Presentation of Revised Draft Paper on Direct-to-Consumer Genetic Testing

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MS. AU: You're welcome. The paper is under Tab Track 7, in case you haven't read it. So here we are again. I thought we were done with this in June.

We are going to go over the Direct-to-Consumer Genetic Testing Paper, and hopefully finalize our recommendations that will go forward to the Secretary. Finalize the paper, actually, because the recommendations are old recommendations that we have.

I would first like to begin by thanking the Task Force -- we had, definitely, broad-based representation -- and thank the new members that joined us in June to help us with our revisions.

For today, our session goals are to come to consensus on the key areas for the Secretary's attention, of course, look again at the prior SACGHS recommendations and action steps that would be aimed at direct-to-consumer genetic testing, and look at any remaining concerns that may require additional action by the Committee, and approve the paper for transmission to the Secretary of HHS.

As background, if you have forgotten, we started this in March, and based on Barbara's analogy of lifespan, and Jim's being here, and Barbara's as a teenager, I would say we are probably a senior citizen and we are near retirement. We had a really fast growth spurt, though.

We started in March of this year to develop the short-term task force, because direct-to-consumer genetic testing was becoming quite a big area, and quite an area within the media. Cathy and I have been dealing with new information coming to us almost on a daily basis. I'm getting e-mails from Cathy saying, did you see that, did you see this. There was just some call for oversight in a JAMA article two days ago, I think.

So the objectives of the paper are to outline the benefits and concerns related to direct-to-consumer genetic testing, highlight our prior SACGHS recommendations that address these concerns, and identify issues that are probably not adequately addressed by our prior recommendations.

In June, we did have a draft paper and discussion and at that point. The Committee decided that we needed to go back and create an executive summary of our 29-, I

believe, page paper, at that point, which we thought was about the size of an executive summary of some of our reports, and make our specific action steps from the prior SACGHS recommendations more relevant to direct-to-consumer genetic testing.

I want to turn to Sarah Botha, who is going to talk to us about some relevant information, that came up as we were preparing this session, about some action that FTC has taken against two companies that were offering direct-to-consumer genetic testing.

MS. BOTHA: Thank you, Sylvia. I'm going to provide a bit of information -- I think the letters have been made available -- on two letters that FTC staff sent out on August 14th, closing investigations of two neutrogenetic companies, Sciona, Inc., and Genelex Corporation.

Sciona was a manufacturer, processor, and marketer of neutrogenetic testing. It's a test kit and consultation service called the MyCellf Program or the Cellf Test. Then, Genelex Corporation was a distributor of that test, so it didn't actually conduct the testing itself. It marketed and distributed the test and forwarded

test samples on to Sciona for processing.

Genelex also markets its own tests that include ancestry testing and paternity testing. So it is otherwise engaged in direct-to-consumer testing.

The MyCellF Program included a cheek swab, as well as a lifestyle questionnaire that consumers would submit. Approximately two dozen SNPs were tested, looking at five health areas, including heart health, bone health, inflammation health.

Consumers would receive a report back based on a combination of an examination of their DNA and their lifestyle questionnaire that would provide them with recommendations for diet and lifestyle choices, and there was no involvement of a physician throughout the process.

Both of the companies made virtually identical marketing claims and the ones that we were concerned with were claims that the diet and lifestyle recommendations that were given as part of the program could significantly impact consumers' health outcomes, including their risk of developing serious diseases. There were both expressed and implied claims relating to that.

There was also claims that having a neutrogenetic

test could help you lose weight and keep off the weight which was kind of just a side component of the marketing, but it was a claim that we thought was unsubstantiated.

We were concerned that the scientific evidence did not support the claims. We consulted with staff at FDA and some other experts and evaluated a large amount of clinical studies related to the particular SNPs at issue and the consensus of our experts were just that the studies at this point did not establish use of SNPs as clinically significant and so we were talking to the company, both companies about our concerns.

The weight loss study, by the way, was actually sponsored by Sciona and there were a number of flaws, including it wasn't placebo-controlled or blinded.

So the advice given by both companies, we thought, was pretty standard to diet and lifestyle recommendations that the general population receives and should receive, quit smoking, exercise, eat right, and we were concerned that there was a suggestion, a strong claim being, that for the people who had these particular genetic variations, that these interventions being recommended could impact their health outcomes more than it would have

an impact on just an ordinary consumer.

So Genelex, during the course of our investigation, agreed to stop marketing neutrogenetic tests all together. So they took down their advertising on their website for the MyCellF Program and also represented to us that they don't have any intention in the future of engaging in neutrogenetic testing.

Sciona actually has ceased operations and went into state bankruptcy proceedings and so they also agreed obviously not to market the product anymore.

We also had consent of Sciona, since they were the company that was processing the test kit, about some of the consumer privacy issues. Sciona made pretty strong confidentiality representations to their consumers through a consent form when they collected the DNA sample and the lifestyle questionnaire and we wanted to be sure that they were complying, following through with the promises that they made to consumers.

So we conferred with them about this quite a lot and they assured us that they had destroyed the consumers' DNA samples. That was one of the things they promised to the consumers in the consent form, that they would destroy

the DNA sample after the testing was done.

They also have destroyed all of the lifestyle questionnaires and the reports that they provided to their consumers. They've also purged their databases of their consumer personal information, names, addresses, other contact information. So they won't, as part of the sale of the assets of the company, they will not be selling any consumer information.

The only thing that Sciona retained were some individual SNP data that they were using to demonstrate the quality assurance of the instrumentation in their laboratory. They are selling some of their lab equipment and they represented to us that in order to maintain certification of their laboratories, they needed some of this data, and it would not be in any way traceable to individual consumers.

DR. BILLINGS: Do you have any sense of how many consumers were serviced by Genelex or Sciona?

MS. BOTHA: I'm not sure that I could disclose that information. These investigations are public to the sense that we are providing information that we conducted the investigations and why we've closed them, but that is

probably proprietary information that I don't think I can disclose.

MS. AU: Is it because they had such strong confidentiality agreements with their consumers that you could take some enforcement action if they weren't going to destroy the data and if other companies didn't have similar strong confidentiality agreements or some other type of agreement, there would be no enforcement action by a federal agency?

MS. BOTHA: Well, that's a good question. From the FTC's point of view, I can't speak to other federal agencies, but we are very concerned with consumer privacy generally. We have a Division of Privacy and Identity Protection and generally the position that we take is that it could be a deceptive or unfair practice by a business if it makes representations to consumers about how they'll be handling consumer information and it does not follow through with the representations that it made.

So from our point of view, it certainly was easier to put pressure on the company because they had made strong confidentiality promises.

DR. EVANS: So that kind of has some frightening

implications for how to get around that, right?

MS. BOTHA: Well, obviously, I can't speak hypothetically to the company that didn't follow the same practices, but, I mean, it could be a question that consumers -- there's always a question do consumers have expectation when they're providing medical data that it's going to be handled in a particular way?

