***Discussion of Draft DTC Resolution***
**Facilitator: Christopher Hook, M.D.**

DR. MCCABE: This is a nice lead-in to our next topic, which is direct-to-consumer marketing. This was ranked as the fourth issue of our top priority issues requiring in-depth study at our last meeting. However, the committee felt that the topic warranted an immediate response to encourage the Federal Trade Commission's efforts in this area. During the next hour we will consider and finalize a draft DTC resolution that was prepared by the DTC task force. The resolution can be found at Table 6 of your briefing book.

I'd like to thank Chris Hook for chairing this task force, as well as Brad Margus, Agnes Masny, Steve Goodman, Matt Daynard, and Tim Leshan for your service on the task force.

Before we begin discussion, I'd like to remind you that NHGRI organized a workshop on March 23rd to consider DTC marketing of genetic technologies and services. So at this time I'd like to ask Alan Guttmacher from NHGRI to update the committee on the outcome of your workshop, Alan.

DR. GUTTMACHER: Sure. Thank you. I'm happy to do that. I should note that Dr. McCabe correctly identified this as a workshop to consider DTC advertising. This was not, for instance, an NIH consensus panel meeting to come up with specific advice or that kind of thing. I think for many reasons it was not that, including the feeling that there had not been enough time perhaps for the field to really look at this to be able to come up with those final detailed kinds of recommendations.

However, clearly, we like the SACGHS, identified this as an area of some potential concern, so we gathered about 50 people together, and they came from several different kinds of backgrounds. There were genetics and other health professionals, there were individuals that represented health consumer organizations, there were individuals from federal agencies, both regulatory and non-regulatory federal agencies, and there were also individuals who came from various industry organizations, or actually industry both organizations and individual companies.

Basically, the morning was spent in looking at the data. We thought that it might make sense to base policy considerations on data, so we spent the morning looking at the data, what do we know currently, and you will see there's a workshop summary for you that's right after the draft resolution behind Tab 6. That you can see is a nice summary. The first four and a half pages go over the morning session, the data presented, et cetera. Then the rest of it describes the afternoon discussions, and you will see the afternoon was really informed by the morning data, a discussion of both the question of is there reason for concern here, and if so, what are the reasons for concern. Then also a look at how one might move forward.

You will see on the last few pages that there are three major areas where there was some kind of general -- I'm not sure I'd use the term consensus, but general agreement among the group. The first was that it would make sense to facilitate the development of a stakeholder consensus document or white paper outlining best practices for DTC advertising in the realm of genetic tests, and perhaps in genetic services as well. There was some discussion during the day about the distinction, as you just heard, between testing and services.

The second was to coordinate and facilitate the development of a formal petition to the FTC outlining the concerns with current DTC advertising practices for genetic tests. The third was research, including specific collaborations with the private sector, and the idea of developing a research agenda able to inform future advertising practices and any policy development.

So I would just call the summary to your attention. Take a look at it. We know that some of the people involved in the group that came up with the draft resolution were involved in this meeting, and I hope somewhat informed by it.

I'll be happy to answer any questions about the meeting itself if you have any.

DR. McCABE: So any questions for Alan regarding this conference?

Yes, Emily?

DR. WINN-DEEN: So not so much regarding the meeting but just what does NIH view as its next step? Are you going to stop with having convened this sort of state of the state kind of conference, or do you have specific plans to go on and make some consensus conference or kind of recommendation?

DR. GUTTMACHER: I think at this point we probably are waiting to see partly what this committee does; and then again, since our focus particularly is on research issues, I think we would be interested in developing and are planning on developing a more precise research agenda in terms of what are the research questions that need to be answered to enable good science and policy.

DR. McCABE: Yes, Hunt?

DR. WILLARD: Alan, were there any representatives there from industry?

DR. GUTTMACHER: Yes, there were. We invited a number. Some chose not to attend, and some luckily chose to attend, including, you'll see, there are presentations from Myriad.

DR. McCABE: So Myriad attended?

