

### **Discussion of Final Recommendations**

*Facilitators: Reed V. Tuckson, M.D. and Andrea Ferreira-Gonzalez, Ph.D.*

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DR. FERREIRA-GONZALEZ: Now we begin our work to finalize the recommendations that will address those gaps. Now, in our January 30th teleconference with the entire Committee, we took a poll as to where the Committee was on all the different recommendations and we started to identify areas that might need a lot more discussions and further information.

We decided to take revising the recommendations in reverse order. So we are going to go from the back to the front because we think actually the recommendations in Chapter 4 require a little bit more discussion. We want to make sure we don't rush through those because we still have all the other recommendations to go through.

We are going to start from the five recommendations in Chapter 6, proceeding to the four recommendations in Chapter 5, and then as to the big ones, recommendations in Chapter 4. We will be ending with the overarching recommendation that appears at the end of Chapter 2 of the report.

We expect that our deliberations and recommendations in Chapter 4 will need the most time, so we hope to be able to move through these other recommendations.

These are the questions to consider. Keep them in mind as we go through the recommendations. Changes made to the draft recommendations are going to appear in lime green as we go through the different texts. For each recommendation, I will provide a capsuled summary and then ask three questions. I'm not going to read the recommendation. You are going to have the recommendation. Any changes that we have made from the original draft that were then changed through the steering committee and the work with the taskforce will be in lime green.

First I will ask you if you have any questions about the recommendation, do you need any more information to clarify the intent of the recommendation. At that point, we will have the taskforce members, who are sitting right over there, to [answer] questions, especially if we need more information [about] what the intent of that particular [language was]. Then I will ask if you have any edits to the recommendations to change the wording or actually the specific recommendations. When I have a sense that we have completed our discussions, I will ask you if we can move on to the next recommendation.

In reviewing again each recommendation, consider the following questions: does the recommendation adequately address the identified problem, and is the wording of the recommendation satisfactory?

We are going to start with Chapter 6. This recommendation calls for HHS to work with relevant stakeholders to identify and address deficiencies in genetic knowledge in education of three key groups: healthcare practitioners, public health workers, and consumers. We actually revised the preamble of the recommendation to recognize the creation of the SACGHS Taskforce on Education.

To Part A of this recommendation, we have added that educational efforts should also take into account issues of medical literacy, access to electronic information, and deficiencies in public infrastructure.

Recommendation 6 also has a Part B. Part B is not new text but it appears in the section. We actually moved this recommendation from Chapter 5 to Chapter 6 because we thought it fit better here.

This recommendation in Part B calls for research and surveillance on how knowledge of analytical validity, clinical validity, and clinical utility can inform the development of evidence-based clinical practice guidelines.

So again, the three questions we are going to be asking through the day. Do you have any questions about this recommendation?

DR. TUCKSON: Yes. This is terrific. I think a lot of this is determining how to have the form and structure. But this is fairly generic, saying people ought to have more knowledge. We just have to be attentive to saying the point of it is that people need to be able, and it is very specific. You can talk about a lot of things with tests. It now is whether or not as a rational consumer. This is about protecting the consumer. It is also about some of the uses, but it is about does a rational consumer have the information and [is he or she] being taught where they can go to understand the safeguards around how they use and access genetic tests.

There is something missing in the sense that this is a little more general than getting to this notion of ultimately saying how do you become an aware consumer of a product in addition to being concerned with how you interpret the tests and all those other things.

So there is something missing in terms of the focus of this activity.

DR. WILLIAMS: I would take issue in the sense that I don't think that we intended that focus, nor should there be, because the deficiencies are across all stakeholder groups. It is not just the consumers, it is the healthcare providers that are ordering the tests, that are attempting to interpret the tests. I think those groups are all articulated in Part A, the three key groups that we discussed, the healthcare practitioners, the public health workers, and consumers.

DR. TUCKSON: Let me try it a little bit differently. I agree with you there. That is absolutely right. But what it is saying is that HHS should work with all these people to identify and address. It doesn't say there is going to be a place where you can go to get the information.

DR. FERREIRA-GONZALEZ: Muin and then Mara.

DR. KHOURY: I'm trying to digest what Reed just said. I agree with him. I think the bottom line is this is about oversight of genetic tests. This is not about the Education Taskforce. We need something. Starting from the back, Chapter 6, now we have done all the oversight stuff and this is now the place to go get information and educate the public, the providers, and all of these things so that the information they need for the implementation and use of genetic tests in practice can be done in an informed fashion.

Maybe we can tweak the words a little bit. Parts A and B seem like it is wonderful. It is like we need to educate everyone about genetics. We have been saying this for years. What is missing here is the management of genetics with the information that has gone through this diagram leading to evidence-based processes and guidelines. That is what needs to be put out in decision support tools and for the general public and the providers to be aware of, not genetic information in general. Am I making sense?

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DR. FERREIRA-GONZALEZ: You are going ahead of, actually, what recommendations are coming. Remember that we have other recommendations about clinical decision support and so forth. Just look at all the other ones, too, to make sure we don't have it in the other ones.

But I would ask Muin and Reed, what language would you recommend? What changes would you recommend to address this issue?

We have Mara and then Kevin.

MS. ASPINALL: First, let me deal with the specific change. In Recommendation A, I think there is one group that is not mentioned, which is the group of payers. So instead of saying three key groups, I believe it needs to be four key groups and include public and private payers as part of the group that needs to be educated, as number one.

Number two, and I'll leave this as a general comment because it comes up a few times, did the Committee think about having a timeline for implementation. I would very much agree this is important, but when you think about getting to all government agencies and interested private parties, that could be a process that could literally take generations. I think putting some parameters around actions or a timeline puts more teeth in the recommendation so that actions will have to be taken over a particular time period to actually ensure they are implemented.

DR. FERREIRA-GONZALEZ: We will take that into consideration. Kevin.

DR. FITZGERALD: I just wanted to get back to Muin and Reed's point. To get some more specificity here, are you looking for a resource, a website or something, a "one site fits all," or are we just looking for some kind of process by which we say to the public, if you are looking for this kind of information this is how you go about getting it.

DR. KHOURY: I can make suggestions to change it right now. The third line, "Address deficiencies in genetic knowledge of education." Replace that by saying "To identify and address deficiencies in knowledge about genetic applications and practice and information on genetic tests and all of these applications." This is sort of like a "Know your genes," essentially.

What we are talking about here is the practitioners, the providers, the consumers, and the payers need to know the value of this information for practice. So instead of saying "genetic knowledge and education," just say more explicitly what we want people to know. That is the only change I would make.

DR. TUCKSON: Where is the one on decision support? Just so I can answer your question. Who knows where the decision support is?

DR. FERREIRA-GONZALEZ: The next one. It is the next one, Recommendation 2 and Recommendation --

DR. TUCKSON: Six? Recommendation 2?

DR. FERREIRA-GONZALEZ: Yes. That is the FDA regulatory one.

So anyway, I guess I am saying, in addition to what Muin is saying, we ultimately are recommending that there be a place for guidance that helps that.

So No. 6-4 does it.

DR. FERREIRA-GONZALEZ: Maybe they can explain that to include --

DR. TUCKSON: I will stay with Muin on that part and then we will get more specific when we get to this one. Great.

DR. FOMOUS: Do we want to add in Muin's language now?

DR. FERREIRA-GONZALEZ: Yes.

DR. FOMOUS: Can you repeat that?

DR. FERREIRA-GONZALEZ: Muin, could you repeat what you said?

DR. FOMOUS: This is in the first sentence?

DR. FERREIRA-GONZALEZ: Yes. "Genetic knowledge."

DR. KHOURY: Instead of "deficiencies in genetic knowledge and education," say "Deficiencies in knowledge of appropriate genomic applications and practice." That is broad enough. It captures everything we want from this oversight mechanism.

DR. FOMOUS: Say it one more time? "Deficiencies in knowledge"?

DR. KHOURY: "Deficiencies in knowledge about appropriate genomic applications and practice," or "genetic applications and practice."

DR. FOMOUS: Genetic and genomic?

DR. FERREIRA-GONZALEZ: Yes. Yes, "/genomic."

DR. KHOURY: How about just "genetic tests"? Because this is a report about oversight of genetic tests.

DR. FERREIRA-GONZALEZ: How about "the genetic test applications"?

DR. FOMOUS: Do we want to change the number of key groups while are at it?

DR. FERREIRA-GONZALEZ: Yes, yes.

DR. TEUTSCH: I would suggest, to Mara's point, that that is just one of a whole series of decision-makers, policy decision-makers. I don't know how broad we want to make that because there are a lot of them that are making policies that influence this environment.

DR. FERREIRA-GONZALEZ: So, do we want to put the number? For example, "In practice and education of key groups in particular." Then we are not saying that these are the only four.

MS. ASPINALL: I think that is better. I did debate over Steve's point, but I think payers are so critical. When you read the rest of the list, they wouldn't be included. So I think eliminating the number and then highlighting "in particular" deals with both.