I'm not saying that we definitely couldn't have asked Sciona to take these steps if they hadn't made the decision.

DR. EVANS: But it might have been a little more difficult to do so?

MS. BOTHA: Possibly, although, I mean, I don't think that they wanted to deal with enforcement action at that point.

DR. NUSSBAUM: You're also describing action against two companies. I imagine that there is a further investigation in the area. Is that something you can speak to?

MS. BOTHA: I can't disclose whether or not we have other investigations ongoing. Certainly, we're keeping aware of what is going on in the marketplace and,

as I said, we coordinated with FDA on this investigation and certainly intend to keep communications open between the agencies.

MS. AU: Thank you very much, Sarah. So getting back to our paper, so again, the intent of this paper was to recognize that some -- well, okay. The intent of this paper.

We recognize that some concerns of this direct-to-consumer genetic testing paper are not unique to direct-to-consumer genetic testing, but apply broadly to provider-based laboratory testing.

We also do identify some issues that may be unique to direct-to-consumer genetic testing, if a consumer's personal health provider's not involved in the health decisions or government regulations do not adequately protect people who are getting direct-to-consumer genetic services.

We added an executive summary, as suggested by the committee, and I'm sure all of you have read the executive summary, digested it, love it. It does highlight three key areas for the Secretary's attention and five specific action steps.

So the first key area for attention is that there may be gaps in the federal oversight of direct-to-consumer genetic testing, particularly in the absence of review of direct-to-consumer genetic testing promotional materials and claims by the FDA due to limitations under current regulatory practices and lack of evidence of clinical validity and utility for most health-related direct-to-consumer tests.

Now, I know that if you read the paper, one of the things is we call them health-related direct-to-consumer tests. That's our interpretation of them. A lot of the companies in their disclaimers of their results say that this is not health-related information. So there is a difference between what we call the tests and what the company might call the test.

The other area of attention is that there might be gaps in privacy and research protections for consumers utilizing the direct-to-consumer genetic testing because most of these are private companies and don't take federal money and so federal regulations may not apply to companies offering direct-to-consumer testing and state-level protections may be inadequate.

As our speakers yesterday talked about GINA and HIPAA, I think that those are some of the things that we're looking at, that GINA and HIPAA may not apply to some of these companies doing direct-to-consumer genetic testing.

The third area of concern, this is the one that I call the blind leading the blind because there's a little disconnect in here, that there's insignificant knowledge about genetics among the consumers and healthcare providers, as we discussed this morning about the education of healthcare providers, and there's a limited involvement of the consumer's personal healthcare provider in providing assistance to consumers who are selecting genetic tests and making their healthcare decisions based on direct-to-consumer genetic test results.

And I think what is going to happen is Jim has actually come up with some suggestions on how we might be able to parse this out so it doesn't seem like we're in one part saying that healthcare providers have insignificant knowledge and then the other part saying that they need to lead their patients in selecting genetic tests.

DR. EVANS: So what we were thinking about, since that did seem to be somewhat confusing, would be to split

this into three bullets.

The first bullet would note that insufficient knowledge among consumers and providers exists. The second bullet would address the issue of there oftentimes being little involvement of the provider of the service, that is, for example, the DTC lab in informing the client about the implications of the test results. And then, three, that there's little involvement of medical providers in general, within parenthesis, that says, for example, see Bullet 1, to indicate this is a circular problem and needs to be attacked as a whole, something along those lines.

MS. AU: So does anyone have any comments about the key areas for attention or the change in this last one?

[No response.]

MS. AU: Great. So I think comments will probably come about our recommendations.

So when we looked at our prior SACGHS recommendations from the many, many reports that we've done, we found that there were nine prior SACGHS recommendations that could apply to some of the concerns with direct-to-consumer genetic testing.

They would address concerns related to oversight

gaps, definitely, marketing claims, promotional materials, analytical validity, clinical validity, clinical utility, standardization, privacy, and, of course, our favorite, consumer and provider education.

So the action steps that we're proposing is that -- and I want to thank Sheila, who stepped out of the room, she'll be back later, for helping us redraft the action steps because we wanted to make them more focused on direct-to-consumer genetic testing.

So based on our prior recommendations, SACGHS is proposing the following actions to the Secretary of HHS to address the gaps and inconsistencies in federal regulations and to accelerate coordination of programs that facilitate comprehensive and consistent consumer and healthcare provider genetics education.

So in order to do that, direct the FDA Commissioner and CMS Administrator to solicit broad stakeholder input through a series of public hearings, then convene jointly to draft and publish an advanced notice of proposed rulemaking that (1) analyzes gaps, inconsistencies, and duplications in regulations related to direct-to-consumer genetic testing and (2) identifies

specific proposals to address them within relevant statutory authority.

I know you guys are going to recognize these because they're just a little bit reworded from our prior recommendations to make them more fit this report.

The second bullet is include laboratories that provide direct-to-consumer genetic testing and services, if HHS establishes a laboratory registry. That's that registry under the oversight report that we talked about.

Now, convene a joint HHS-FTC task force, I love we're convening another task force, with industry, consumer, academic, and government stakeholders to propose specific guidelines for direct-to-consumer genetic testing, advertising, promotion, and claims consistent with existing statutory authority.

The task force should also identify gaps in the authority relevant to the mergent industry. These guidelines, which will form the basis of a more targeted federal enforcement of claims that are misleading and/or not truthful, should be grounded in evolving evidence standards which are accepted by experts in relevant fields for identifying and evaluating competent and reliable

scientific evidence of a direct-to-consumer genetic test performance consistent with the claims made by direct-to-consumer companies related to these tests.

In the spirit of our long recommendations, we'll have another long one.

Direct the HHS Office for Civil Rights, with support from the Office for Human Research Protections and other relevant HHS agencies, to identify specific gaps in state and federal privacy protections for personal health information that may be generated through direct-to-consumer genetic testing and propose to the Secretary specific strategies the Federal Government can undertake consistent with its existing authority to address these gaps and inform consumers of potential risks to privacy.

The next one. Develop an initiative within the Office of The Assistant Secretary for Planning and Evaluation focused on genetics education, including information specific to direct-to-consumer genetic testing and links to HHS educational resources for consumers and health practitioners.

ASPE should also follow up its March 2009 report, "Consumer Use of Computerized Applications to Address

Health and Healthcare Needs by Conducting Research and Evaluating Studies Specific to Direct-to-Consumer Genetic Testing, Developing Policy Analyses, and Estimating the Costs and Benefits of Policy Alternatives and Potential Regulations Under Consideration by HHS."

The following concerns may benefit from more evaluation by SACGHS and appropriate federal agencies. Now, these are recognized in our paper but we do not have prior recommendations that address these areas and the committee might want to look at addressing these areas in whole or some of the issues.

Non-consensual testing. That's the testing that we had talked about where the person getting tested hasn't consented to be tested, stealth paternity testing, things like that.

