. BERRY: Well, this language in that last paragraph there is supposed to address that, but it may not do it well enough. Maybe we need to actually use the words "improved health outcomes."

This part where it says, "The Secretary should provide financial support to assess the clinical impact of genetics education and training." What is meant there is is it making a difference? Is it improving outcomes? But maybe we just need to state that more directly.

DR. KHOURY: Let's do that.

DR. LEONARD: But it's the words, "the clinical impact" that was used in place of "health outcomes." So I think it's redundant to put the clinical impact. I mean, what clinical impact means is improved health outcomes.

MS. BERRY: How about get rid of the word "clinical" to assess the impact of genetics education and training on improved health outcomes.

DR. TURNER: (Inaudible.)

DR. WILLARD: That would be the hope.

DR. TURNER: Or just the impact on health outcomes.

MS. BERRY: Does that do it, Muin, do you think? Can you see it?

DR. KHOURY: I think clinical impact was okay. I was maybe working from this.

MS. BERRY: Yes, look at it.

DR. KHOURY: There are so many changes that have happened since then.

MS. BERRY: Right now it reads, "The Secretary also should provide financial support to assess the impact of genetics education and training on health outcomes." Then it goes on about competency.

DR. EVANS: You can probably get rid of the two after the "thereby," and "thereby integrate genetics."

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DR. WILLARD: I think we're reaching the saturation point on this recommendation.

MS. BERRY: Is everybody okay with it?

DR. LEONARD: Can we vote without Reed?

DR. WILLARD: I can jump in ahead of my role tomorrow, if need be. Do we have a recommendation on this one?

PARTICIPANT: Can you read it all together?

DR. WILLARD: If you can scroll it, Suzanne, so people can see the top of it. Do we have a motion?

DR. McCABE: So moved.

PARTICIPANT: Second.

DR. WILLARD: All those in favor, if you can raise your hand.

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: The recommendation passes unanimously.

We can move onto Number 9.

MS. BERRY: Number 9. One more.

DR. McCABE: Well, there are some more after that.

MS. BERRY: Well, the other stuff has to do with kind of the body of the report, some technical changes and things like that, so it's not as critical. We can get to that if there's time. It doesn't go to the meat of the recommendations.

This last recommendation, Number 9, has to do with a little bit of public education, making sure that the public has reliable, accurate, trustworthy information about how to gather and utilize family history, genetics, and genetic technology so that they can make informed decisions with regard to their health care.

We received some public comments on this. One of the comments caused us to make this change here in the second paragraph. "The Secretary should leverage HHS resources to develop and make widely available reliable and trustworthy information about how to gather and utilize family history, genetics, and genetic technologies to guide and promote informed decision making."

We didn't have too many comments on that, just a few. That was the one change that we made at the task force level. Does anyone have anything?

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DR. EVANS: As a newcomer, reading this, the very first sentence struck me as being rather confusing. At first I thought it was talking about reliable and trustworthy information about family history. That makes it being available on the web, that makes it sound like it is quite concerning. I don't want my family history on the web, right?

Maybe we should use that same phrase, "reliable and trustworthy information" gathering pertinent family history and information about genetic technologies. Something like that.

DR. WINN-DEEN: I think we meant to have a comma after genetics. So by gathering family history, genetics, and genetic technologies. Genetic and genetic technologies are meant to be two separate thoughts, right?

MS. BERRY: Is there a way to squish this?

DR. McCABE: Cindy?

MS. BERRY: What?

DR. McCABE: I would suggest that we start, and we can decide whether we have a need for that first phrase now, but that we should let people know where we're going. So patients and consumers need the tools to evaluate health plans, or need to have the information to evaluate health plan benefits and health providers so that they may make the most appropriate and the most financially responsible decisions about themselves and their families.

DR. WILLARD: Or just begin at "in order to allow patients and consumers," and just take that bottom phrase and move it to the top.

DR. McCABE: Yes, and we need to throw genetics in there somewhere, too. I see what you did. But still, it is a pretty long sentence.

MS. BERRY: We haven't fixed it yet. So what part do you want to move up?