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DR. FERREIRA-GONZALEZ: We are going to put "practice and education of key groups, such as."

DR. FOMOUS: I'm hearing two different things.

[Pause.]

DR. FERREIRA-GONZALEZ: That will get to the point that Muin and Reed had. Then Gurvanet has a comment.

DR. RANDHAWA: I thought when we were initially writing what was there that we were describing a general gap in the knowledge and not specific genetic tests or applications. While that may be where we want to go, then we are getting into each specific test and each specific matter in education. Are we making it more specific or are we still about the more general where are we in terms of education deficiencies and how do we overcome that?

DR. FERREIRA-GONZALEZ: What would you recommend to change? Marc.

DR. WILLIAMS: Just to respond to that before we discuss it, I think that is a good point but I think that the other points that Reed and Muin brought up are probably more pertinent given the focus of the report. This is appropriate. It doesn't mean that those other problems don't exist, and I think we do articulate the breadth of the problem in the language of the report.

I also feel less concern that we need to be as broad here given that we have another taskforce that is going to be devoted solely to that issue.

From my perspective, I'm comfortable with the changes that have been proposed to keep this within the context of what this report is supposed to be doing.

DR. FERREIRA-GONZALEZ: Now I think we are okay with this, but thinking back to the point that Mara brought up, the timeline, do we want to put a timeline in this?

DR. WILLIAMS: Yes, I would love to. But I have no idea how to set it. I really don't. I understand that these things can go out and they can disappear. We heard talk about the processes of this going around since 1995. But I think that probably, again, I would defer to the Education Taskforce to maybe be a little bit more prescriptive about this because I'm not quite sure I could even begin to get a handle on how you would set up a timeline for this.

DR. FERREIRA-GONZALEZ: It might be that we don't need a timeline for every single recommendation that we have. The other thing we can do is just think about this. Remember we are going to go back through all the recommendations tomorrow. With that in mind as we go through the process, tomorrow we can go back to a specific timeline.

Mara and then Kevin.

MS. ASPINALL: I was going to say exactly that. I would like to suggest that the Committee keep in mind the issue of timelines and then we can come back at the end and we will be, likely, more realistic. It may not be ideal, but I'm going to advocate that we put some parameters around this, and we can do it for the report as a whole, maybe, or major sections as opposed to one by one.

DR. FERREIRA-GONZALEZ: Since you brought it up, we are going to charge you to be looking for that. Kevin.

DR. FITZGERALD: Just a technical question. Perhaps we are going to need different input to figure this out. But, are we talking about payers with an "E" or "payors" with an O?

[Laughter.]

DR. FITZGERALD: We have to be consistent in the report. How are we supposed to refer to this?

DR. FOMOUS: What did you do?

DR. FITZGERALD: Suzanne, where are you? "Payors," right? E? We did E? Okay.

DR. FERREIRA-GONZALEZ: I think we need to be consistent.

DR. FITZGERALD: I just wanted to be consistent.

DR. FERREIRA-GONZALEZ: I'm glad you are here, Kevin, to keep us straight. Are there any changes in B? Sarah is keeping me straight here. Chapter 6, Recommendation 1, Part B. Are there any changes? Gurbaneeet.

DR. RANDHAWA: It is not a change so much in the wording, but I think this recommendation is sort of broad. The issue and the processes that are inherent in creating outcomes in evidence and making guidelines based on that is very different from the issues and processes in terms of implementing those guidelines in practice and changing practice. So my only concern is this is so broad as to be not very informative. Maybe we can split it up into two recommendations, one on making the practice guidelines, how we develop the knowledge on the different domains, and then a separate one on actually the dissemination, implementation, use, and practice.

DR. FERREIRA-GONZALEZ: Marc, do you have any comments to that?

DR. WILLIAMS: Yes. I'm sensitive to those. Obviously, I think our intent here is to try and take advantage of whatever the Secretary can do to set a research agenda around these issues, whether that be through AHRQ or NIH or some other mechanism.

But we couldn't really come to a good decision about how best to specifically articulate where this should go and as a consequence we have left it broad. I would like to be more specific. If you have some specific suggestions about what we might be able to direct the Secretary to do to move this along, that would be most welcome.

DR. FERREIRA-GONZALEZ: Reed, do you have a comment to this?

DR. TUCKSON: Yes. I really appreciate what Marc just said. I think that where the specificity is, and it is embodied in some of our other recommendations, is that the Secretary should ensure that there is adequate research resources available to advance analytical validity, clinical validity, and clinical utility for multiple purposes, including so that it would be included in evidence-based clinical practice guidelines.

Here I think where the danger is, is that there is no such thing as evidence-based clinical practice guidelines without all that other stuff. You don't need to conduct research on how it might be. You need to say "Give us the damn research."

DR. FERREIRA-GONZALEZ: So, are we comfortable? Steve.

DR. TEUTSCH: I think one of the reasons we have wrestled with whether this is Chapter 5 or Chapter 6 is it deals with two sets of issues. One is the clinical utility and guidelines and the other is from the guidelines into practice. We could have separated them out. We decided that probably wasn't very helpful because they are closely linked, and that is why it is sitting here in this chapter.

I think it is what you are getting at, if I hear you right, Gurveet, that there are really two separate components. I guess we could break it at least into sentences here.

DR. FERREIRA-GONZALEZ: With the comments that Reed just made, changes to the language of the recommendation, will that address specifically the issues that Gurveet and we all are bringing up here?

DR. WILLIAMS: I think it makes sense to me because the Secretary obviously can't conduct the research, but I think [he can make] the resources available.

DR. FERREIRA-GONZALEZ: Reed, can you go back and say the language?

DR. TUCKSON: Again, I have to go back and remind myself. We have a bunch of recommendations in our gap analysis. Our gap analysis specifically said "Insufficient resources to establish analytical validity, clinical validity, and clinical utility." That was a gap, so there are reasons why that is important.

What we probably want to do is find the right place to summarize to say that the gap in that results in stifling some extremely important things, one of which -- you will have a list -- is not having evidence-based clinical practice guidelines to inform the translation of this into clinical practice. Therefore, we recommend that there be adequate resources to achieve this purpose. That is what I'm saying.

DR. FERREIRA-GONZALEZ: So the language change would be that "The Secretary provide adequate resources" --

MS. CARR: How about just "sufficient resources are provided to research and surveillance"?

DR. FERREIRA-GONZALEZ: Say that again, Sarah?

MS. CARR: I don't think we have to say "The Secretary." We can just say, at the beginning, "Sufficient resources are provided."

DR. FERREIRA-GONZALEZ: Now, we are going to go back, remember. What I'm hearing here is we also have other recommendations in other chapters. Remember we are going to go back at the end after we have gone through all the different recommendations to make sure we don't have overlap with where these should be broken or where they should be placed.

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DR. TUCKSON: What I hear you saying, Madame Chairperson, is that we will accept for the moment that there will be some duplicative recommendations. We can go back and smooth the stone a little later on.

DR. FERREIRA-GONZALEZ: Remember we will be going over this tomorrow. We are going to go back to all of them.

DR. TUCKSON: We can start catching the redundancies as we go along and then figure out when you might want to smash this together with something earlier and just have a more complete statement. We will worry about those niceties later.

MS. CARR: Is this the extent of the change that needs to be made? There was your point, Reed? Look at the preamble, remember.

DR. TUCKSON: "The Secretary should provide sufficient resources to conduct research."

MS. CARR: "The following strategy" --

DR. TUCKSON: No, the issue is not how the knowledge can inform. You don't need all that stuff. Everybody knows that that is how you do it. You can't do evidence-based clinical practice without it. You are basically saying give us the resources to advance evidence-based clinical practice.

DR. FERREIRA-GONZALEZ: Let's step back for just a second.

DR. TEUTSCH: I was going to speak to that issue.

DR. FERREIRA-GONZALEZ: Go ahead.

DR. TEUTSCH: Because Chapter 5 actually talks about supporting the public-private partnership and getting adequate funding to do the research and surveillance and get all of this evidence right and develop guidelines. That is in Chapter 5. So it may be that we can shorten that first sentence and actually get down to the second part, which is the translational piece, which also needs adequate information and research base.

DR. TUCKSON: Gurveet's agency has like zero dollars. So the thing I don't want to do is ask the Secretary to give his agency a bunch of dollars to tell us how to translate this stuff into evidence-based guidance. They know how to do that. Give them the information.

DR. FERREIRA-GONZALEZ: So the idea is "Sufficient resources should be provided for the development of evidence-based clinical practice guidelines." Is that where we are?

DR. WILLIAMS: No, I think what I'm hearing is there are really two pieces. I think this gets back to dividing it up. Again, as we get to Chapter 5, we may take out that first piece of that and reflect that in Chapter 5.

I think what Reed said is really the critical issue here. AHRQ doesn't have a lot of resources to actually do the translation. What we are really asking for is that they have adequate resources to be able to take the stuff that we recommend in Chapter 5 and create evidence-based guidelines and to study how that should be translated into clinical practice.