Limited data on the psychosocial impact of direct-to-consumer genetic testing. We had discussed that in the June meeting.

Impact of direct-to-consumer genetic testing in children and minors. We had discussed that, too, in June.

Potential exacerbation of health disparities, one group getting tested because they have funds to pay for the

testing, other groups not having funds to pay for the testing.

Inadequate protection of research use of specimens and data derived from specimens. We had discussed this because companies that have these samples and data might not fall under the federal regulations for privacy protections. Also, what happens when these companies are sold or go bankruptcy?

Impact of direct-to-consumer testing on the healthcare system is a big issue because how does the whole direct-to-consumer testing work in this healthcare system of people bringing in test results and ordering their own tests.

So what we would like to do today, of course, is finalize the direct-to-consumer paper. We want to know are there any significant issues or action steps that are missing from the paper, is the paper approved for transmission to the Secretary, and what, if any, additional actions are warranted for issues that have not been addressed by our prior SACGHS recommendations, and I guess with that, what is the priority of addressing these issues separately or within other reports and studies that we're

doing?

So with that, I think we'll open it up to discussion by the committee.

Paul.

Committee Discussion/Decisions: Direct-to-Consumer Genetic Testing

DR. BILLINGS: Thank you. Sylvia, I think you did an absolutely masterful job in this task, which was complicated, and so I want to commend you personally, and your committee, for the job you did.

I'm curious about the recommendation that calls for a new task force to look at the gaps and so forth. To what extent does that recommendation extend our previous oversight recommendations for genetic testing, in general? And if FDA, for instance, decides that this whole area is under their regulatory control, will we still need that task force?

MS. AU: Well, I guess that depends on if FDA is going to tell us that they are deciding it's all under their control.

DR. MANSFIELD: All I can say from the information that we have about most of the direct-to-

consumer tests, is that they would fall under the rubric of medical device. Therefore, FDA does have authority.

As you know, that doesn't mean that FDA does premarket review or postmarket control. So I would say that it's possible -- I mean, I don't want to tell you that it's true, but you should discuss this. Given that, do the previous recommendations from the oversight report apply or not?

MS. AU: I think that was one of the problems with making these recommendations more focused on direct-to-consumer genetic testing as recommended by the committee last time, was that at the beginning of this report, one of the goals was to highlight previous recommendations so that the new Secretary could take those recommendations in a new light and with that recommendation, I think we were looking at it as broadly genetic testing with DTC thrown in.

The way the wording has changed now because the committee had decided that we should be more specific to direct-to-consumer genetic testing, it really does make it so it seems like it is a separate task force that would be developed.

Yes, Marc.

DR. WILLIAMS: The question that I would have that would, I think, be relevant to this is the thing that is missing from the previous oversight report, which is the role of the Federal Trade Commission relating to claims and that's the piece that I don't understand, is whether, assuming that FDA does take some ownership of this, whether that ownership would extend to these claims or whether that would remain under the purview of the Federal Trade Commission.

If it's the latter, then I think having a joint task force would probably be a valuable thing because that does fall outside the realm of what we previously recommended. If that's something that would fall completely within the purview of the FDA, then perhaps it's not necessary to do that.

DR. BILLINGS: My question was simply to say if the current authorities will provide oversight, then we don't need another joint HHS-FTC task force. If they don't, then we might and that was really my point.

PARTICIPANT: We don't know if they will.

MS. AU: I think FTC wants to say something.

MS. BOTHA: Yes, I actually had a question about this recommendation, as well, when I was reading through because these have come in since our last conference call.

From FTC's point of view, we have a very broad statutory authority to go after unfair and deceptive acts and practices affecting commerce and we also have more specific authority to go after false advertising for healthcare products, including devices.

We have a very longstanding memorandum of understanding with the FDA regarding our overlapping authority and the understanding is that FDA takes primary jurisdiction for labeling for products and the FTC takes primary jurisdiction for advertising for products, the exceptions being prescription drug advertising and restricted medical devices.

So with regard to DTC genetic testing, I think it clearly falls under the Federal Trade Commission Act and our very broad authority. I don't think that there's a question about there being a gap in authority for the FTC.

I think that the problem that we've had, and it made our investigations complicated, is the lack of agreed-upon evidentiary standards because for advertising claims,

FTC's requirement is that there's a reasonable basis to support any expressed or implied claim and for health and safety claims, that consists of competent and reliable scientific evidence, which is evidence that would be agreed upon by experts in the field as being sufficient to substantiate the claim and that's really sort of where the gap is now because of the lack of agreed-upon standards for clinical validity, clinical utility, and that's really the problem.

DR. BILLINGS: So this sounds a little bit like the Patent Office discussion we had yesterday which is that the Patent Office is once more expertise, too, and so we are defining kind of an area of need which this committee could provide some direction to the various agencies and potential resources to the various agencies since there are experts even on this committee.

So it does seem to me, though, that the recommendation should say convene as needed further oversight or something like that, so that if there's already very clear ownership of the issue, then really not set a task force up but provide the current agencies with the expertise that they need.

MS. AU: Yes, I think we can probably tweak that a little bit and then in the report we can make some explanation of what we meant as needed, especially for the expert opinion.

Okay. We have Marc and then Muin.

DR. WILLIAMS: And the other thing that I think, based on what Sharon just said, is that perhaps we should tighten this down and rather than giving this very long laundry list of things that this task force could potentially address, that it sounds like the prime issue here relates to this evidentiary standard which does in some ways relate to issues that we brought up in the oversight report, as well, but it sounds like that's really the priority area focus and if we could reflect that in the action step, I think that would be good.

MS. AU: I think I would like to do that with a lot of the recommendations after the patents report yesterday.

Yes, Muin.

DR. KHOURY: Just going back to the discussion about the evidentiary standards and also looking at the oversight report, which had some of the many

recommendations as a creation of independent panels, like EGAPP, that would look at clinical validity and utility and put these evidentiary standards.

So we took that into perspective when I think the EGAPP Working Group has been discussing various issues over the last year and I think they have a couple of these topics on their radar screen, one for diabetes and one for cardiogenomic profiles, which probably they will come up with sort of piecemeal recommendations, but during our workshop that we held last December, an NIH-CDC workshop where we brought everyone together and we talked specifically about the scientific standards for personal genomics and they were published in the August issue of Genetics and Medicine, I mean it's very clear that there is not much evidence for clinical validity, especially utility, for most of these things, whether they're GWAS-based or individual, I guess, genetic variants that people are selling.

So I think we can discuss that ad nauseam and if you think about the field of genetic testing where the field of personal genomics has kind of run ahead of the more established areas where you have pharmacogenomic

applications, diagnostics, screening, at least they go through some hoops for validation, of validity and utility. Here there is nothing.