DR. McCABE: If you do it Hunt's way, and then we can see whether it's too long a sentence, but patients and consumers need the genetic information --

DR. WILLARD: That wasn't my way.

DR. McCABE: Oh.

DR. WILLARD: I would just start the sentence "To allow." Take the last two lines of the existing recommendation. "To allow patients and consumers to evaluate health plan benefits and health providers and their families."

MS. MASNY: But are they evaluating these plans and benefits related to genetic services?

DR. McCABE: See, the way Hunt is doing it, then it's a comma, reliable and trustworthy information about family history. So it comes in, but at the end.

DR. LEONARD: It's my thought that this isn't really related to choosing health plan benefits and health providers, as much as it is in helping in the medical decision making for their own care,

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and the care of their families. There are two aspects to this. But I think evaluating health plans and health providers is really sort of secondary to really helping to participate in their own medical care and the decision making. Genetics is very much this is your choice, what do you want to do.

If they are not informed, they can't participate in that process as effectively.

DR. WILLARD: But it does bring in Muin's point. It ties it back into coverage and reimbursement, because some plans may provide coverage, some may not. That's relevant, therefore, to their choice between Plan A and Plan B.

DR. WINN-DEEN: Could we add the word "clinically appropriate?" "To make the most clinically appropriate and financially responsible decisions for themselves." So that ties in sort of the medical side and the -- I mean, it's always a balance, right?

MS. AU: What was your definition of financially responsible?

DR. WINN-DEEN: I think each family has to determine do they have the means to pay for something. If they are in a health plan that has a huge deductible, is that the kind of thing they want to be in? Or do they want a \$10 copay? I think that's what we were trying to get at with financial. It is within your own personal financial resources. What is financially responsible for you as a consumer.

MS. AU: I guess my problem with that working in a public health agency is financially responsible to us is societal, financial responsibility versus personal financial responsibility. I didn't know what you were qualifying it as.

PARTICIPANT: Do you mean financially feasible?

DR. LEONARD: So why can't we just say that the most appropriate clinical and financial decisions for themselves and their families?

MS. AU: Yes. That's good.

DR. KHOURY: How about just the most appropriate decision? The most appropriate decision involves all of the above. Clinical. The most appropriate decision.

DR. WINN-DEEN: So can we add the same comment after "genetics" in the second paragraph?

DR. LEONARD: Is this now getting redundant? What's the difference? Maybe I'm missing something, but what's the difference between the second paragraph and the first? Why are they separated as two?

MS. BERRY: Well, they don't have to be. We can mush them together. The first paragraph just sort of says patients need access to information. The second part of it is what the Secretary can do to help get them information.

DR. LEONARD: So you can stick it up there. It won't go?

DR. WILLARD: If that's all you're trying to say, I think you could just say, "The Secretary should leverage HHS resources to develop and make widely available, reliable, and trustworthy

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information." It refers to the previous sentence. Otherwise, you're repeating the same words two sentences in a row.

MS. BERRY: Put, "To make such information widely available."

DR. KHOURY: Cynthia, what does the term "should leverage HHS resources" mean? If you look at Recommendation 8, it was different. It was, "Should provide financial support for assessment." Are we asking HHS to -- I mean, leveraging HHS resources somehow implies a zero sum game to me.

You have all these resources and you move things from here to there. That image, I'm not sure who came up with that word. Aren't we asking the Secretary to do something to develop and make widely available?

DR. McCABE: Well, I think leveraging does mean something different than a zero sum gain. What leverage means is we want the Secretary to invest some money. So you get more. Leveraging to me means you get more than the money you invest. There is some strategies where you're going to get more out of it than just putting the money in and getting a product out.

DR. LEONARD: Can we just say "Should make such information widely available," and then just come to the end, "through federal government websites and other appropriate mechanisms," and take out everything in between?

MS. BERRY: Maybe we should take out "develop." Because you don't develop such information through websites, do you necessarily?

DR. LEONARD: Well, you make it available.

MS. BERRY: So just add, "make it available." So "leverage resources to make such information widely available through federal government websites and other appropriate" --

DR. LEONARD: No, I think it does need to be developed.

DR. WINN-DEEN: Yes, you have to develop the content that you're going to put on the websites.