DR. GUTTMACHER: They did, and gave a presentation, in fact.

DR. McCABE: Yes, Kay?

DR. FELIX-AARON: Following up on the earlier question, were there representatives from the provider organizations, particularly not necessarily hospitals but physicians, because I would imagine that provider and clinician perspectives would be important here.

DR. GUTTMACHER: There were.

DR. FELIX-AARON: There were. And who were they?

DR. GUTTMACHER: I don't remember the names. We can get you the list of the people that attended, if you'd like.

DR. FELIX-AARON: All right. That would be very helpful.

DR. GUTTMACHER: Come see me afterwards.

DR. McCABE: Could you provide that to the committee as well, please?

DR. GUTTMACHER: Sure, we'd be happy to. I don't have any reason to think it's not a public document.

DR. McCABE: Thank you.

Other comments or questions?

(No response.)

DR. McCABE: If not, let's move forward.

Thank you very much, Alan.

I'd like to call your attention to the written public comments that are in your table folders in response to the resolution on DTC, and note the public comments we heard this morning.

I'll now turn to Chris Hook to lead the discussion on the DTC resolution.

Chris?

DR. HOOK: Thank you, Ed.

I'd like to begin my comments by thanking the members of the task force, and as Emily had acknowledged, our tremendous debt to Fay Shamanski and the staff for putting this document together on top of the significant amount of time and work that they had done on the other documents that we've been discussing. Thank you very much for that.

In fact, the process was relatively easy for the task force because of that. The first draft had been circulated for comment. Most of the changes were of a clarifying nature. There was some discussion that I should highlight again to make sure that the concerns were

addressed. Brad had raised a good point, and that was that as we bring these concerns forward, with the intent of this document really to encourage the FTC and the FDA and other agencies to begin to put these issues on their radar screen, we did not want to completely close the door on the possibility that there may come a time in which some of genetic testing could very easily be done in a marketer or provider direct-to-consumer relationship.

We hadn't necessarily acknowledged that we were at that stage, but we didn't want to close the door so that that was not a possibility. So as we get to that point in the document, we'll bring that up and make sure that others are satisfied with the language that keeps the door open to some extent in that regard.

In terms of reviewing this document, I would ask if the Chair would agree, because of its brevity, that we just read through it in its entirety so that, rather than starting to wordsmith paragraph by paragraph, we're all again reminded that perhaps a concern that someone has at a given point may have indeed been covered later on in the document.

Is that all right, Ed?

DR. McCABE: Sure, Chris. You missed the discussion yesterday. The document may show brevity. I hope our discussion can be informative but as brief as we can accommodate. Thank you.

DR. HOOK: Indeed.

With that, then, I will just quickly run through the document, and then we can begin the wordsmithing thereafter.

"Whereas the Secretary's Advisory Committee on Genetics, Health and Society is established to advise the Secretary of Health and Human Services on the range of complex and sensitive medical, ethical, legal and social issues raised by new technological developments in human genetics;

"Whereas scientists are daily discovering new genes that play a role in disease and health and developing genetic tests that help diagnose and predict disease, at the present time the majority of the more than 1,000 genetic tests available or in development focus on rare diseases or single-gene disorders. For many human genes, definitive links to a particular disease or health outcome have not been validated. We are only beginning to understand the basis of the complex links between genes, the environment, and common diseases or behaviors;

"Whereas recent marketing practices which can be directed at both advertising and selling genetic tests and services to the general public have included promotions in print media, television, and increasingly the Internet;

"Whereas there may be valid and appropriate genetic tests directly marketed to consumers, we are nonetheless greatly troubled that some entities are misrepresenting genetic information in order to recommend unsubstantiated health and dietary changes to consumers which in some instances may divert individuals from appropriate treatment options;

"Whereas examples of websites that market questionable genetic tests include those offering genetic profiling to assess risk for diseases such as diabetes or heart disease, genetic testing to predict risks of behavior such as addiction or impulsivity, and neutriceutical products tailored to an individual's genetic profile;