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DR. FERREIRA-GONZALEZ: What I'm hearing is that "the conduct of research surveillance and knowledge of analytical validity" is already covered in Chapter 5 recommendations.

DR. WILLIAMS: Right.

DR. FERREIRA-GONZALEZ: If we take that part out, we are dealing with a duplicate of the two recommendations. Only develop these recommendations with that specific issue of funding for AHRQ to develop --

DR. TUCKSON: To do the translation of that into evidence-based practice.

DR. FERREIRA-GONZALEZ: Wait. We need to look at the language that we are going to put here to reflect that. So we have, "Sufficient resources should be provided for the development of evidence-based clinical practice guidelines and how that information can be translated into clear practices that enhance the quality of the care and health outcomes, including dissemination and implementation of recommended genetic tests into clinical and public health practice."

DR. TUCKSON: I would just say take out "how that information can be" and just say "how it can be translated into clinical practice guidelines that enhance the quality of care and health outcomes."

DR. WILLIAMS: You're saying leave that but take everything after that out.

DR. TUCKSON: You don't need "how that information can be." They know how to do it.

DR. FERREIRA-GONZALEZ: Wait. Hold on.

DR. WILLIAMS: Undo what you just did.

DR. FERREIRA-GONZALEZ: Hold on a minute.

DR. TUCKSON: "Sufficient resources should be provided for the" -- by the way, it would be terrific if you could put it in the very beginning. So you would say, "Given that there are resources to enhance the knowledge of our clinical validity, utility," et cetera, then "Sufficient resources should be provided for the translation of that knowledge into evidence-based clinical practice guidelines that enhance the quality of care and health outcomes." Period.

DR. FERREIRA-GONZALEZ: Do we want Reed to work on this one during lunch?

DR. TUCKSON: Then everybody can shoot that down.

DR. FERREIRA-GONZALEZ: You did that to us, so we are going to do it to him before he leaves.

DR. TUCKSON: We got a lot done here before the lunch break.

DR. FERREIRA-GONZALEZ: With these changes and edits that we have done, remember that we are going to see them again tomorrow, are we done with this recommendation?

DR. FOMOUS: Do we want this repeated, "translated into evidence-based clinical practice"?

DR. FERREIRA-GONZALEZ: Reed is going to work with you over the lunch time.

DR. TUCKSON: I will show it to you during the lunch break.

DR. FERREIRA-GONZALEZ: I think we are at a good point for the break.

DR. TUCKSON: Does it have to be 45? So, 30 minutes. Go clog the line. If you see a member with a tag, let them in before the other people from HHS.

[Lunch recess taken at 12:36 p.m.]

DR. TUCKSON: On the board is the new thought. The operative part of the recommendation is the first sentence. "Based upon increased research regarding analytic validity, clinical validity, and clinical utility, sufficient resources should be provided for the translation of this knowledge into evidence-based clinical practice guidelines that enhance the quality of clinical care and public health outcomes."

Now, apparently the Committee's sentiment may have gone beyond that to what is reflected in the second sentence, which I personally believe is not within the domain of this taskforce but in another taskforce somewhere else. But intellectual honesty prevails upon us to put this here for the Committee to tell us no, this is what we darn well meant.

"The Committee recommends the Secretary ensure the availability of information regarding the clinical use of tests to determine the adequacy of information and its translation to ensure that the adequacy of information and its translation meets the needs of improved clinical care and outcomes."

In other words, you are saying you want to monitor how the tests are actually used to be able then to have it as part of the feedback loop for oversight. I believe that you are actually talking here about the regulation of the practice of medicine and not oversight of tests. But there are some who feel that in fact, no, you want this information about how it is actually used and how well are these tests being translated into clinical practice as a part of the oversight mechanism.

So you need to tell us, Committee, if that is what you really meant and you feel strongly about that.

DR. FERREIRA-GONZALEZ: Marc.

DR. WILLIAMS: This came out of the idea that as we discussed testing in the report we talked about testing as a process that doesn't just end with a laboratory test being done but there is communication before the test is done, after the test is done, that there is adequate understanding of how the test information should be used, and that it has an impact in appropriate care. What we were trying to capture here is the idea that we do need to understand this.

It also reflects the sentiment that has come out and will be discussed in previous chapters about the whole idea of post-market gathering of information. Some of this will relate to appropriate use, not just if you use it right does it work.

So we thought it was reasonable to reflect this here. However, on our little break, there is also the possibility that this group will be proceeding with another taskforce that had been put on hold as part of our visioning process where this would, I think, arguably fit much better.

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DR. TUCKSON: With that very cogent analysis, and this is, I think, much ado. I don't feel strongly about falling on the sword about this point. Quickly tell us if you want it in or not. I'm more than fit to keep it in.

DR. FERREIRA-GONZALEZ: If you want it out, raise your hand.

DR. TUCKSON: Move it quick. Which way do you want it? In? So, all the "ins" put your hands up.

[Show of hands.]

DR. FERREIRA-GONZALEZ: No, out.

DR. TUCKSON: Okay. Those are the "ins." Now the "outs."

[Show of hands.]

DR. TUCKSON: So we have two "outs."

DR. EVANS: The reason I think it should be in is simply that it says "The Secretary should ensure the availability of information." That doesn't address practice.

DR. TUCKSON: Paul, you and I are going to be overruled. Andrea doesn't get a vote because she is chair.

[Laughter.]

DR. FERREIRA-GONZALEZ: Since when?

DR. TUCKSON: It is in, and we are moving forward. Next issue.

DR. FERREIRA-GONZALEZ: What have we decided?

DR. TUCKSON: It is in. You won. Go.

DR. FERREIRA-GONZALEZ: Oh, lordy. Lordy, lordy.

[Laughter.]

DR. FERREIRA-GONZALEZ: Recommendation 2. Recommendation 2 calls for FDA to engage relevant federal agencies' advisory committees to the secretary and other stakeholders to gather perspectives on the appropriate regulatory framework for clinical decision support systems. The only change that we made to this recommendation was to add a reference to the Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children as another advisory committee that should be engaged in the discussions of the appropriate framework.

Do you have any questions about this recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Do we have any edits to this recommendation?

[No response.]

DR. TUCKSON: Let's just make sure, folks. Even though we have a lot of FDA-CLIA mish-moshing to do, you are starting with this one because this is off to the side a little bit. You are saying this is not center. You are basically saying the FDA should then prepare guidance articulating the basis of its authority to regulate clinical decision support systems as opposed to actual drugs.

Because the basic assumption in this is the FDA is the key organization here.

DR. FERREIRA-GONZALEZ: They claim to have statutory authority.

DR. WILLIAMS: That was what was brought forward in our discussion. They have in fact exerted statutory authority over this area. We have thought about this probably in the smaller construct of decision support that is associated with interpretation of a test result, so an IVDMA that has an algorithm that runs to be able to interpret the result.

However, there are clinical decision support systems that are running in clinical practice that we also have indications that FDA may or may not choose to exert support over. So this is to reflect the fact that we need clarification of exactly what their intent is.

DR. FERREIRA-GONZALEZ: Steve.

DR. GUTMAN: You need to just tell me a little bit. You can ask, and obviously, as a committee, your request will be respected. But there are two different issues on the table. One is to explain the basis for authority. I think that that strikes us a little bit as anomalous because we have actually been exerting authority for decades, but not impossible. I'm certain someone who has a great legal mind could in a sentence or two explain that it meets the definition of a device. That strikes me as a legal authority. I might even be able to do that, but I'm not a lawyer so I won't.

The second I think is more profound because I think we have a long history of grappling with the thorny issues of software and trying to communicate to stakeholders where they are. There is relatively little interest in writing a sentence saying it is a device. There is great interest in trying to, either as an independent agency or in collaboration with stakeholders, create more clarity in terms of what being a device might mean.

For us, for example, we would characterize laboratory information systems as devices. They have historically been Class 1 exempt. The good news is they don't require any pre-market review by FDA. The bad news is they actually have to work, and if they don't, we will come in and take action.

DR. TUCKSON: We have to move this one fast because we have bigger ones ahead.

DR. GUTMAN: We think this is a pretty big one.

DR. FERREIRA-GONZALEZ: This is really big.

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DR. TUCKSON: The word here is clinical support systems in general or those that are related to drugs and devices? Is that what this means?

DR. GUTMAN: I guess drugs and devices are combination products. So it is both, yes.

DR. WILLIAMS: Actually, it is beyond this. There has been experience within the clinical decision support community of free-standing clinical decision support for clinical practice, specifically in our institution with glucose control in an intensive care unit. We have had FDA basically say cease and desist relating to dissemination of this protocol because this is a device and we are not treating this as an exempt device.

This has been discussed at the AHIC as well. This is a very big concern because we do not understand where FDA is in fact going to choose to exercise control over the range of --

DR. GUTMAN: But what I'm trying to say is I think it is different. I don't know that that is easy, but I think that is something that we do owe our stakeholders.

DR. TUCKSON: So we do need to clarify it. I wish you hadn't chosen an example of glucose but had chosen an example of how a patient or a doctor works through the decision tree on treating diabetes.