MS. BERRY: But you don't develop such information, do you, necessarily?

DR. WINN-DEEN: Sure you do.

MS. BERRY: Do you develop content to put on a website?

DR. WINN-DEEN: Even if you're just pulling stuff from the literature, you have to develop the content and put it together in such a way you can post it to a website.

DR. McCABE: And if it's going to be evidence-based, there may even be a research component to check the validity of the information before you put it up.

DR. KHOURY: Remember the Surgeon General family history tool that was developed.

MS. BERRY: Right. All right. How does it look?

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DR. WILLARD: Why don't we take a moment to read through it?

DR. LEONARD: Could we accept the changes so that we can see it all as if it is written normally?

DR. McCABE: We need a synonym for information.

DR. FITZGERALD: That's right, because you're referring to it again, though, right? I think it should stay as information, because you're saying such information refers back. This isn't meant to be a best seller. It's simply meant to be understandable.

DR. LEONARD: But you could say they need reliable and trustworthy information about family history, about gathering family history, genetics, and genetic technologies.

DR. WILLARD: Suzanne, don't touch it. Consider changing the order so that it is trustworthy information about genetics, genetic technologies, and gather and utilizing. So just change that order so that it's clear.

DR. EVANS: Don't they really need trustworthy guidance about gathering this information, as opposed to trustworthy information about gathering information?

DR. LEONARD: I agree with what Hunt said about moving the genetic technologies.

MS. BERRY: You can say trustworthy information about genetics, genetic technologies, and gathering and utilizing family history.

DR. TURNER: Cindy? Over here again.

MS. BERRY: I keep hearing it over there.

DR. TURNER: To start it with "To allow" I think frames it in a way that gives it a paternalism that we probably don't need. So if we were to say, "In order for patients and consumers to evaluate health plans and benefits to make the most appropriate," and take out that "so that they."

DR. WILLARD: Maybe with that change, we can look at it one more time and see if this does about what we can expect it to do at 5:00 in the afternoon.

MS. HARRISON: In order to utilize family history, you have to gather it. Can you just take out "gathering" and it will cut down on the wording.

MS. BERRY: Unless -- oh, he's gone. I was going to say Muin thinks that the gathering part is a part of the Surgeon General's family history initiative. Do we need to leave it in there for that? I have no strong opinion at all.

DR. McCABE: Let's get rid of the utilizing if we're going to do it. Let's just, about genetics, genetic technologies, and family history.

DR. WILLARD: Let's read it and see if we can't get to a motion.

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DR. LEONARD: But Jim, you had raised the concern about family history. I think in this context, though, it's differently worded such that it is not saying that individual family histories are going to be published on the website.

DR. WILLARD: So if Suzanne will put her hands in her lap, don't touch the keyboard, let people read it and see if we're getting close.

DR. FITZGERALD: Now the way it reads, I think you need a comma after "family history" just to set all that aside. Thanks.

DR. McCABE: With that comma, I move approval.

PARTICIPANT: I second.

DR. WILLARD: All in favor?

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: We are unanimous in accepting that recommendation. We have soldiered through all nine recommendations.

Cindy, what else do you have for us?

DR. McCABE: Could I ask that at the end of the day, I know this is hard on staff, but maybe if this could be printed up for us so that we could look at it one more time tomorrow on a piece of paper.

DR. WILLARD: A clean version of the recommendations? Did any staff hear that request? Okay.

MS. BERRY: Hunt, I don't know if you want us to do this or not, but there really were a couple of minor, and then one a little bit more significant, changes to the body of the report that we made at the task force level in response to public comments. I don't know if you want us to go through those now.

DR. WILLARD: Well, I think we've been in the spirit of accepting the task force's good work on behalf of the committee as summarized here. They don't look too substantial to my eye, unless anyone would like to discuss them.

DR. WINN-DEEN: Do you want to just give a brief outline of what the areas were so that everybody knows what they were?

MS. BERRY: Sure. The first has to do with revising the introduction section of the report. We rephrased the sentence so that it now reads, you can look at the blue part in your paper there, I won't read it out loud, but it addresses the issue of reimbursement levels for covered tests.

DR. McCABE: Move approval.