"Whereas SACGHS recognizes that many consumers value access to information about new health care technologies and products made possible through direct-to-consumer advertisements;

"Whereas the Food and Drug Administration, in its role in implementing and enforcing the Federal Food, Drug and Cosmetics Act of 1938, regulates devices to assure that they are not misbranded as a result of manufacturer advertisements and promotional labeling;

"Whereas the FDA currently does not regulate the marketing of genetic testing devices;

"Whereas the Federal Trade Commission Act grants the FTC broad jurisdiction over unfair or deceptive acts or practices and false advertisements for drugs, devices,

and services, including genetic testing services;

"Whereas SACGHS plans in-depth study of direct-to-consumer marketing in the future, the committee wishes to express concern at this time about marketing of genetic tests.

"As such and in light of the potential health consequences to individuals, SACGHS believes that genetic tests should not be sold directly to consumers without the informed guidance of an appropriately trained health care professional, at least at this time; and that in order to protect the public interest, we urge the Secretary of Health and Human Services to take the following steps to ensure that the marketing of genetic tests is appropriately overseen:

"Direct the FDA to monitor the marketing of genetic tests under its statutory authority and to continue to explore ways the FDA can enhance the oversight of genetic tests offered as services;

"Work closely with the FTC to act against those companies or providers engaged in misleading marketing of genetic tests;

"Engage other colleagues at the federal and state levels, and health professionals and test developers in the private sector, to promote the appropriate use of validated genetic tests and prevent their inappropriate marketing so that the full promise and benefits of these genetic technologies will be realized for the public good; and

"Encourage the public to discuss the implications of a genetic test with a health professional before seeking a genetic test."

DR. McCABE: Okay, so that's a quick read through. I take it that since Chris was not interrupted, it's accepted in toto?

(Laughter.)

DR. HOOK: So moved.

(Laughter.)

DR. HOOK: Actually, Deb was quite busy over here with her pen.

DR. McCABE: I'm sure that people were just being polite, Chris, and now we'll begin to move through it. Let's try and do this from top to bottom in some sort of organized fashion.

So if we could take "Whereas the Secretary's Advisory Committee on Genetics, Health and Society was established," I think that's straight out of our charter, so I don't think there should be a whole lot of discussion about the first whereas.

MR. MARGUS: I actually have a question about the title.

(Laughter.)

MR. MARGUS: Not to change the title, but a question I think the committee has to consider about the whole resolution, and that is that what we are really bothered by about marketing, because marketing is a very broad term, including advertising and/or selling and delivery, and while the marketing is what we have seen so far mostly, and that troubles us, under different scenarios, maybe not sleazy sensational websites, but if a major pharmaceutical company tomorrow had an ad like the Claritin ads, where they advertise, they have all the little fine print, and then they send you to a physician or a person who knows what they're doing, we don't seem to have a problem with that consumer marketing as long as it's being delivered through the right thing.

So if someone were advertising a genetic test in the same way but it was delivered with genetic counselors and everything, would we still have a problem with it? Are we having a problem with all direct marketing, or is it primarily the concept of selling or delivering the genetic test that troubles us? If that's what it is, then maybe we should be a little clearer and not just say broadly, globally marketing, but we should say it's the delivery part.

We don't have to change the title, but somewhere later on -- for example, after all the whereases, the first thing we say is tests should not be sold directly to consumers. So when we get active about it, we're focusing on the delivery, not that we mind the advertising so much. That kind of became less clear to me after the task force finished.

DR. McCABE: I'll let you respond, Chris, but I think it's important to recognize the point that Gail Javitt made in the public comment session, and that is that there is direct-to-consumer marketing and there's direct-to-consumer access to genetic tests, and those we always have to separate, recognizing of course that direct-to-consumer access is not really going to be terribly profitable unless there is recognition that this access is available, which is the direct-to-consumer marketing. So you can have direct-to-consumer marketing with or without direct access, but part of the concern with genetic testing is the access.