I mean, you take genetic variants identified in GWAS and then you put them out and with odds ratios that vary from 1 to 1.5. You may or may not make claims, like some companies make claims, so you go after them, but the more clever ones, they disguise the claims under may increase your risk, this, that, and the other, but it's clear that there are no scientific standards for validity and utility for all of the personal genomics tests that are out there.

Now, whether you need a new task force or you embed that under the recommendations for oversight, it's something the committee needs to discuss, but given that the horse is out of the barn, so to speak, and our own surveys from Health Styles and Life Styles showed that many people are aware, many people are using them, less so than being aware, providers are being asked questions and the ones that are being asked questions, people bringing these things to them in at least three-quarters of the instances are taking action on the basis of those personal genome

profiles that patients are bringing to them.

So it already is having some impact on the healthcare system. So given all these data, I mean, I think the time for action is now.

MS. AU: Liz.

DR. MANSFIELD: So given what Muin has just mentioned in the oversight report, it recommended that FDA take a risk-based approach. So perhaps rather than having the task force evaluate all of these things, it might be of some interest to indicate where these direct-to-consumer tests are believed to fall in the continuum of risk because if FDA were to go forward with any type of regulation of laboratory-developed tests, it's most likely to be on a risk basis and it would be very helpful for us to understand exactly where you feel these fall in relation, for example, to BRCA1 and 2 testing, pharmacogenetic testing, so on, to give an analysis of that.

MS. AU: So that would be risk-based analysis of all direct-to-consumer genetic -- because it runs the range.

DR. MANSFIELD: Well, I guess to the degree you wanted to encompass all of it, but you could certainly say,

well, these particular tests appear to be of high risk or these results appear to be of high risk and these results appear to be of moderate risk and these of low risk or something.

MS. AU: I remember that recommendation, but I can't remember exactly what we recommended. Was that to convene another task force?

DR. FERREIRA-GONZALEZ: They needed to convene the stakeholders to discuss further.

DR. TEUTSCH: I think one of the intrinsic things here is when it's direct-to-consumer, it's intrinsically higher risk than when it's done through a knowledgeable provider. That's one of the concerns about DTC.

DR. MANSFIELD: Well, that is not -- well, I shouldn't say not. I don't believe that that's a basis on which FDA assigns risk.

DR. BILLINGS: I think that also --

DR. MANSFIELD: We could look into that.

DR. BILLINGS: -- there needs to be a factual basis for that claim.

DR. MANSFIELD: You could recommend that we look into that.

MS. AU: How do we do that?

DR. TEUTSCH: I think the point is that some of the things that we heard when people take action --

DR. BILLINGS: I understand, but misinformation for a very sick patient who might die shortly thereafter if a test provides misinformation is different than mostly healthy consumers searching diet information, --

DR. TEUTSCH: Oh, I understand.

DR. BILLINGS: -- let's say.

DR. TEUTSCH: I just had the same test being done in different -- the same test being done under those same circumstances is likely to be higher risk --

DR. BILLINGS: Absolutely.

DR. TEUTSCH: -- being done without --

DR. BILLINGS: An intermediary.

DR. TEUTSCH: That's what I meant. I didn't mean intrinsically all the tests.

DR. BILLINGS: Okay.

DR. TEUTSCH: I'm sorry.

MS. AU: Okay. I understand now. Gurvaneet.

DR. RANDHAWA: I want to go back to the point of what is it that we're trying to focus on here.

It's not the oversight per se. What I think we're getting into is the evidentiary standards and what Muin was discussing raises an interesting issue of evidentiary standards for what?

The clinical guideline developers have a slightly different perspective from, say, reimbursement coverage decisions which is a little bit different from regulatory decisions, and I think we need to -- if we get the task force or working group, it should be fairly narrowly defined into what is the focus of the evidentiary standards.

MS. AU: Yes, Mike.

DR. AMOS: I think one of the things that the committee could -- maybe the language could be a little stronger with regard to how good or bad are these tests. I mean, the problem is that we've talked about this for a couple years, right, and we've had people come in and talk to us about the clinical validity and clinical utility, but I would like -- I don't know exactly how to do it, but the document I would like to see a little more forceful or even ask HHS Secretary to sort of make a statement about these tests and from an education standpoint to try to keep the

public from making bad decisions.

The other thing, too, is when you try to limit the information that people have where they make good or bad healthcare decisions, I don't think you can just limit it to the DTC and you might open up a can of worms because we get all kinds of information in the literature that people make good or bad decisions from, whether you should eat more oatmeal or whatever.

MS. AU: Barbara.

DR. McGRATH: Sort of following on that, I really would like to applaud the even tone of the report that I saw when I read the revised version, that we may have opinions about DTC, good or bad, with such heavy language, but the reality is they're out there. They're going to be used and we've had other speakers talking about they're a source of consumer empowerment which is a movement that's only going to be growing with healthcare reform and just with time.

So I think I like the even tone, that we're not saying there's no place in the landscape for DTC, but rather focus our attention on looking for evidence and messaging and all those other things, but to leave the sort

of do we want them to go away tone out which I was appreciative of that. I didn't read that in this.

MS. AU: I just wanted to go back again to the goals of this paper when we first envisioned it, and I think definitely it would be great rewording it, making shorter recommendations, things like that, but one of the things that it doesn't only apply to direct-to-consumer testing.

One of the things that we really were trying to do was trying to get the new Secretary to look at some of the old recommendations that we really wanted her to look at and using direct-to-consumer testing as the new child, to kind of take it up to that level.

I think personally, I'm hoping that she would read this and say, well, there's more than direct-to-consumer testing. We should have a registry for all genetic testing and make it broader up at the Secretary's level, but because this paper is on direct-to-consumer testing and because the committee really last time thought that the recommendations were too broad, either we are going to have to keep it really focused on direct-to-consumer testing, so that this can be the vehicle that

hopefully will get the Secretary to pay attention to some of the other recommendations and in her wisdom broaden the scope of it, or maybe this is just the start and, as it becomes successful, we can get her to broaden and do more within the areas that we're looking at.

So I'm just a little troubled with trying to redo a lot of the recommendations because they are our old recommendations and now that we have focused them on direct-to-consumer testing, I don't want to go back and broaden them again because we're just going to go back and forth, back and forth for years and I think Cathy and I want to get this out to the Secretary while it's still a hot issue before the next issue comes up.

DR. AMOS: I wasn't saying to broaden it at all. I was just saying that we have to consider the fact that information is for information's sake and there's lots of information and to segregate genetic information from the other thing, people make real bad decisions for a lot of reasons.

MS. AU: Oh, yes. Like buying a house with zero percent down.

Yes, Marc.

DR. WILLIAMS: The thing that I think is a unique aspect of at least some of the direct-to-consumer tests that I'm not seeing reflected here, and you can maybe enlighten me in terms of where you envision this to be, is the issue of trying to have a company separate itself from undergoing scrutiny because they're saying we're not providing health information, and I think it would be extremely critical to have -- and I have no idea how this sort of pronouncement would be made or how this would be analyzed.