DR. WILLIAMS: That is where the discussion line goes. If a physician can reasonably do this on their own, then that is considered to be low risk. But, where do you define that.

DR. TUCKSON: The only question is the word "then." Does it have to be sequential or can it be simultaneous?

DR. WILLIAMS: I would think it would be simultaneous.

DR. TUCKSON: The word "then" makes it do all this other collaboration and then FDA is going to do something. It sort of falls off the edge of the earth. Why can't that be part of it.

DR. FERREIRA-GONZALEZ: Where is the "then"?

DR. WILLIAMS: It is in the second sentence.

DR. TUCKSON: "FDA should then prepare a guidance." As part of this collaborative process they should prepare the document.

DR. WILLIAMS: Yes.

DR. TUCKSON: So just lose the "then" and we are all right. Go ahead.

MS. ASPINALL: Two comments. I don't think it is a big deal either way, but I thought the "then" was after engaging all of the others, then they should do it. So they should make comments before they engage.

DR. FERREIRA-GONZALEZ: That is part of the process FDA is developing.

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DR. TUCKSON: So you have a lot of people talking but you don't know what the FDA authority is. You need the FDA authority to follow the conversation and everybody is working together. Otherwise, you have to reconvene everybody else again.

MS. ASPINALL: I have another point. I'm not sure if this is the right time, but it is sort of a broad point around this to maybe inform this process. The assumption in the report, and I think industry-wide, has been that any regulatory authority in any way comes under device regulation and that the assumptions all over the map are all about within device and which part are device and which part aren't.

I'm going to suggest something, and maybe it is bigger than we can handle in the report given the historical nature of it. But I have to say I wonder, when device regulations came about they weren't an asterisk under drug regulations because drug regulations were first and device regulations came thereafter. We are now talking about regulation in an area, whether you believe there should be more or less, but an area that in my mind is a separate, independent industry.

While we have become accustomed to many definitions that these are truly in some way devices or there are some parts of tests that are devices, I think the average person would have said no, a device is something much different from a test.

Maybe we can come back to this at the end, but just given Steve's comment I wanted to mention it as really thought-provoking. But whether, in the midst of this, some of the challenge we have is that there should be regulation that is truly specific to diagnostics and that it is not an asterisk in some way under a different industry but something that is distinct and representative of the strong, independent industry. When I say "industry," I don't mean commercial, profit, not-for-profit, research, academia, universities.

It really is a separate area and classifying it as devices, I have to tell you, I believe will never going to work. It is going to be piecemeal from what is there.

DR. FERREIRA-GONZALEZ: Marc.

DR. WILLIAMS: I think just the pragmatic response to that is while I don't disagree, the reality is that as we raise these issues this is how it is currently working. The interpretation of the statute I believe dates back to 1976, which of course means we are interpolating an awful lot about what was really intended given that decision support for the most part and genetic testing for the most part really wasn't around. That is what we are working from.

So we wanted to try and start from where we are, but I don't disagree that maybe, as we look at a bigger picture and a bigger version, that maybe we need to go there.

MS. ASPINALL: I appreciate the practical nature of it, but in this moment of time when we have the opportunity to think about that, I don't want to completely lose it before we finish the report.

DR. FERREIRA-GONZALEZ: Do you have a specific response to that?

DR. GUTMAN: It is directly related to that. When you parse out "diagnostic," you have to realize that it is not just in vitro diagnostics. It is radiologic, it is echocardiographs, it is, frankly, demographic information. It is much broader than just the lab. It is not your father's Oldsmobile.

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MS. ASPINALL: No, I think that that is fair. In the broadest definition, and it is broad, I would still say it is different from devices. But there are some that include it and many that do not.

DR. FERREIRA-GONZALEZ: I think it is something that we can keep in the back of our mind as we go through the recommendations. I think it has a lot of value what you are bringing up, Mara. Thank you.

MS. ASPINALL: Remember it.

DR. FOMOUS: Did we decide to lose the "then"?

DR. FERREIRA-GONZALEZ: That is the question. Any more edits? Are we okay with this?

DR. WILLIAMS: A clarification. Before the word where you have your cursor, where "FDA" is, just before that, I would just say "As part of this process." I think that gets at Reed's comment that it is not sequential but it also doesn't put the second sentence just kind of hanging out there, which is it is not related to that process. I think it is important to link them but not necessarily sequentially.

DR. FERREIRA-GONZALEZ: We are ready to move to the next recommendation?  
Recommendation 4.

DR. TUCKSON: Three.

DR. FERREIRA-GONZALEZ: I really want to finish. Recommendation 3 recognizes the need for genetic expertise to support the best genetic testing practices and requests that HHS act on recommendations in the 2006 SACGHS Coverage and Reimbursement of Genetic Tests and Services Report. We did not make any changes to this recommendation.

So, we do have any questions about this recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Any edits?

[No response.]

DR. FERREIRA-GONZALEZ: Can we move to Recommendation 4 now?

[Laughter.]

DR. FERREIRA-GONZALEZ: Recommendation 4 requests that HHS allocate resources to AHRQ, CDC, HRSA, and NIH for research and development of clinical decision support tools and resources. We have made no change to the wording from the draft report here.

Then we revised this recommendation to include engaging providers and payers in education efforts and to provide incentives on protections in order to ensure participation in the design, dissemination, and implementation of clinical decision support.

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DR. WILLIAMS: Andrea, just a comment. That paragraph was added in response to a number of public comments that expressed concern about these issues. So this was in response to those comments.

DR. FERREIRA-GONZALEZ: Do we have questions about the recommendation? Gurbanet.

DR. RANDHAWA: Just a clarification here. In this recommendation, is there a specific sense to tie in the clinical decision support to clinical guidelines? If so, is it the sense of the Committee that the clinical guidelines as they are being developed or formulated currently need to be cognizant of how clinical decision support tools are developed and so have a better linkage with that?

DR. FERREIRA-GONZALEZ: I think AHIC is actually specifically working on those.

DR. WILLIAMS: Yes, I think that is a really important point. The clinical decision support proto-recommendations overarching the entire AHIC are specifically looking at developing ways that guidelines can be constructed so that they are much more easily computable.

I don't know that we need to add that level of detail here, unless you really feel strongly that we should.

DR. RANDHAWA: I think I'm coming more from the perspective of having worked with some of the guideline developers. I know there is a great deal of interest in the informatics community. I'm not sure it has percolated up to the guideline developing community in that how they formulate the guidelines they need to be cognizant of how they are being used downstream.

DR. WILLIAMS: That is true. We are trying to begin to develop that engagement.

DR. FERREIRA-GONZALEZ: Remember that in the report we are saying that these should be looked into in other activities that the Secretary is using through the Personalized Healthcare Initiative.

Do we have any more edits to this?

[No response.]

DR. FERREIRA-GONZALEZ: Can we move to the next recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Recommendation 5 requests that HHS set up efforts to assess implications of direct-to-consumer advertising and testing and implementation of strategies to protect consumers. We revised these recommendations to include social stigmatization and privacy concerns to potential negative impact of direct-to-consumer testing.

We also added HRSA to the list of the relevant federal agencies that should be involved in issues related to direct-to-consumer advertising and testing.

Do you have any questions about this recommendation?

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DR. WILLIAMS: Again, just to emphasize that these were added specifically related to public comments. There was actually some data which will be added into the report indicating some concerns about how the information was being collected from people and that either DNA information or information relating to the types of tests that were being ordered might be available to people that purchase lists for contact and those sorts of things. That was really compelling and, to a large degree, disturbing, and that I was not aware of.

DR. TUCKSON: Again, I'm trying to remember going back to the earlier recommendations, so you will have to let me know whether there are going to be some that will get more specific.

This just sounds very weak to me. At the end of the day, I thought we are supposed to say stop screwing with people. This is saying he should step up his efforts. We are not telling him how. Don't we need to be more specific?

I don't know [about] you all, but the stuff that I heard today on the phone worried me, by the way.

DR. WILLIAMS: I will take a shot at that. I think you are right. The challenge that we have had, and this is reflected in the gap analysis, is that it is not absolutely clear of that alphabetic list of agencies there who really should take ownership of this.

I think that you are absolutely right. What we could probably do is to add language to indicate that this is something that really needs to have specific oversight but that the Secretary has to decide which of the agencies under his or her purview is going to have the primary responsibility for this.

DR. FERREIRA-GONZALEZ: Reed, there are differences in direct-to-consumer advertising and direct-to-consumer testing. Here is geared to direct-to-consumer advertising.

DR. TUCKSON: Right.

MS. ASPINALL: And consumer-initiated genetic testing.

DR. FERREIRA-GONZALEZ: And consumer-initiated genetic testing. But we have other recommendations that say some of these consumer-initiated are not currently under CLIA [and] CLIA needs to be, maybe, revised to see if those will be under the CLIA regulation. So we have in Chapter 4 other recommendations specific to this. Will that actually respond to some of the concerns that you have?