Looking at this, I thought that it was pretty straightforward and it did not confuse marketing and access the way I know some other documents have in the past. But I'll let you respond, then, Chris.

DR. HOOK: I would just echo what Ed just stated in that I think because we did focus on the access, that that was in our specific recommendations, that was highlighting what we thought to be the most important point of our concerns or the focus of our concerns. We could change marketing to break it down to say advertising and sales of genetic tests to acknowledge that we recognize the distinction between the two. But I think as you look at the whole document, it's the sales which comes through. So I don't know that we need to change that.

MR. MARGUS: I just wanted to emphasize that I believe the day is going to come, hopefully soon, when there really are legitimate tests that we may want to communicate to the public are now available, not that we want them to be delivered directly, and when those communications become more common, I don't think we're as much against them as we are against them direct access.

DR. WINN-DEEN: I think the other thing that we have to be very clear about are tests with an established legitimate medical utility and consequence, so either lifestyle modification or treatment or something that you do with that information, versus the thing that you bring up I think in paragraph 4, the tests that are being put out there with unsubstantiated claims or with specific recommendations for, say, neutriceutical intervention, which are not well established as medically useful and might prevent someone from seeking an appropriately validated medical treatment.

That, to me, is the thing that concerns me as well. So I think we've got sort of multiple scenarios, and I think we almost have to work through what is our stance on validated tests like BRCA1 marketed to the consumer. We have a very good case study with Myriad and that test to discuss. Then we've got the unvalidated thing marketed to the consumer. Do we even think that marketing message should be allowed to go out? And then the third is do we recommend or not recommend direct access to the results without the involvement of a health care professional?

DR. HOOK: Could I just reply to that? Then Cynthia, and then Ed.

I agree that ultimately we will need a firm and clear distinction between various scenarios, as you proposed, but I think we're ahead of where we are trying to be with this statement. In other words, we're trying to bring this to a level of awareness to the leadership of the FTC and to other government agencies. We have not gone through the full process that ultimately this committee will undergo where we will look at those various scenarios.

So my question to you, Emily, is the language of this particular document sufficiently obtuse or opaque as to be making firm statements already that we shouldn't be? In other words, at this point in the discussion, are we overstepping what we should be saying at this point?

DR. WINN-DEEN: I guess my concern is are we ready to have a resolution? Because a resolution to me is sort of a call to action, that you have something specific that you would like to make specific recommendations for action by the Secretary. If we're just informing -- I'm not sure we're totally informed as a committee on some of these things and ready to make a resolution. I guess that's my concern here, not that anything that's in this is an incorrect statement, but do we need to, instead of working on this as a resolution, work on it as what are the

specific things we're concerned about, where do we need to get information so we could for scenario 1 say this is our recommendation, scenario 2 this is our recommendation. I just don't know if that's a more productive way for the committee to operate than working through a resolution that I'm not sure we have the information at hand to actually make specific recommendations to the Secretary.

DR. HOOK: Cynthia?

MS. BERRY: Well, Brad brought up a good point which I hadn't thought about until he just said it. But if direct access is what we're concerned about, then it does seem to me -- even though I laughed when he was talking about the title, we probably should change the title maybe and have it be direct-to-consumer access instead of talking about marketing, and we could have in the whereas section an acknowledgement that the reason right now we are taking this stance against direct access to these tests and services is because there is misleading marketing going on out there. There are tests that just simply require interpretation by a competent health care provider, genetic counselor, and people need that in order to reap the benefit of these technologies -- and and and, we can sort of go on and lay it out, and then say therefore right now, we think that there should not be direct access, and we can come up with future recommendations.

Maybe there are going to be circumstances when we get additional information, maybe there are services or tests where direct access might be okay once we satisfy ourselves that it is okay. I agree with Emily that for some of these things, we probably don't have all of the information before us yet, but we probably can make at least this preliminary statement in the form of this resolution.