But the idea that there could be a statement made to say, wait a second, you can't self-define this as not being about health. If you're testing about something that relates to health, then it's health testing and you're subject to whatever we have there, and I would just like to see that very explicitly put forward to the Secretary in this, although I'm a bit lost in terms of how that would actually be characterized as an actionable step.

DR. FERREIRA-GONZALEZ: Sylvia, can I follow up on Marc?

I was having trouble with that specific issue, too, due to the fact that one of the issues that we

discussed at the last meeting is that these are direct-to-consumer testing for personal genomics that consider themselves that don't fall under CLIA and CMS has come out and said they don't fall under CLIA either.

So this idea that we have this specific concern for there's a need to be addressed, I was trying to figure out if that falls under the first bullet point on --

MS. AU: That was what it was supposed to fall under.

DR. FERREIRA-GONZALEZ: Okay. I know what we're trying to say, but I didn't really get clear that that's the first issue that we're trying to do through this FDA and CMS getting together to discuss this specific issue, I guess. So there is a need of statutory change to make sure that either they do or they don't fall under this.

The FDA might consider them devices, but again they're providing services and some of these companies actually, what they're doing, they're contracting with CLIA-certified laboratories to provide them the data, the data that is transferred back to the companies and the claim of that company is not subject to CLIA regulation because they don't produce analytical data.

So I think that that's an area that needs to be specifically addressed. I can open up some company out of my garage and my own laboratory could be doing the genetic testing and all the analysis and I don't fall under these regulations.

So this is a point that we were trying to make very clear that I'm not sure if it comes across on the first bullet point.

MS. AU: In the text of the report, and again I think one of the problems we have is because we're using this as a vehicle for past recommendations, how far do we revise past recommendations?

DR. FERREIRA-GONZALEZ: But we have specific recommendations and where this issue needed to be addressed and this health-related needed to be addressed.

MS. AU: Do we have a prior recommendation in the oversight report?

DR. FERREIRA-GONZALEZ: We do have in the oversight, there is a specific recommendation on that.

MS. AU: So we can pull that out.

DR. BILLINGS: Isn't the point that a direct-to-consumer test, whether it's just a data processing or

interpretive thing or whether it's the full laboratory bag, is a genetic test and we want it covered by the oversight issues that we've suggested for other genetic tests? Isn't that the point, Andrea?

DR. FERREIRA-GONZALEZ: But can we bring that specific recommendation here? It wouldn't be a new recommendation.

MS. AU: Yes.

DR. FERREIRA-GONZALEZ: It would be that that needs to be addressed, and I think it's covered here when you talk about that the FDA and the CMS should get together to do an advanced notice of proposed rulemaking to analyze the gaps, inconsistencies, and duplicative regulations, and identify specific proposals to address relevant statutory authority, but we have very specific language that says that maybe the statute needs to be changed to really incorporate this into CLIA, for example.

MS. AU: Okay. We can pull that one. Jim wants to say something direct to that and then we'll move on.

DR. EVANS: Right. So I agree with what Marc said and with what Andrea said.

I think that to me, the overriding issue in all

of this is reconciling reality with claims because that's where people are going to get into trouble. That's where they're being misled, et cetera.

I was pleased reading the product in the sense that I thought that the action step which says, it's not up there now, convene the joint FTC task force would go a long way towards that.

Now, perhaps it's a little oblique, a little opaque, and what we could consider and maybe even do this at lunch or something is come up with a much shortened action step that has a one-sentence preamble about reconciling claims with realities and then therefore we recommend convening a task force and then take some of this verbiage and fold it into the rationale for the recommendations so you aren't overwhelmed by the volume of it. Does that make sense?

MS. AU: I think that makes sense.

MS. BOTHA: If I could respond, I think that would be useful. When I read this recommendation, I really wasn't clear what the goal of the task force would be because FTC, at least, is not primarily a regulatory agency. We're an enforcement agency. We have some

regulations, but we're unlikely to issue regulations in an area like this, especially where the science is emerging and evolving.

So if you're looking for a guidance document, I'm just not clear on what the goal would be.

DR. EVANS: Right. And I think most of us around the table are advocating exactly what you all do, which is, there are procedures, regulations you guys follow to decide whether claims are being substantially met or not, right?

MS. BOTHA: Right. But as I tried to explain before, it's really a pretty standard policy that we have regarding health and safety claims about competent and reliable scientific evidence and that just gets us back to the question of what would comprise competent and reliable scientific evidence in these cases.

So are you expecting that this task force would go to defining that because I don't know if FTC -- we would participate but we don't have the scientific expertise for something like that.

MS. AU: I think the task force is supposed to be helping advise FTC, right?

DR. EVANS: And, as it says, to propose those

specific guidelines. So it would bring in the experts that would then provide --

MS. AU: You would need to tell them what you needed. I think that's the position of FTC on the task force, if I remember correctly.

MS. BOTHA: Well, I still have a concern that setting, then agreeing upon standards, I'm not sure of the usefulness of that when you're dealing with science that's developing constantly, and would these standards be set in stone and all of the tests are testing different things. They're making different claims. It's just difficult to establish, I think, specific guidelines, more specific guidelines.

DR. EVANS: I'm actually not sure it would be quite as difficult in the sense that, yes, the science is changing rapidly. Nevertheless, the types of issues that Muin articulated with regard to showing clinical utility, showing at least clinical validity, those are really not contingent on the type of technology, et cetera.

So I think it's doable, but obviously you'd have to work out details in such a task force.

MS. AU: I think in the task force, the experts

would be able to help guide that process because they also would know that you can't have everything in black and white and never move. So that's part of the expert guidance, hopefully.

I have Muin. He has been waiting to say something. Okay, Mike.

DR. AMOS: I was just going to say that I support Jim's language because it's really critical that these recommendations be technology independent because the technology is emerging.

Right now, the issue with GWAS is that there's nothing technically wrong with them. It's the paradigm. It's the approach to find something out. It's really the approach and the quality of the information you get back to make real decisions.

Very soon, I think, it's going to be possible to get an entire human genome done. Everybody's going to have this information. It's going to be a massive amount of data that's going to have to be managed and I think that maybe that you will find something there, who knows, but it's got to be technology independent.

DR. EVANS: Right. I completely agree. The

beauty of that is that again the rules have changed in medicine, right, and we can apply clinical validity, clinical utility, et cetera, regardless of whether it's a whole genome sequence or array data, not that that's trivial, but it's doable.

DR. AMOS: And when you talk about standards, you're talking about standardization. You're talking about procedures and things like that for interpretation. It's not quite the same as materials to support the technology which is a different area, and we've actually decided to stay away from the GWAS and things like that as far as standards because we actually think they're going to go away but focus on next generation sequencing.

MS. AU: Getting back to Andrea's recommendation about the CLIA, I think Penny from CMS had some concerns about statutory changes.