DR. TUCKSON: Go back and put this in context with the stuff that we continue to applaud, the collaboration between FTC and FDA. Is that sufficient here? We don't reference that, by the way, here.

We have been praising that collaborative as being something that deals with this problem. I think we should reference that somewhere, that we recognize this is going on. Then, I guess, by de facto, are we saying that that combined effort is okay and that we don't need to codify that anymore?

DR. WILLIAMS: I think the point that you made we should definitely include in the report in terms of the collaboration there. Maybe, as I look at this, what we should do is to say something more to the effect of HHS should convene relevant federal agencies, e.g., a parenthetical

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statement, states and consumer groups to assess the implications and decide who has oversight authority.

That is a little bit more directive than just saying "and if necessary." I don't know if that is getting at your [point.]

DR. FERREIRA-GONZALEZ: Let's go to Mara and then Paul.

MS. ASPINALL: I like the way Marc is going, but I would agree with Reed. I know it comes up later, so it may be that at the end we need to harmonize them. But I wonder if we need to be more specific and say at a minimum "to ensure that these tests are covered by CLIA and/or any future regulatory system."

DR. FERREIRA-GONZALEZ: Yes, that is a separate recommendation.

MS. ASPINALL: I know, but I guess --

DR. FERREIRA-GONZALEZ: Remember that recommendation is going to be before this one. It is Chapter 4, that recommendation.

MS. ASPINALL: Right, and we are doing it backwards.

DR. FERREIRA-GONZALEZ: Remember that.

MS. ASPINALL: I understand that it is there. I just wonder whether we need both. I don't know. I can't quite harmonize them now as we are doing it this way, but I think that if that is the case, does this really say anything that is very significant that it wouldn't just say harmonize under the one under No. 4. I'm not sure we need both from my reading to date.

DR. FERREIRA-GONZALEZ: Paul.

DR. BILLINGS: My English isn't always that good, but does direct-to-consumer advertising of genetic testing and consumer genetic testing "has" the potential or "have" the potential? That is one question I had. I'm not sure what the proper English is.

DR. TUCKSON: Anybody with a bow tie should know that kind of stuff.

MS. ASPINALL: Can I ask the fundamental question? Do we need this recommendation?

DR. FERREIRA-GONZALEZ: Let Paul finish.

DR. BILLINGS: That was my trivial point. What I don't understand about this is, this is in a study of oversight of genetic testing and this is about direct-to-consumer advertising as it relates to genetic testing. So, one, is this genetic exceptionalism? Are we really objecting to direct-to-consumer advertising of anything to do with testing or maybe direct-to-consumer advertising in health care, potentially? What really are we trying to get at here?

DR. FERREIRA-GONZALEZ: Some of the issues that the Committee discussed are not just the direct-to-consumer advertising but it is the truth of the advertising that you do. If you are going to do advertising for a specific test and you make claims that a test is meant to [do something], then it is under the review of the FTC.

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DR. BILLINGS: Does the advertising cause social stigmatization and privacy concerns? Are we saying that that is a necessary and proven result of direct-to-consumer advertising? I wonder about this.

DR. TUCKSON: One of the reasons we got to this was Francis Collins brought in this Nutraceuticals for the Millennium. Remember that one? It was this really odd, off-the-wall thing.

Now, Steve, I don't know. In the collaboration between FDA and FTC, do we now know based on all this kumbayah that we have been describing earlier for the last two meetings about what is going on between FTC and FDA -- so you have the answer.

MS. CARR: I just wanted to point out that the Office of the Secretary is actually getting the agencies together to do more collaboration. They are having another meeting in a couple weeks. I think FTC's Matt Daynard is going to be participating in that meeting. CDC. NIH is involved.

DR. TUCKSON: That is helpful. Let me just ask you real quickly. Because we have given you all this praise about you all coming together and doing things together, is the problem solved or is there something else that needs to get done?

MR. DAYNARD: Addressing the problem is just beginning, of course. But I think it is important to note in the recommendations that the collaboration is working and HHS needs to ensure that it continues to work.

As far as it goes, the advertising issue is going to be additionally addressed not only by the FTC, and I will let Steve respond to this also, but [by the FDA.] If the FDA decides that it has jurisdiction and in its discretion will pursue, for example, that some proprietary software is a medical device, it therefore will have jurisdiction over advertising as well, and it will make the collaboration even more important.

So I do think it is important to have something like this definitely in the report, but HHS should do what it is doing.

DR. TUCKSON: I hear uncertainty about whether or not they have oversight or not.

MR. DAYNARD: I can't speak for the FDA.

DR. FERREIRA-GONZALEZ: Steve and then Paul.

DR. TEUTSCH: I think one of the concerns is how strictly should this be regulated. I think part of the concern is, and we have talked about it with FDA, if they are health-related there is a higher bar than normal for most types of advertising. But like what we have heard earlier from 23 and Me, if they don't even consider this health-related, then why would FDA regulate it?

We recognize that all of this has potentially substantial risks and there needs to be oversight of the advertising at a higher level than you might otherwise for routine consumer products.

DR. FERREIRA-GONZALEZ: If this health-related testing comes under CLIA or the FDA, some of this advertising will be dealt with through that realm.

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DR. TUCKSON: But if the manufacturer can self-declare. If I decide, hey, you know what, I'm just having a good time. This ain't really about health. Then you can't regulate me. I have decided to take myself voluntarily out of it, but I didn't take myself voluntarily out of selling this thing to people.

DR. FERREIRA-GONZALEZ: We need to start coming back. Mara and then Marc.

MS. ASPINALL: My point is simply just what Reed said: to make sure that everywhere we do this, and again I'm not convinced we need two separate recommendations, that we make it clear that both the advertising and, more importantly, the testing itself needs to fall underneath some regulatory umbrella.

DR. FERREIRA-GONZALEZ: Marc.

DR. WILLIAMS: The language that I would propose, given what I'm hearing, is that we could say that "The Committee recognizes the ongoing efforts of collaboration to address these issues. We ask the Secretary to explicitly add direct-to-consumer advertising for genetic tests and consumer-initiated genetic testing as issues for consideration by this collaborative and would request an update about the issues for further deliberation," or something to that effect.

DR. TUCKSON: Let me give you a counter one, just to play devil's advocate and try to find some way to polarize you so you make a decision.

"The Committee is concerned at the public being preyed upon by unscrupulous people who will market their products to an unsuspecting public that is ill prepared to understand some of the complexities of these things and who can be harmed as a result. Therefore, we recommend to the Secretary immediately conclude the effort that we understand is underway to determine jurisdiction between the FTC and the FDA," and anybody else that has to be done, "and that you report back to this Advisory Committee within six months as to the answer so that the fundamental purpose by which we were convened is dealt with." Thank you. No fooling around.

DR. FERREIRA-GONZALEZ: Paul.

MR. MILLER: I think this is a really important conversation. The only thing that I would add is that I think it is really important, given the intensity of the feelings around this table about this issue, that we come up with something that is concrete, directed, and an action item to recommend.

Anybody who has been around the block in Washington knows any recommendation that basically says you should convene a group and talk about it some more isn't really a recommendation. To the extent that we actually can come up with something concrete to say to move the Secretary or move the process along that is a deliverable, I think that it is time well spent to come up with drafting one such deliverable.

Reed, you came up with an idea, a soft idea, but maybe we can make it a little harder.

MR. DAYNARD: I just had a suggestion that if you do keep this recommendation you change the word "advertising" to "marketing" because the FTC's hook is advertising and only advertising. Our charge is not the safety of the American public as it would be the FDA. You are talking about broader than just advertising. You are talking about bringing this test to market, which involves the FDA and CMS, et cetera.

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DR. FERREIRA-GONZALEZ: Do we want to work a little bit offline on recommendation language for this? Mike.

DR. AMOS: I just had one comment on Reed's strawman recommendation where you said "and do harm." We have to have data to back that up.

DR. TUCKSON: Potential.

DR. AMOS: Because I don't see where the information that comes from this type of thing would potentially be any more harmful than somebody making a health decision based on some Nutraceutical advertisement. You have to differentiate. You have to really clearly support that with data if you are going to say we are thinking it is doing harm.

DR. TUCKSON: Or the potential thereof.

DR. AMOS: It has to be stronger than that. If you are going to make a recommendation this strongly, then you really have to have something to back you up that says there is really harm being done.

DR. FERREIRA-GONZALEZ: Marc.

DR. WILLIAMS: Well, the specific issue that came up that really crystallized this for me was this. If somebody sends in a cheek swab because they want to look at diabetes susceptibility testing or something of that nature, there is evidence that those [lists of those] individuals that are tested for potential diabetes susceptibility are being sold to people that are marketing diabetic devices and other things.

Now, they would characterize that as providing information to consumers who really espouse a need for it, but I'm not sure that on the front end when the person is sending in that cheek swab that they have been adequately informed that this information is going to be used to basically target them.

Again, you can define that as harm or not, but I think there is some evidence that that does in fact happen.

MR. DAYNARD: If you have such information, Marc, I would certainly like to know about it.

DR. WILLIAMS: I will see if I can pull it together.