Conversely, if folks felt that we wanted to make a statement about marketing, because that is one of the conclusions at the end here -- it talks about working with the FTC to act against those engaged in misleading marketing -- then we could change the title to really include both marketing and access if we wanted to make that conclusion that we want to take a stance against direct access, but in the meantime there's this concern that we do have about misleading marketing that we want to work with the FTC on. I have no problem with that either, but I think we should probably clarify with a view towards going down the path that Emily has talked about, collecting additional information, because we probably need to make more specific recommendations once we get that information.

DR. HOOK: Ed?

DR. McCABE: I just want to remind the committee of why we undertook the process of drafting this resolution, and that was because of concerns about direct-to-consumer marketing. So access is an issue. I think this is really focused on the marketing. I think the one area where it could be confusing and we may wish to delete it so as not to open up other doors but to focus it on marketing is under the bullet one of the resolution, and that is the second clause there, "and to continue to explore ways the FDA can enhance the oversight of genetic tests offered as services."

Really among the resolutions, that's the only one dealing with services. The rest are all dealing with marketing, and part of the concern was the information we had received that indicated that there really was misleading marketing going on. Our interest in moving forward quickly before we did the in-depth study to give FTC primarily, but to some extent the FDA as well, the opportunity, based on this resolution, to within their agencies look into direct-to-consumer marketing, and particularly the misleading marketing.

MR. DAYNARD: My question for the committee would be do you believe that one of the aspects of misleading marketing is that it may fail to tell consumers that the intervention of the medical profession is necessary? Because if that's the case, then it makes a little bit more sense to me to include them both in here.

We had a situation once where there was a very low calorie diet being offered to consumers, and very low calorie diets require the intervention of a medical professional

because it can be dangerous to have an 8,000-calorie diet. You lose weight very rapidly and it can be obviously very dangerous to your health. But the advertiser wasn't saying that. It was just offering the very low calorie diet. But part of the marketing problem was that it didn't tell consumers you'd better consult a professional, you could be in deep trouble.

So if the committee thinks that part of the misleading marketing is that omission of material information, then maybe you ought to say so in here.

The other -- well, I guess that's enough for the moment.

DR. McCABE: I was just going to comment that I think that's sort of in there under the final bullet of the resolution, "encourage the public to discuss the implications of a genetic test with a health professional before seeking a genetic test."

MR. DAYNARD: Well, then I guess I'm just saying that it really isn't a distinction -- it is a distinction without a difference, because the access is part of the marketing issue. As long as the resolution focuses on the marketing, then I think you've got it right.

DR. McCABE: It does talk about that marketing practices, under the third paragraph, the third whereas, marketing practices can be directed at both advertising and selling genetic tests and services to the public. But again, then it reverts back to the issue about marketing. It says "have included promotions in print media, television, and increasingly the Internet." So I think that access is an issue, but this is focused on marketing, with the exception of that one clause in the first bullet of the resolution, which we could strike to keep it very focused.

DR. SHAMANSKI: I just wanted to comment on that third whereas statement. In defining marketing practices, we were trying to make it clear that marketing practices include advertising and selling, which includes access. So if it's not clear that access is included within marketing, we can clarify that. But I just wanted to point that out.

DR. HOOK: Matt, I'm sorry. You were tuning in there to her reply.

MR. DAYNARD: Well, because the FTC has no general distinction between marketing and selling. I mean, if you can sell the service without advertising, more power to you. But it's not likely. So anything that's said -- we're talking about a test kit versus coming in for a test, right?

DR. WINN-DEEN: No.

MR. DAYNARD: Tell me what the difference is between marketing and a service here.

DR. WINN-DEEN: Okay. A kit is regulated by the FDA, and it has very specific claims. Most genetic tests are marketed as services where the laboratory develops the reagents themselves, and then they can market that test for whatever purpose. I think that's the issue, that most of the marketing issues are not around kitted reagents, products that the FDA has reviewed. They're around home-brew lab-developed tests that the lab is in some way taking on a responsibility to create a clinical utility, which may or may not be real.