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PARTICIPANT: Second.

DR. WILLARD: I'm not sure we need to vote on this.

DR. McCABE: I think we do, because it's the final.

DR. WILLARD: Okay.

DR. McCABE: Unless we're going to have a vote on the final document.

DR. WILLARD: And I don't believe we are.

There has been a motion to accept that change and a second. All in favor?

(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: That's unanimous.

MS. BERRY: The next one had to do with we had a section on what is genetic/genomic tests and technologies, what are they. There were a lot of public comments about that, fearing that it is too long, it's too confusing. So our task force recommendation was to indicate that really the text is meant to be a description rather than any kind of hard and fast definition. Discussion?

DR. WILLARD: Any discussion on that point from around the table?

DR. McCABE: We've always had this very long definition of genetic tests. Partly it was historical that we were using the definition that had been developed two committees ago. Have we already buried it, Suzanne or Sarah? Have we wavered from that definition of a genetic test already?

DR. WILLARD: I think we spent some time discussing that. At least it was modified to also include genomic tests.

DR. McCABE: Okay. That's fine.

DR. WILLARD: Any further comments on this change?

(No response.)

MS. BERRY: And the last, we have already talked about, which was to be consistent when we talk about providers so that the terminology is the same throughout the report.

DR. McCABE: Why don't we just for formality sake, I'll move to accept those changes as well.

PARTICIPANT: Second.

DR. WILLARD: All in favor of accepting those?

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(Show of hands.)

DR. WILLARD: Any opposed?

(No response.)

DR. WILLARD: With that, Cindy, are you done?

MS. BERRY: Done. Fini.

DR. WILLARD: Well, I'm sure I speak for our real chairman in thanking Cindy and the task force and staff, especially Suzanne, for an extraordinary amount of work in getting this document done and shepherded through both public comments and our own attention to it.

As is traditional, Dr. McCabe always has something to ask. Yes?

DR. McCABE: Well, it's just we had said that according to the schedule, these changes were going to be made, and we were going to approve it, you all were going to approve it in October. The question is does the committee need to see it again, or is it approved as it is now? Could it move forward at this point, rather than waiting another quite a few months?

MS. BERRY: I think we have to go through and still where we are in the process of incorporating some technical changes and comments that were made.

DR. McCABE: But I looked at those, and those are grammar, that we spelled "peck" instead of "pack" for lawsuit and some things like that. I trust that staff could do that.

DR. WILLARD: Right, and I believe that's the spirit of the timeline that Cindy proposed to use earlier, that there will be final minor revisions through the summer, and then in the fall, it will be transmitted. There isn't a step, at least not written, as to come back before this committee.

DR. McCABE: Okay. So it will be transmitted without coming back to the committee.

MS. GOODWIN: Well, the committee will get one last chance by email to review the entire text of the report once we've gone through all of the public comments. But that will be done by email probably.

DR. McCABE: Any guess at a schedule on that?

MS. GOODWIN: We'll probably have a final draft ready by the end of the summer, possibly earlier. We hope that the report will be approved by the next meeting in October.

DR. McCABE: So that email will include a letter to the Secretary that will go along with this?

MS. GOODWIN: Yes.

DR. McCABE: Okay.

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MS. GOODWIN: The report will also, what is not in the report now is an executive summary, and staff will be preparing an executive summary, in addition to making some other technical changes to the report.

The committee will have an opportunity to have one last look at the entire thing before it gets transmitted to the Secretary in the fall.

DR. McCABE: I just think that we've belabored this, and I'm sure we could wordsmith it for another 18 months. But I think it's important that it move forward as quickly as possible.

DR. WILLARD: This glacier is done.

Mr. Chairman, or Sarah, are there any final announcements before we adjourn for the day? I believe we're done.

DR. TUCKSON: We have to talk about dinner. We need to get the information on dinner.

MS. CARR: Actually more than that, I was wondering if you'd like to go over what decisions we made today. You might tell everybody about, Hunt, tomorrow, and then that would free Hunt up from having to do this tomorrow.

The three things we did today. You know what? We have them written out.

DR. TUCKSON: Good. I was just going to grab my notes, though.