DR. FERREIRA-GONZALEZ: Focus on what we need to actually make recommendations. What are we going to do with this recommendation.

MS. ASPINALL: I guess I wanted to get to Marc's example because I think the bigger harm comes from the test is wrong and somebody says they don't have diabetes susceptibility and therefore they go about doing higher risk behavior rather than selling the advertising piece, which I understand is harm. But from the health perspective, I think it is focused on that piece.

So I come back to what Reed put together to take a stronger stance on saying, one, that HHS needs to take some action; two, that all tests that are direct to-consumer must be covered by the current regulatory environment. We may not want to deal with that here, whether it is CMS or FDA or otherwise, but I think that we need to take that stance.

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If you look at some of the public comments, I think there were at least six of them, in my quick tallying, that also said exactly that, that we need to have stricter regulation around direct-to-consumer testing.

So I'm not quite with the wording Reed had, and maybe we can take that offline, but I'm pretty close.

DR. FERREIRA-GONZALEZ: Cathy.

DR. FOMOUS: I think a lot of the suggestions that I have heard are really terrific, but in my mind, they seem to apply more to our recommendation in Chapter 4. So I'm thinking maybe we can think about that wording and apply it to the recommendation in Chapter 4.

I actually have a question for Marc for this recommendation. When I read it, my impression is that you are saying there is a gap in what we know about the impact of all of this. We are making some assumptions here and we don't have the knowledge to really know what kind of impact direct-to-consumer marketing and testing has on consumers.

In my mind, that is what this recommendation is trying to get at. Are there harms being done. That will guide us going forward. What are the positive aspects of this type of testing and what are the negatives.

So to me, the recommendations were very different, and a lot of what I have heard really applies to what we have in Chapter 4.

DR. FERREIRA-GONZALEZ: Sarah.

MS. CARR: I just want to add to that that this recommendation in the way Cathy just expressed it, if that is the intent, has been the Committee's position for several years. In an earlier letter we called for more data on the public health impact. CDC has been working on that. We heard last July or November an update from CDC on its work. So that does seem to be what we are after here.

There is also a role for the states -- Judy Yost can speak to this better than I -- in terms of who can order and who can receive test results. I don't think it is solely a federal matter as to what the regulatory scheme would be in this area.

Then I also think we have, from a regulatory standpoint, addressed it more in Chapter 4.

DR. FERREIRA-GONZALEZ: We have Paul, Gurvaneet, and then Reed.

MR. MILLER: To the extent that we have gone around and around, I think the issue is on the table. I think that where we are is to basically have an offline conversation to look at Recommendation 4 vis-a-vis this, see if it can be collapsed together, and then maybe come back tomorrow.

DR. FERREIRA-GONZALEZ: It is going to be covered in No. 4.

MR. MILLER: Yes, exactly.

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DR. FERREIRA-GONZALEZ: Maybe we need to tweak No. 4 a little bit. I think we need to keep in mind some of the issues you are bringing up.

DR. TUCKSON: If I can just add one thing, if we are going to do that. I think that is rational. Could I just get two seconds of a summary of the collaboration between FTC and FDA that we have been talking about so far? Just tell me what is it that you all are doing. What area are you working on?

DR. GUTMAN: Aside from the public advisory that we put forth, actually I can't comment on anything else that we might be doing.

DR. TUCKSON: Can you remind us of what the advisory said?

DR. GUTMAN: It said that these are unsubstantiated tests and you should beware. It was made as public as we possibly could.

DR. TUCKSON: Matt.

MR. DAYNARD: That is accurate. I think we can say that the FTC is looking at the area specifically to see whether there are representations being made about genetic test services that warrant pursuit in investigations.

MS. CARR: And you are relying in FDA.

MR. DAYNARD: In part, yes.

MS. CARR: In part. There has been that exchange, maybe not recently, but where you were providing --

DR. GUTMAN: No, it is ongoing. You would be surprised at how clever the feds are at communicating with each other.

DR. TUCKSON: When we get to Section 4 we will revisit it, as Paul said.

DR. FERREIRA-GONZALEZ: We can look at Recommendation 4 in the next piece and have it right on the side.

DR. TUCKSON: Yes, we can do that. I just want to make sure I'm summarizing what I'm hearing for when we get there, and then we can get off this.

DR. GUTMAN: Not that we have even been specifically named. I know how horrifying it is, the thought that we might actually regulate. But this is, from FDA's perspective, very nuanced. I think there are legitimate things here which are medical devices and which have implicit enough or explicit enough claims that drive you to think they are medical devices.

I think in this universe there is stuff that we wouldn't, under our current statutory definition, call medical devices. I don't know that Judy's group would call everything. I won't mention any, but gender identification tests are not, from either CMS or FDA's perspective, currently medical devices.

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DR. TUCKSON: So we have a big gap in understanding. Then the FTC point of view, Matt, you just made. You made an explicit point earlier. Define the limits of your purview?

MR. DAYNARD: With genetic testing, as with any product out there, health care-related or not, it is what the advertising claims and whether they have competent and reliable scientific evidence in relation to health care advertising to support what the claim is. It doesn't matter what the device is, what the product is, what the service is. It is all the same.

DR. TUCKSON: When you go after them, or when you investigate because you are concerned about the scientific validity of their statements, where do you go to get that answer of the science?

MR. DAYNARD: I'm a lawyer. I make it up.

[Laughter.]

MR. DAYNARD: Just kidding, just kidding. I go to Steve Gutman and his staff and I go to private experts and I go to NHGRI.

DR. TUCKSON: I want to be disciplined and nail it. At the end of the day, it doesn't matter whether or not FDA has oversight over it. You can go to them and say "I want to understand the science of it." Then they say, "I will tell you what we understand about the science," whether or not it is in your regulatory purview or not. You are providing a consultative science opinion to the FTC. So you are good as long as it is about advertising.

MR. DAYNARD: Absolutely. We do coordinate.

DR. TUCKSON: You are not good on, you said, marketing.

MR. DAYNARD: To the extent that it is something other than advertising, that is correct.

DR. TUCKSON: Thank you. Did everybody sort of begin to understand something about the fact base?

DR. BILLINGS: Can I ask one other question about the fact base? So, aside from the advisory which has been referred to, have there been specific actions against companies in this area?

MR. DAYNARD: Nothing public. All investigations that we might have are non-public. So unless my next phone call will be from a jail cell, I have to tell you that.

DR. FERREIRA-GONZALEZ: We need to start wrapping up this and move forward. Mara, you have a comment. Then Gurvaneet.

MS. ASPINALL: I guess it is a placeholder to come back to Steve's comment about the current regulations of CLIA around health-related testing because the gender issue is a very interesting one, as I understand, not regulated as health. But we know families are using that to look for X-linked diseases. So while gender in and of itself may not be health, it is being used very much in a health-related way to make determinations around a pregnancy. So I think we need to reevaluate that.

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DR. FERREIRA-GONZALEZ: That issue is in Chapter 4. Gurvaneet, and then we are going to move forward. We are going to leave the way we are currently the recommendation. After we review the recommendation in Chapter 4, we will look at this right there.

DR. RANDHAWA: Thanks. This is sort of responding to Reed's albeit provocative contrarian here. I'm not a constitutional scholar or legal scholar by any means, but the concerns that I heard here were more public health, health outcomes, whereas I don't see any mention of health or public health in that paragraph at all.

So whether it is gender testing, whether I came from India or if I have genes from Africa, paternity testing, nothing is there to help per se. I don't know to what extent this Committee or HHS will be regulating that.

To some extent, I think that is part of the constitutional right, is for a person to make their own determination of what is harmful and what is not. So I think we should be careful how we frame this and not be overstepping and thinking of a very broad definition here.

DR. FERREIRA-GONZALEZ: That is a very good point.

DR. TUCKSON: We will need to be very attentive again on one of the criticisms that we had of the first draft, how we define the word "genetic testing" as it relates to this function, and what is in and what is out.

MS. ASPINALL: And health-related testing. We may want to suggest a new definition.

DR. HANS: We said earlier we would take a look at this map when we are doing this. I would just say, if we are going to be redrafting, look at the map and which knowledge gap this is supposed to be attached to. We seem to have drifted.

DR. FERREIRA-GONZALEZ: We are moving to Chapter 5, Recommendation 1. It calls for HHS to create and fund a public-private entity to assess the clinical utility of genetic tests. We revised this recommendation to include examples of evidentiary standards and levels of certainty for different situations, and we also added data from electronic medical records as a source of data for research.

Part B of the recommendation calls for the development and funding of a research agenda that will address gaps in knowledge of analytical validity, clinical validity, and clinical utility on population health impact of genetic tests. The only revision in Part B involved movement of a section to Recommendation 1 in Chapter 6.

Do we have any questions about this recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Any edits?

[No response.]

DR. FERREIRA-GONZALEZ: Can we move on to the next recommendation?

[No response.]