MR. DAYNARD: Okay. I just wanted to point out that as far as the FTC is concerned, there's no distinction. If you advertise a test kit or a service, it's all in the same --

MR. MARGUS: But there has to be a difference between if you advertise and then people can buy it directly from you, or if you advertise and then people have to go through a channel like a physician to get it, or a genetic testing center or something like that, where you're going to get counseling. From the advertising point of view I know it doesn't matter, but the question we had are what are we most concerned about.

Just to be clear, if we want to cover it all, then I think we should just leave it as it is. That one sentence Ed had said to change is a good idea. But in business school, marketing includes the delivery. It includes not just the promotion and the advertising, but also the delivery, the access. My only question at the very beginning was if you don't really have a problem, if you really think about it is our biggest problem the access part, not the advertising, in which case we should make it more clear. But if we want to cover it all, and since the biggest

point Chris made is that this is just the resolution to get it on the radar right away, we're telling them that we're going to be deliberating much more, why don't we just say marketing and we'll get back to them on what parts we really care about later.

DR. HOOK: And just to reinforce Brad's comment, I think that there are elements of delivery, as well as advertising, that can be issues of concern for us. So the broader language isn't necessarily inappropriate for our larger set of concerns. Again, I'm hoping people are not looking at this as the final statement of our conclusions about all the different permutations. That work has to be done. But if we're going to partner with the FTC and others, they need to be encouraged to spend the time and the labor to get some of the data we need to make our final recommendations, and that's what the purpose of this was.

Debra, and then Ed.

DR. LEONARD: Well, Gail Javitt pointed out that there is state to state variation in whether you can market medical services directly to consumers. So I think that has to be taken into account as we decide what blanket kind of statements we're going to make, and maybe the marketing of genetic states has to be consistent with state regulations, unless we want to override those.

What? Oh, sorry. I thought there was a comment back there.

The other concern that I have is that once the whereases are done, we're very strong about saying that genetic tests should not be sold, and we're specifying the selling part, directly to consumers, but I don't see anything in the bullets that is a mechanism for achieving that. So especially the last bullet, which is "encourage the public to discuss the implications of genetic tests with a health professional," and it's not clear who a health professional is, because many doctors don't even know how to interpret genetic test results, "encouraging" is different than "should not be sold directly to consumers." I think that we wimp out in the bullets, basically.

I don't know why we can't just make the statement that's the beginning of the paragraph it if we're going to do further investigation. Maybe, following up on Muin's comment, ask the CDC to start collecting information in the public health interest of what marketing is going out to consumers and if there's harm, et cetera. But basically have two bullets, one is that it shouldn't be sold directly to consumers, and ask the CDC to collect more information to inform out future discussions.

DR. McCABE: Well, I was going to, I guess, wimp out completely, then, since we hadn't addressed that in the bullets, and remove that and take the first sentence of the lead-in paragraph to the resolutions and say, "As such and in light of the potential health consequences to individuals, and in order to protect the public interest, we urge the Secretary", and take out that about the selling, because I think that brings us into state issues about differences state to state, and what we were really trying to do was get something quickly out to the Secretary to make some recommendations to those agencies that fall within his purview, which here was directed at the FDA.

I think if you wanted to include some sort of monitoring of direct-to-consumer marketing of genetic tests, that would be good in a bullet, and that could be covered here. But I think it's important that we keep this tight and focused so that we can get it out quickly.

DR. HOOK: Emily, and then Hunt, and then I'm going to suggest a procedural approach thereafter.

DR. WINN-DEEN: Just listening to the discussion, it sounds like what we're really recommending is not that we direct FDA to monitor but that we basically declare a moratorium on direct marketing and access to genetic tests until such time as we can come up with some very specific recommendations for the appropriate level of -- I'll call it oversight, but I don't want to confuse that with the sort of standard lab practice oversight.

But we need to have some very concrete recommendations for the different

scenarios. So for the scenario of an established medical utility with a reputable provider, how do you know when a test should be allowed to go directly to a consumer or when it needs to involve a health professional? We need to discuss that in depth and come up with a recommendation. Are there any scenarios where a consumer should be able to get direct access, and what are those?