MS. KELLER: Hello, everyone. I'm kind of here to answer any questions, but I can update you on what we're doing about direct-to-consumer testing because I actually read the 200-page report, that was one of my first duties, and one of the things we are doing is we are monitoring all the companies and we are just as familiar with them as the

FDA and the other agencies.

What we attempt to do is contact them and go through the e-mails, calling them, whatever we can do, contacting the states, and try to educate them because a lot of the information that they posted is for information only.

So what we do is we contact them, ask them for information about their tests, including their requisition form, their testing description, as well as the test report that they generate and send to the consumers or to the providers to see what they're actually saying, and if the information can be used for health assessment by the provider, then we educate them and say, well, no, that falls under CLIA, even if you use it for information, and you need to qualify for CLIA or one of the accrediting agencies.

So that kind of makes it complicated because not all genetic tests is considered as falling under CLIA, as Dr. Gonzalez mentioned. For example, one of the companies was testing for bitter tasting, a gene where can you taste the sour lemon or not. We didn't consider that a CLIA test and the report just tells you whether you have this gene

that everybody else has who can taste it or not and so there wasn't anything else associated in that report as far as needing treatment or some kind of assessment. So we told that particular company at the present, that didn't fall under CLIA. So that's the criteria we're using. We're using our definition as far as the assessment.

Even if they claim it's not a diagnostic, we still ask for the information and we have to educate these people, but that is what we're doing. So some of them have actually applied for CLIA. Some of them don't respond to us. We e-mail, we contact, but some of them don't get back to us and, unfortunately, unless they apply for CLIA, we don't really have the force in the statute to go after a company that isn't doing our type of testing or who does it who isn't a laboratory or falls under CLIA. I hope that helps.

MS. AU: So, Penny, --

DR. FERREIRA-GONZALEZ: Can you give me a little more clarity between those services that actually contract their testing, analytical part, with CLIA-certified laboratory? Are you going after the service, telling them that they have to comply with CLIA or would just doing the

testing in a CLIA-certified laboratory be sufficient in your view?

MS. KELLER: We've checked with our General Counsel because we've had split -- well, not split. We've had passionate conversations about this, but right now, until there's, I guess, evidence that we need to be more stringent, our General Counsel has advised us to just stick with our definitions.

So let's say, I know 23 EMEA is a big well-known name, they don't have a laboratory but they do interpretation and our counsel have said that the laboratory that actually generates the data, that has the testing personnel that run the tests, that all falls under CLIA, but what 23 EMEA are doing is they're taking literature that's out there, the advisor committee, and doing an interpretation very similar to a provider and that does not fall under CLIA at the moment.

MS. AU: So that means, Andrea, pulling your recommendation about CLIA would not cover this instance because again --

DR. FERREIRA-GONZALEZ: It's a gap.

MS. AU: It's a gap.

DR. FERREIRA-GONZALEZ: So that needs to be addressed, because what you're telling me now is that there is these groups that only does the interpretation that doesn't fall under CLIA. They're still taking laboratory data and turning it into a report for their patients or consumers or customers.

MS. KELLER: Normally, we change that if we see a pattern. I mean, there are some states that are coming up with new state statutes that are separating that interpretation software part out of the laboratory part, but --

DR. FERREIRA-GONZALEZ: You're talking about California?

MS. KELLER: California, and there are other states that are considering it, as well. I can't really divulge it because I'm not sure where, at what stage those are at, but the current CLIA laws do not extend to that interpretation part because they look at it as the practice of medicine.

So whoever oversees the practice of medicine has to try to get involved with these companies that do that, but that's where our General Counsel has worked with us.

DR. FERREIRA-GONZALEZ: We're splitting hairs. I mean that's like what we do in a laboratory. We do an interpretation.

MS. KELLER: Yes.

DR. FERREIRA-GONZALEZ: CLIA laboratory provides a service where we provide interpretation in the context of that particular patient.

MS. KELLER: Yes, and that is a service that laboratories provide because that is very useful to the physician, but that is not something that's explicit in CLIA that you --

DR. FERREIRA-GONZALEZ: It needs to be addressed in the recommendations. There is a big gap there.

MS. KELLER: We don't, in CLIA, specify how much of that interpretation should include the practice of medicine, that interpretation. So we leave it up to the laboratories to do that. The fact they provide a lot of information to the providers, we applaud that. Obviously, it is useful to the providers, but our statutes do not cover that at the current time.

MS. AU: So that our recommendation was that we need to look at the relevant statutes and see where the

gaps are so that we might have to revise and get the statutes revised. Not us, somebody. The Secretary.

David's been waiting. It's David, Gurvaneet, Marc, Jim.

DR. DALE: I pass.

MS. AU: Okay. Gurvaneet.

DR. RANDHAWA: I go back to the evidence standards and I'll be more specific here. If you can go the slide, there you go, there are two issues.

One, I thought I heard Jim say that the evidence may change but the evidence standards are more or less the same.

DR. EVANS: The technologies can change.

DR. RANDHAWA: Right. So that's one word that comes up here, evolving evidence standards. So there's a difference between evidence and evolving evidence standards, and I agree with the fact that standards actually don't need to evolve. You can look at new technology and look at the evidence and say does it meet the standard or not, but that's not what this bullet here says.

The other thing is, is it really desirable for us

to have the same evidence standard for all decision-making contexts? I've heard the clinical utility being mentioned here and we have at least one example from EGAPP when they looked at cytochrome P450 testing in depression and looked at ampli-chip as one of the tests which has undergone the FDA process and is available for use, but the EGAPP recommended against its use and clinical utility was not considered in that decision-making.

So I think we have to be very clear in terms of what the decision-making context is and what the standard should be.

MS. AU: I have Marc and Jim.

DR. WILLIAMS: So this is directed back to Penny. Just a couple of clarification issues that relate to the idea of self-defined as a non-health-related test.

So in those companies where you do have contact with them and they respond to you and you say, no, wait a second, we understand you're saying it's not but we're telling you it is, then is there any communication to say, FTC or someone else, to say the materials that are being provided do not recognize this as a health test. CMA is considering this a health test. We think there's a

discrepancy in claims that would need to be addressed.

And then the second question is for those that are not responding at all, given that you don't have any sort of enforcement, is that a potential role where there could be communication to an enforcement agency, like FTC, to say could you help us get these people to respond or something?

I'm just trying to look at things that address the health versus non-health issue and a role of this potential joint task force.

MS. KELLER: One of the things we have been doing is working with the FDA on the materials that we receive from these companies because when you have a regulatory body saying, oh, yes, the information is relevant, we need scientific support, so we have asked the FDA for the technical support, and we provide these companies -- we don't just say yes or no. We give them reasons of what was inadequate or adequate. So we provide a summary so that they correct the problems and they qualify then. We're more than happy that they provide the analytical data and appropriate. But you have to look at CLIA as a whole laboratory. So we're looking at approaching them on all

other quality management systems.