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DR. FERREIRA-GONZALEZ: Recommendation 2 for Chapter 2 requests HHS to act on recommendations in the 2006 Coverage and Reimbursement of Genetic Tests and Services and asks public and private healthcare payers to develop mechanisms, such as coverage with evidence development or phased reimbursement, to facilitate the collection of clinical utility evidence for high priority tests and applications.

We revised this recommendation to include determining whether mechanisms to collect clinical utility evidence enhance or hinder innovation, understanding of effectiveness, and proper utilization.

Do we have any questions for this recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Do we have any edits?

DR. TUCKSON: I'm just trying to understand, re-reading it again cold now, the recommendation to continue." Public and private healthcare payers should develop mechanisms, such as coverage with evidence development or phased reimbursement, to facilitate the collection of clinical utility evidence.

I'm not following the trail here. We are saying we want to collect information of clinical utility evidence through reimbursement.

DR. FERREIRA-GONZALEZ: Steve.

DR. TEUTSCH: This is really an extension of what CMS has proposed to allow innovative products to get on the market and that there be a process that, if they agreed to get paid for it, that there will be evidence collected along the way so that we will know about the clinical utility and a subsequent final decision can be made. It is a way to try and get the evidence generation underway for some of these technologies. It is just a mechanism.

DR. FERREIRA-GONZALEZ: James first, and then Muin.

DR. EVANS: This is also known as conditional coverage, right? It is a potentially important mechanism to try to prevent the bar being so high in terms of clinical utility -- which we don't have for 90 percent of what we do in medicine anyway, right? -- before things get covered. It is a chicken and egg issue.

DR. TUCKSON: It is basically saying we are encouraging coverage even when the evidence is not there. By the way, once you cover it, we can then have a larger base of evidence upon which to make further decisions. It looked like it was saying we were going to solve the evidence problem by covering.

DR. FERREIRA-GONZALEZ: If you don't actually cover, the tests will not be offered and we can never get to the point.

DR. TUCKSON: With a little language tweak we will be okay.

DR. FERREIRA-GONZALEZ: So I have Paul.

DR. BILLINGS: Was this meant to be only for high priority tests and applications, or is this a general recommendation?

DR. FERREIRA-GONZALEZ: I think it is a general recommendation but we thought that maybe starting with the high priority first.

DR. BILLINGS: And then, does the last sentence again add more barrier, essentially? You are saying that they ought to look at effectiveness and utilization and the hindrance or fostering of innovation. Does that sort of muddy the water, essentially?

DR. TUCKSON: What it definitely leaves unsaid in this recommendation is any mechanism of who pays for the collection, where does it sit, who houses it, how do you do it. It is a muddy issue, and I think it is something we have to attend to here.

Muin used to argue a lot, I think, for CDC being the place where you put the money for post-market surveillance. This is the same sort of deal here. It is sort of hanging out there.

DR. FERREIRA-GONZALEZ: Marc.

DR. WILLIAMS: As we discuss this in the report, there are some examples. Again, I think that if you get to Paul's point, there are different levels. For the ultra-rare tests, a program like the SET program has been brought forward through the CDC. The intent there is that we may never get the amount of evidence that we would like to have to meet a bar, so this is a process by which we are going to actually encourage these tests coming to market with the express intent and funding for collection of that evidence.

I think on the other end of the spectrum you have something like, let's say, a pharmacogenomic profile for Warfarin where the impact on that is potentially for hundreds of thousands of people, where I think you could reasonably expect utility studies to be done before that test is introduced into the marketplace.

Then, in the middle ground might be something like has been done with the Children's Oncology Group where you are dealing with a collection of things that are somewhat rare and the only way to collect sufficient data -- and in the genetic realm probably newborn screening is a good example of this -- is to collect it under sort of a consortium arrangement. But all payers are covering for children's oncology knowing that that data is being collected and we are learning new things from it.

So I think that this shouldn't be looked upon as a "one size fits all" and maybe we need to tweak it to reflect the fact that different models may be appropriate but that the intent is that we don't want to just set a high bar so that most things don't come to market or a low bar so that everything comes to market and we don't learn anything.

DR. TUCKSON: But at the end of the day, what this recommendation basically winds up is putting the onus on public and private payers to develop the mechanism for creating the information, organizing it, and doing something with it. I just don't see how that is going to happen.

DR. FERREIRA-GONZALEZ: Steve.

DR. TEUTSCH: I don't know that they actually have to do the evaluation. For instance, one of the examples that CMS had was for lung volume reduction surgery for emphysema. They agreed to pay for the procedures as long as it was part of a clinical trial so that at the end of the trial we would know whether that was an effective procedure and there was something learned about exactly who benefitted and who didn't.

In fact, in that case it was a fairly limited amount of benefit for a very selected group. They continued to pay for that group, but essentially nobody availed themselves of that service.

But it is for a high priority. You can't do this for very many things. So it is for a fairly selected number that you would think are likely to be of important public health or economic impact.

DR. FERREIRA-GONZALEZ: Mara and then Muin.

MS. ASPINALL: I agree with what Steve said in terms of looking at it, but I think, as Reed said, there is no mechanism to do it now. I think the challenge is laboratories themselves can't do it because the fundamental piece of this is looking at outcome data and laboratories don't have access to outcome data.

In the report itself, that is implied in the fuller piece of the text. Maybe we can bring that out in the recommendation. I haven't formed the words. But I think it is important to acknowledge this is not just shifting the burden but there has been discussion about laboratories doing this sort of evidence under HIPAA regulations and which otherwise laboratories cannot do.

So I think there is a reality here that needs to be at least acknowledged that this is not an optional thing. If we want to get this data, payers have to be part of the system. If you believe one of the things we have talked about in the pharmacogenomics report, this is not just for academic purpose. These tests will actually reduce inappropriate care and reduce cost for the system. So there should be enough incentives for payers to want to do this.

DR. FERREIRA-GONZALEZ: Muin.

DR. KHOURY: I think this is a complicated issue. Maybe we should put Recommendation 1 and Recommendation 2 together.

DR. FERREIRA-GONZALEZ: I was going back to that.

DR. KHOURY: Part of the current dilemma, which I call the evidence dilemma in genomics, is that clinical utility is the last information that is to be collected. Many payers won't pay until you have clinical utility. If you don't pay, you don't get tested. So it increases disparity and discourages development of new applications.

So if there is a public-private stakeholder group that would come together and oversee these discussions, so to speak, and then set the parameters for what is enough to meet a certain threshold beyond which you move a certain application from being research to being conditionally covered under a controlled research and practice environment in which you do those clinical trials.

Obviously you can't do it for everything, and the payers shouldn't pay for everything. It has to be a shared burden between the public and the private sector.

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That is part of our dilemma right now. The clinical utility piece is missing for most genomic applications in practice, but you need at least a good analytic framework, good clinical validity, and proficiency testing. Then if there is enough biologic plausibility, perhaps a few applications can move. Certainly for rare diseases, if you don't do that, the rare disease environment is not going to be implemented.

So at least there is a process for the rare disease environment to be done, but for the common genomic applications, we are still struggling with where to draw the bar. Where do you put the threshold. I think, putting it with Recommendation 1 to work together with Recommendation 2, we can make more progress.

DR. FERREIRA-GONZALEZ: I think in Recommendation 1 we already recommended a sustainable public and private entity of stakeholders to assess the clinical utility. So this will fall within the clinical utility of the test where you add these other things of evaluation of the clinical utility by providing additional issues of payment with condition of payment and so forth.

DR. TUCKSON: I think that would be good. If we can roll this in with No. 1, that is good. I will tell you, I have sat on too many IOM groups and every kind of group you can think of where all the health plans and CMS are sitting around trying to figure out who is going to pay for these kinds of essentially health service research types of initiatives.

We finally, after a lot of effort, just got this Center for Comparative Effectiveness funded, which was an enormous effort. It is funded. It is funded at like a toe in the water level, but they didn't get where they need to go.

So my point only is that we have been through this a bunch of times. This is that again. If we don't say that CDC or AHRQ is going to step up and be the agency to pull this doggone stuff together, then you are not going to get it. Maybe you can roll it into the first one where we say there needs to be this whole group that actually gets funded to do several specific things, one of which is this.

DR. FERREIRA-GONZALEZ: Steve, do you have any comment on that?

DR. TEUTSCH: In my own mind, these are quite separate things. The first one creates the public-private group that is actually going to develop a lot of the information. This one actually harkens back to the reimbursement issues and the need for evidence on utility by payers. Then the question is, what do they do, and how do we begin to make those things work.

That seems to me a little bit different. I don't know that we would include this reimbursement stuff in the first part of this recommendation.

DR. FERREIRA-GONZALEZ: The reimbursement fits from the data that will be generated from this public-private partnership in developing the infrastructure to evaluate how you determine the clinical utility. So this will be, maybe, another component of that group, kind of the back end.

DR. TUCKSON: So we are going to pick a couple quick ones. Again, it is a little dangerous to keep postponing things, but I think we are talking about trying to see if we can, with an appropriate bridge ala Steve's comment, lump this into No. 1.

The one thing you have to be doggone sure is you can't call for too many separate funding things in this report given that the government ain't got diddly-squat in terms of money left.