Then the next level, which is to me the most concerning, are the tests which are being falsely advertised. So they're making claims and/or recommendations which are not substantiated. We need to have a mechanism for policing those things. What is the right mechanism? Is that FTC? Do we just send all that stuff over to Matt and hope that he has some time to deal with it? How do we get to those things? I've seen some of them that I personally find extremely concerning, primarily because they're recommending alternative therapies when there are good established, FDA-approved therapies available which are not mentioned.

So I think I'm a little concerned about direct to the FDA to monitor the marketing of genetic tests as our first -- it sounds, first of all, very directive over an agency which has waffled on whether it even really feels it has the authority to regulate the delivery of information from clinical laboratories. So I'm not sure this is the right time to try and tell it that it must take that authority in hand. But we need to have some clear statement here about for the time being, this should not be done, period, and what are the circumstances under which we would recommend moving away from this should not be done, period, to where is it appropriate.

DR. WILLARD: I guess I'm coming down on a similar side. If I was the Secretary, I'd look at these four bullets, and it's not at all clear what I'm supposed to do, and none of them has any teeth, so it does come off as a very wimpy sort of approach. The closest one to a true action item, other than hopefully give Matt a bigger budget, because we heard at the very first meeting that he can't possibly do all this stuff, so telling the Secretary to tell Matt to do all this stuff isn't going to be very effective.

The closest one is the last bullet, although the language "encourage the public" is not very meaningful. I mean, are we asking for an advisory bulletin? Are we asking for a moratorium? And if we're not ready to say what we want because, after all, we need to study this, and we've already said we want to study it in depth, then perhaps we're at the point that Emily made 10 minutes ago, which is that we don't really need a resolution because we're not resolving anything at this point. We're not resolute in anything until we've done the in-depth study.

DR. HOOK: At this point, I see us potentially going through a couple of approaches. I think that, one, I'd like to clarify, because there's a whole variety of proposals about what this statement is supposed to be accomplishing still circulating among the discussion, and I think we have to come to closure on what it is that we're going to achieve today and what it is we're deferring to a larger amount of effort and intervention in the future.

I would submit that we are, again, attempting to assist Matt and his colleagues and others in getting this to be an issue of consideration by the government. I think this is an opportunity to ask our colleagues in public health to begin collecting the data, as was previously mentioned. I think that we are suggesting that, at the present state of the art and practice, we can change the language to be more firm, but that genetic testing should be done in the context of a relationship with appropriately trained health care providers who can help to know whether it's worth doing the testing or how to interpret the results of that testing.

In terms of going down the road of taking each possible permutation, obviously we're not there yet. But I don't believe that we have to have that information in order to go forward with this discussion.

So I would propose, with the Chair's comment, that we at least quickly review the paragraphs of the whereases, the background information, the fact set that's bringing this question forward. Are there any modifications we need to make to those statements? And hopefully we can do that briefly, and then spend the remainder of our time wordsmithing at least the bullet points at this time as to what we think is appropriate.

Yes?

DR. McCABE: This is Elizabeth Mansfield from FDA.

DR. MANSFIELD: FDA. I'd just like to make the comment that I think that FDA has probably very limited jurisdiction, if any, to monitor the marketing of genetic tests over which they have no oversight. I don't believe that we can do that unless somebody decides that we will have oversight over these tests.

DR. HOOK: Forgive my ignorance, but don't you have oversight monitoring over pregnancy tests and things of that nature that are directly marketed?

DR. MANSFIELD: We have oversight over test kits but not over laboratory-developed genetic tests, which is the majority of genetic tests.

DR. McCABE: But it says "under statutory authority," which would mean at this time kits.

DR. MANSFIELD: We do monitor the marketing of kits, and so far that hasn't been a serious issue.

DR. HOOK: So when a direct-to-consumer marketer of genetic tests sends a packet out to collect a buccal swab and to return that information, are you monitoring those and giving them approval to do that?