We haven't been at this long enough to get to a point where we've transferred any of the information over to the Federal Trade Commission on the ones who haven't responded because we want to give them time because what I've noticed is sometimes we'll go three months before I hear anybody because everyone's busy doing something and they're not all lost, but there are some that actually use international laboratories and those are even more difficult to contact, but we do make an effort.

So there has to be a point when we decide, okay, we're no longer going to make an attempt after three attempts or four attempts. I'm not sure. We haven't really gotten to that point. We're kind of gingerly getting at this because it's not like we have an enforcement group right next to us who are going there. We have to rely on other agencies and unless there is a complaint that was lodged against that particular facility that we can forward, my inquiry by myself really doesn't generate a whole lot of interest.

I hope I answered your question.

DR. FERREIRA-GONZALEZ: Could I ask a further

question to that one?

I mean, I think one of the issues that we had in the report, also, is that we came across this issue that CMS has no enforcement. When you find a laboratory that is not complying with CLIA, you cannot go and shut them down. You have to go turn around to somebody else to inform them what is happening and so forth.

So we ask in our report to change this to give them the ability to have some enforcement. So maybe we need to pull that into this report, also, specifically, so then they can actually have some teeth to their enforcement.

MS. KELLER: Our enforcement extends to our CLIA labs. That's correct, Dr. Gonzalez. So if there's a CLIA lab who is doing a DTC test and there's a complaint about it, we'll go in, we'll take a look at it, and they'll either have to correct it or they have to discontinue the test. We have that much of an ability as far as enforcement.

But if they're not a CLIA-certified lab or accredited lab, yes, we have to ask another agency, unfortunately.

MS. AU: So, Penny, your plans are that eventually the labs that aren't responding to you, you will be turning over that --

MS. KELLER: We are -- well, I have what you call a makeshift database. It's a personal database and we're just accumulating information at the moment. We have to actually get approval by our General Counsel on what we can or cannot include in that before we share it with our regions or our states, but at the moment, like any other agency, we collect information. We keep a running record of all our communication, everything that's going on, like the letters that came out will be in our database for anyone who's inquiring.

Our regions and our state surveyors all know that if they have any questions on direct-to-consumer testing in the area, to contact us because we keep track of it, plus we might know something about it from another state that they're not aware of. So we are educating our surveyors.

MS. AU: I think Muin has a comment.

DR. KHOURY: I think to make sense of all of this, I like Appendix B. Appendix B is the place to start from because it shines a light on what SACGHS has done over

a long period of time and I think what you tried to do in those pages where you took stuff, you tried to relate one to one what you thought might be the gaps that are specific to DTC and make them a bit more spotlighted, but at the same time, we kind of lost Appendix B. Now it's an appendix.

So one suggestion may be to bring all of Appendix B back into the list of recommendations because they do apply to DTC and point out the something extra specific that needs to be done. That way, you're essentially saying this needs to be done for everything, includes DTC, and it's not relegated to an appendix, but it's really the heart of what needs to be done with all these areas, from claims to education to oversight to clinical validity, because right now Appendix B is kind of lost. One idea.

DR. FERREIRA-GONZALEZ: I think we have to be cautious in doing that because I think we went back and forth with these issues, and the idea of this white paper is to bring light to issues of direct-to-consumer because it's very publicly discussed in many different forums and people might not realize that they can go to the oversight report to look at all these issues.

Then we're just going to highlight some areas of DTC and then refer them to the report. We put the report and oversight here.

MS. AU: Yes. I think that's what the goal of the paper was and so that's why we ended up with Appendix B because we went back and forth on how much to dilute the DTC stuff.

DR. KHOURY: It kind of lost the essence of Appendix B, in a way. By putting these kinds of broad recommendations, it doesn't give us -- maybe I should read the whole thing again. I got lost on what is important here, and you want the Secretary to act on prior recommendations. There is more urgency to act now because of DTC and all of these gaps and the oversight and other areas and lack of education, et cetera.

So, you give an extra nudge for acting on all of these areas. The registry would be great, because it forces people to deposit information. Then independent bodies like EGAPP will spring into action. All of these things could be highlighted.

So I don't think it will dilute. It may be just another way of presentation. People won't read Appendix B,

I can tell you that. They only read the executive summary. So unless Appendix B is in the executive summary, no one else will read it.

MS. AU: How about if Cathy and I take a look at that and see how much we can incorporate, bring forward to that? I want to bring this back to Steve.

DR. TEUTSCH: We have about half an hour, and we need to bring this, I think, to some closure. The idea was to wrap it up this time. We can do some formatting. I don't think we were talking about any real revision.

I've heard a number of points that can be emphasized and strengthened. We've talked about simplifying some of the recommendations, making clear that we see these as, generally, about health tests with some limited exceptions, but I think what we need to do is to now go through and figure out, are these the right things to say, and get to some agreement, hopefully, that we can send it forward to the Secretary so we don't have to bring it back to this committee again.

There are a lot of issues, as we know, in DTC. It's a moving target. There are some things that, as Sylvia indicated here, that we need to monitor on an

ongoing basis, and we may need to take up in a larger sense, but we need to get to a point here where we crystallize the things that we want to convey to her, basically, between now and our next meeting.

MS. AU: So I think the things that we have are definitely the preamble to the FTC Joint Advisory, what they are supposed to be doing, to make that clearer, the "Reality versus Claims" paragraph, I think that Jim talked about; the CLIA issue that we talked about that Andrea brought up with the enforcement.

Also, CLIA may be expanding their scope to these services that only use CLIA-certified labs but aren't really labs -- they are just the service that takes the data and does the interpretation -- whether CLIA should be expanded to include these type of companies.

Other than that, tightening some of the recommendations maybe, and putting in Appendix B, and formatting some of that up into the report.

Muin.

DR. KHOURY: So as part of this monitoring function that Steve alluded to -- I just don't see it in any specific recommendation -- to continue with evaluating

the real impact of DTC on consumer awareness, health impact, and so on, the kinds of surveys that CDC and others are doing, we need to do more of this because that is the only way we're going to find out what is happening. Maybe it's there and I missed it.

MS. AU: I think part of it is on the things that we haven't had prior recommendations on, some of the things like DTC testing on children, psychosocial impact. Those are some of the issues that the Committee might want to take up to make new recommendations for how the Secretary might want to monitor or address some of those issues. Those aren't addressed by some of our prior recommendations that we pulled out.

The recommendations that we have, does the Committee feel that these are the adequate ones? We're going to include the CLIA one. Other than that, I think that was the only additional recommendation that we talked about.

MS. WALCOFF: I'm not sure. What is the CLIA one?

MS. AU: What happens is that some companies contract with the CLIA-certified lab and they get the data.

The company that gets the data has no enforcement. They do the interpretation. Some labs do the testing and interpretation. So everything is covered under CLIA.

MS. WALCOFF: We are trying to recommend the statutory change to CLIA, or is that encompassed in one of the recommendations that we would try to do that?