DR. FERREIRA-GONZALEZ: I think we have Mara and Gurveet.

MS. ASPINALL: I agree with Reed. We can't ask for too many, although I see it Steve's way. I think it should be kept separate because it is specific to the reimbursement area. I don't think we lose anything to have it separate. We are not asking for any more. Recommendation No. 1 is a particularly lengthy one. So I think it gets lost in the midst of No. 1. Leave it as a separate one.

DR. FERREIRA-GONZALEZ: Then, would you want to recommend the creation of a stakeholders group for this?

DR. TEUTSCH: This is just talking about mechanisms. It could vary by payer. It doesn't need a stakeholder group.

MS. ASPINALL: I don't think so. To me, it stands on its own. It is all part of No. 5, and it is highlighted separately and will get more focus this way. We are not asking for any more or less money by combining it. So I would leave it.

DR. FERREIRA-GONZALEZ: Gurveet.

DR. RANDHAWA: I think it is useful to combine the comments that have been made before for the purpose of the public-private entity that establishes an infrastructure. That is certainly one recommendation, and this is a different recommendation which focuses on the actual implementation of research for different tests that we are thinking about. The question then becomes who exactly is going to be paying for it.

Reed's observation did resonate with me that there is no need just for the payers alone to have the burden of being singled out here because what we have been discussing so far is where we stand right now in our infrastructure. The clinical labs don't have access to the outcome and to pay also from the payers. But that isn't really true if you are thinking about electronic health records being used more often and the capacity of collecting de-identified data that is pretty rich in outcomes as well as lab information.

Although we are not there yet, AHRQ has already funded two projects on the Distributive Research Network Initiative, which is actually doing the same thing, looking at electronic health record-based information which resides in different databases, perhaps clinical labs, prescriptions, or in hospitals.

So I think where we go in the future, there may be more entities than just the payers alone that can fund these kinds of special research topics and not just focus on one group.

DR. FERREIRA-GONZALEZ: So, your recommendation, then?

DR. RANDHAWA: My recommendation actually would be it would be useful to have it in a separate recommendation but add not just the healthcare payers but other folks who may be interested in clinical utility to make use of the mechanisms that we are constructing in the first recommendation.

DR. FERREIRA-GONZALEZ: I think there is a sense in the Committee that we will leave the recommendation as is, adding some of the changes that Gurveet has just recommended. Do we want to work on the wording now? Do you want to add, Gurveet, the edits?

DR. RANDHAWA: Give me some time to work on it.

DR. FERREIRA-GONZALEZ: We will do it during the break. Just keep a tally of who is doing what during the break.

So, are we ready to go to the next recommendation? Recommendation 3 requests that HHS conduct public health surveillance to assess health outcomes, surrogate outcomes, practice measures, and the public health impact on genetic tests. We did not make any revisions to this recommendation.

Do we have any questions about this recommendation?

[No response.]

DR. FERREIRA-GONZALEZ: Do we have any edits?

[No response.]

DR. FERREIRA-GONZALEZ: Let's go to Recommendation 3, the first part of Recommendation 3.

DR. TUCKSON: So I guess as the flow goes forward, is this different than stuff we have already talked about? Haven't we talked about this? What is the difference here?

DR. TEUTSCH: It is certainly similar to the one we stuck at the end of No. 6 that we talked about before. This is really using surveillance to make sure that the utility is realized.

DR. TUCKSON: I thought we already did this.

DR. TEUTSCH: The other option is to do what you suggested and get rid of the sentence that we added in No. 6 where we had some disagreement and leave this one, if you would prefer that.

DR. FERREIRA-GONZALEZ: The idea is to look at the one in Chapter 6 and this one in Chapter 5?

DR. TEUTSCH: Isn't that what you are referring to?

[Pause.]

DR. TUCKSON: Which one are we on?

DR. FERREIRA-GONZALEZ: I think it is 6-1. Yes, it is 5-3. How about 6-1? 6-1-B. We talked about this and we added that.

DR. TEUTSCH: That's right.

DR. FERREIRA-GONZALEZ: That is where there is redundancy, because we added this.

DR. TEUTSCH: If you take that out there, you can leave the one in No. 5 because it has more specificity. A little bit more.

DR. TUCKSON: Do they have to be in different places?

DR. FERREIRA-GONZALEZ: No, they don't have to be in different places.

DR. TUCKSON: Let's keep them together because you will make the reader crazy.

DR. FERREIRA-GONZALEZ: No, no. We are talking about deleting this part of Chapter 6, Recommendation 1, the part we added. So Chapter 6-1, Part B, there is an overlap with Chapter 5, Recommendation 3. The reason is because we added some of the language to this.

I think we need to decide to do we keep it in 6-1-B or we keep it in 5-3. Marc.

DR. WILLIAMS: Actually, to speak to Reed's point, I think that what we could do here is if we keep this recommendation from No. 5-3, Recommendation 3, Chapter 5 in, then we can basically just in 6-1-B say we reference this recommendation, the recommendation in Chapter 5, Recommendation 3. Just say we need to have that information provided for translational purposes, and then that's it. It does refer to the quality improvement piece.

DR. FERREIRA-GONZALEZ: Exactly. So, do we want to make changes to this one, then?

DR. FOMOUS: Do you want to start with the changes here first?

DR. FERREIRA-GONZALEZ: Yes.

DR. WILLIAMS: Just get rid of the last sentence and cross-reference. "See also Recommendation 5-3."

DR. FERREIRA-GONZALEZ: We are going to do the cross-reference to the recommendation in Chapter 5. Now we have dealt with the overlap. Going back to Chapter 5-3, do we have any edits for this one?

PARTICIPANT: Excuse me. Did you lose a little bit on the availability of the data with that deletion? I think that last sentence spoke to making sure that the data was clearly available for people's use. I don't think 5-3 specifically states that. It almost, I would think, worked out to take that last sentence and actually move it as a clause to No. 3 under Chapter 5, Recommendation 3. Make it one, two, and three. Or put in some statement about ensuring that the data is available.

DR. FERREIRA-GONZALEZ: Steve.

DR. TEUTSCH: This just gets into the definition of surveillance, which is the collection, analysis, and dissemination of data to those who need to use it. What I'm hearing from Greg is that may not be the definition that is widely understood. So if you feel there is a need, you can include it.

DR. FERREIRA-GONZALEZ: So, Steve, what you are saying is it is already implicit?

DR. TEUTSCH: I think it is there. It is in the standard definition of surveillance that is used. If it needs to be clarified, you can add something, but it is there.

DR. FITZGERALD: That can go in the text, right?

DR. FERREIRA-GONZALEZ: Yes. So we can put this in the text.

Can we move to the next recommendation? Chapter 5, Recommendation 4 asks HHS to advance appropriate use of interoperable patient-level data for research and to enhance the quality of decision-making. We revised the recommendation to include implementation in the efforts to advance the use of interoperable patient-level data.

Do we have any questions about this recommendation?

DR. TUCKSON: The only challenge we have is AHIC is in a transition mode and will not exist under those terms, I don't think, by the time this comes out.

DR. FERREIRA-GONZALEZ: Is there an AHIC 2?

MS. ASPINALL: Why not.

DR. TUCKSON: They are moving to a public-private partnership. What you might want to say is "SACGHS and AHIC (and/or its successors)".

MS. ASPINALL: Yes.

DR. WILLIAMS: Cathy, just to fix the parentheses problem there, take out "particularly." Lose those two parentheses, take out "particularly," and say "and other workgroups addressing," and then lose beyond. Leave the close parentheses after "successors." Then get rid of that line.

DR. TUCKSON: Move it. That works.

DR. FERREIRA-GONZALEZ: So, can we move now to the further recommendations? Are we done?

What we are going to do now, before going into Chapter 4, Recommendation 1, we are going to have public comments.

DR. TUCKSON: Are we?

DR. FERREIRA-GONZALEZ: I'm sorry.

DR. TUCKSON: Comments from who?

DR. FERREIRA-GONZALEZ: We have completed two chapters, going through them. We have to go back. Yes, Muin.

DR. KHOURY: My only plea to the group is to try to [keep in mind], after we take a look at all the recommendations, even if we implement all of them, how far will they fix our current broken system.

DR. FERREIRA-GONZALEZ: After the break we might go back to see the map. Sherrie was telling us to keep that in mind.

We had earlier mentioned our steering committee added experts and ex officio members that had specific expertise to form the taskforce that worked through the entire document. Throughout the

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development of the document we have been tapping back into the knowledge of the different taskforce members to seek their advice continuously.

So as we go through also the review of the public comments in going back to changes and edits to the text and the recommendations, we will also seek the advice of the taskforce members.

Again, to give them another opportunity to provide input directly to this Committee, we have invited all the taskforce members that might have comments to the public comments or any changes that we have made to the report to come and talk to you and tell us about what they feel about the current state of these final recommendations and the draft.

One of our taskforce members took us up on that offer and decided to come and address the Committee. We are looking forward to Kathy Hudson providing us some comments.