MS. CARR: We just need a moment.

DR. McCABE: As usual, Sarah is way ahead of us.

MS. CARR: Yes, members who are joining us for dinner tonight should meet in the lobby at 6:40. We're having dinner at 7:00 at Clyde's. Would you like to go earlier? We could certainly see to that. If so, when?

MS. BERRY: As our reward for finishing early.

MS. CARR: 5:00? 5:30? 6:00?

MS. HARRISON: As a local person, the earlier, the better.

MS. CARR: Okay. We'll meet at 5:45 in the lobby.

DR. TUCKSON: And then as far as tomorrow, our friend Hunt will take the chair role tomorrow. I have to be away with an unavoidable conflict that I just have to attend to. I apologize to the committee. It's the first time I have missed one, but thank you, Hunt. He's well prepared. We've gone over all this. You're in terrific hands. Besides, you can take a sigh of relief that you don't have to deal with the crazy guy.

With that, the summaries on genetic discrimination, copies of the DVD are available to the committee. You can get it, and copies will be made available to the public on the website. As you see, continue to monitor developments in the House of Representatives, make compilation of public comment DVD of public perspective analysis, I've already said that. That's good.

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DR. LEONARD: Does broadly available include giving it to Ms. Biggert's office specifically?

MS. CARR: If she asks.

DR. McCABE: She already has a copy because she asked.

DR. TUCKSON: Right, she asked for it, and we gave it to her. We were very clear on that.

Number two, large pop studies. Yes, review report of NIH. We all are asked to read that report carefully.

MS. CARR: Well, this is the charge to the task force. But yes, the rest of the committee should review.

DR. TUCKSON: The committee is supposed to read the report.

MS. CARR: Yes.

DR. TUCKSON: Okay. Now, from that, let's go to the task force. They have to read the report, too. Identify other potential policies that need to be addressed, and recommended process or pathways for addressing them. Plan a public consultation meeting or meetings in October if possible to gather perspectives of the general public and the scientific community. You left out the scientific community.

MS. CARR: That's in the third bullet.

DR. TUCKSON: Third bullet? Okay. About the idea of the U.S. mounting a large population study and whether they would support such a study.

Just an addendum to that is the challenge the committee is going to have is how do you in fact ask for public comment on something that nobody understands? So the task force is going to have to take a good, hard look at explaining what this thing is, and then making that part and parcel of the announcement.

DR. LEONARD: Tim, is there any sort of summary, executive summary kind of thing of that report?

MR. LESHAN: Yes, I believe there is. I haven't read it in the last little while, but I believe there is an executive summary to that report.

DR. TUCKSON: Then plan a public consultation meeting or meetings in October to gather perspectives from the scientific community broadly.

I think the idea would be though, at least the assumption is you need to think about whether those go together, or are separate. I want to be careful about the administrative burden of trying to do separate things. You may determine that you can't do them together for time reasons or whatever, but it is something the committee needs to think about.

DR. McCABE: This is one where I would encourage the committee to move forward deliberatively as opposed to expeditiously. First of all, I doubt that there are the resources

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currently in hand to engage in such a study. I think that the U.K. ran into problems where the public was not prepared when they tried to roll it out.

So I think there is an opportunity for this one to be deliberate. You may save time in the long run by being deliberate.

DR. TUCKSON: Good. I just want to make sure I didn't miss anything. They got them all.

Then direct-to-consumer marketing. We're going to send a letter back to the Secretary describing that we are pleased with the initiatives that are ongoing, that there has been movement there. We are going to commend the agency's efforts to respond, and recommendations about the public impact, recommend increased efforts to enhance public understanding offered directly to consumers.

So we are asking the Secretary to think about this, recommending increased efforts to enhance public education of genetic tests, including the issuance of a general consumer alert, and then urging the FDA to consider the Internet a form of advertising and labeling.

Those are the things I had in my summary. Did we miss anything? Then we just did the stuff.

It has been an extremely productive day. You ought to feel good about yourselves. You did a good job. Thank you all very much.

Tomorrow morning at 8:30. You should be on time or, oh my God, the woe that will befall you.

(Whereupon, at 4:55 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Thursday, June 16, 2005.)