MS. AU: In the oversight report, there is a specific recommendation about CLIA, the gaps, the gap that CLIA does not regulate those services. So we want to pull that recommendation out, which we don't have with us right now, but we know that there is that. Of course, Andrea knows that recommendation is in the Oversight Report.

MS. WALCOFF: Yes. I remember that and how that differs from the specific action steps that we have in the first --

MS. AU: I think it's just a more specific, explicit --

MS. WALCOFF: Just acknowledge that it's not covered by CLIA.

DR. FERREIRA-GONZALEZ: It's not clear that we also include in that part, because sometimes we talk about CLIA laboratories, they just look at that. We want to make

sure this is specifically addressed.

MS. WALCOFF: CMS can have oversight enforcement over CLIA -- I mean, through CLIA over this part that is not currently encompassed by CLIA, according to general counsel, right? So that would either be through statutory or regulatory change.

MS. AU: That's right.

MS. WALCOFF: Which I think is in there.

MS. AU: It's in the report but not the recommendation.

MS. FOMOUS: I think the other thing that we want to do is add to our list of prior recommendations, the one from the oversight report that calls attention to the fact that the issue that Penny pointed out where if the lab is not CLIA-certified or CLIA-accredited, their hands are kind of tied. They can't do anything.

We had a recommendation that addressed that in the oversight report that we want to include, that we want to add to this paper.

DR. BILLINGS: Do we need a specific recommendation that says that we need clarity about what a health test is? I mean, shouldn't the Secretary seek to

finally define that, let's say, a genealogy test is not a health test but everything else that these DTC companies are doing is.

MS. FOMOUS: I think that's sort of part of that recommendation that we had from the oversight report. It was really to bring together FDA and CMS and other relevant agencies to really kind of look at what we mean by health-related tests and what is the scope of each agency related to that. So I think it's encompassed in that.

MS. AU: I think maybe we just have to be more aware.

DR. BILLINGS: So we're not as a committee saying what we think the health-related test is. We're saying the agencies are going to get together and tell us what a health-related test is, is that right?

MS. AU: Well, these experts and the agencies, yes, but --

MS. FOMOUS: Reading from it, it says, "relevant federal agencies should collaborate to develop an appropriate definition of health-related tests."

MS. AU: So any other comments? Barbara.

DR. McGRATH: I wonder, maybe I'll put it out as

a proposal to discuss, addressing the issues that weren't reported on other reports, recommendations something along the lines of increased funding priorities to study outcome -- to evaluate outcomes -- let's see.

Priority for social and behavioral research to evaluate consumer outcomes or outcome evaluations, something like that. That would cover some of the -- then on to that could be -- sorry. Including dealing with certain populations, specific populations, research with children and stuff like that.

MS. AU: So that is one of the recommendations and one of the issues that SACGHS just could take up?

DR. TEUTSCH: It's also in the oversight report under the Clinical Utility, where we discuss exactly those issues about getting the information about the value of including those subpopulations.

MS. AU: Okay.

DR. McGRATH: I would just shut up. The social and behavioral research.

MS. AU: Under Appendix B. I'm going to bronze Appendix B for you and send it to the CDC. So we're going to add that then.

Other than that and our little reformatting, does the committee think that the -- oh, and Liz now.

DR. MANSFIELD: I just have a question about the one that was the advance notice of proposed rulemaking. Can you go to that recommendation?

MS. AU: Right here.

DR. MANSFIELD: So what is the rule? Do you want to make a rule specific to direct-to-consumer testing, that says we're going to treat direct-to-consumer testing differently than all other types of testing?

MS. AU: Well, this is what happened when the committee decided that we wanted to make our recommendations specific to direct-to-consumer genetic testing. This made it go from broad, go from genetic testing to direct-to-consumer genetic testing.

MS. WALCOFF: I think the idea was to look for an actual mechanism that might be possible within the current authority of the Secretary and of the agencies to address some of the gaps, like the one that Andrea just raised, the concerns that were otherwise not addressed.

DR. MANSFIELD: Would it require additional rulemaking?

MS. WALCOFF: Yes.

DR. MANSFIELD: You want to look for things that would require new rulemaking?

MS. WALCOFF: Yes, because it couldn't ultimately be implemented without some other kind of change. That's what my understanding was from the limitations of the current statutory and regulatory authority that CMS was saying in terms of the CLIA lab. I think it's a good example.

DR. MANSFIELD: And would these apply just to direct-to-consumer tests or would there be gaps that would be larger?

MS. AU: Under this report, they would only apply to direct-to-consumer genetic testing.

DR. FERREIRA-GONZALEZ: I think we said it very clearly in the report, that if there are issues, gaps, they go to all of genetic testing, not only DTC but also all types of services. So here, we're just bringing up specifications with direct-to-consumer testing, like this gap between managing the data versus the laboratory actually doing the test as an example.

MS. AU: So I think for us in the preamble, we

clearly identified that these are not issues only specific to direct-to-consumer genetic testing, but in the action steps, we really are trying to focus on direct-to-consumer genetic testing just because that is the subject of this paper.

As I said, we are hoping on the wisdom of the Secretary's Office that if they're looking at this, they say, well, if we're doing this, we might as well look at all genetic tests or a broader range of genetic tests than direct-to-consumer genetic testing. If they did that, that would be a bonus for our committee. If they only look at direct-to-consumer genetic testing, then that would be a start.

So seeing that everybody looks like they want to have lunch, this is perfect. I can hold them captive.

Does the committee -- do we take a vote on advancing this or do we just -- Steve, do we take a vote on advancing this?

DR. TEUTSCH: Yes. I mean, I'm not sure I can cite all of the changes that we have just gone over, but --

MS. AU: We've noted them all.

DR. TEUTSCH: -- we have all of the comments.

What we would like to do is to have the approval of the committee to finalize the report. I would suggest that it will go out to you one more time so that you'll see it and then that it can go forward to the Secretary.

MS. AU: And that would be, Cathy, going out to them in what?

DR. TEUTSCH: I don't know that we need a date

MS. FOMOUS: We had initially asked for --

DR. TEUTSCH: You want to go ahead and if you have -- let me ask first. Beyond the conversation we had here, do you all feel that you need to put in specific edits that you want to see? Will we get any if we do that? I can assume that most of the work is going to be done by staff, and why don't we aim then to incorporate all of that and get it out the third or fourth week of the month? No? When? Okay. When can you have it?

MS. FOMOUS: Before Thanksgiving.

DR. TEUTSCH: Before Thanksgiving with a due date before Christmas, aim to get it back before Christmas, probably mid December with any final changes, and then it can go out.

MS. AU: And the Secretary will have it for New

Year's.

DR. TEUTSCH: A New Year's present for the Secretary. All right. So all in favor of approval of this report and the process going forward, please raise your hands.

[Show of hands.]

DR. TEUTSCH: Paul said yes already. 14. All opposed. Abstain. Congratulations, Sylvia.

MS. AU: Thank you.