DR. MANSFIELD: Not unless the kit has been cleared or approved by the FDA. Most of those direct-to-consumer are lab-developed tests and are outside our regulatory authority at the moment.

DR. HOOK: But then you would have regulatory authority to step in to make sure that the collection mechanism is appropriate. Is that not correct?

DR. MANSFIELD: No, not that I'm aware of.

DR. HOOK: It's a marketed kit for the collection of --

DR. MANSFIELD: Right, but we don't regulate laboratory-developed tests, so we don't have any jurisdiction over how they're marketed.

MS. HARRISON: Just a point of clarification. Would it be that the collection itself was monitored but not the test that's done on it? Is that the --

DR. MANSFIELD: Collection devices are regulated as collection devices, how they perform; for example, blood tubes and so on. But the actual collection of the sample by whoever is not.

DR. McCABE: I guess before getting into the details on this and spending a bit of time on it, I would just ask our ex officios whether they -- the purpose of this was to assist the ex officios in the interim while we developed a more complete report. So I would ask the ex officios whether they see any value in developing this resolution. If it is not going to be of any value, I think we need to then consider next steps.

Is that okay, Chris?

DR. HOOK: Matt?

MR. DAYNARD: Well, first, I can't speak for the FDA, of course, but I deal with them every day. As you know very well, their charge is to protect the public health and safety. If the committee's concern is the public health and safety in the direct-to-consumer marketing or delivery of these tests, I might suggest you want to make a stronger recommendation now or later to the Secretary to try and get implemented a change to the FD&C Act. I mean, if you don't have authority over these things, it's going to be very difficult for the FTC under any circumstances to do the kind of job you'll want to get done without the help of the FDA, because we can't do our job anyway without the help of the FDA in many other areas.

So that's important. All throughout this I've been wondering, and folks at the FTC have been saying, well, this is really FDA's job. We're talking public health and safety here, aren't we? Why should we be concerned about marketing? I have a decent response for them, but it's not a complete response because they're likely to feel just that way, that if the committee's concern is public health and safety, then, darn it, the FD&C Act should cover them.

But yes, I do feel that a resolution is important because the FTC at some point should be involved, and maybe in the near future this resolution will help get it on the FTC's radar screen. So I am in favor of it.

DR. McCABE: Taking Matt's comment, would it be appropriate, if we decide to move forward with this and just keeping track of these things as they come up, to change the first bullet under the resolution, "Direct the FDA to monitor the public health and safety impact of the marketing of genetic tests under its statutory authority"? Is that something that would be more acceptable, Elizabeth?

DR. MANSFIELD: I don't know that we have any statutory authority to do that now, but if it were to change the Act, if your intent is to get the Secretary to change the Act, then possibly yes.

DR. McCABE: Our concern is for the public health and safety. That's why we decided to move forward with this resolution and we felt that it could not wait for the in-depth study.

DR. MANSFIELD: Yes, I understand that. However, at the moment, lab-developed genetic tests are considered to be practice of medicine or a service, and we don't regulate the practice of medicine or services. So the Act either would have to be changed or someone's mind within the FDA would have to be changed in order to give us oversight.

DR. McCABE: Well, is a better way to go, then, to say "Direct the CDC to monitor the public health and safety impact of marketing of genetics tests"? I mean, if this isn't going to be helpful to FDA, and if we're concerned about the public's health, then perhaps we move it to look at another agency.

DR. HOOK: Please, Paul. Go ahead, Paul, and then we'll go down the list here.

MR. MILLER: This is not particularly my area, but in listening to the conversation, two things sort of strike me. One is that what you might think about doing, if the FDA is an HHS agency, and the FDA is not sort of embracing regulatory authority in this area, is that within the Secretary's purview to interpret the statute in such a way that the FDA does have regulatory authority? Is there enough leeway within the statute? Then, in fact, that would be an action resolution, to say that we recommend to the Secretary that the FDA be used in this way because there is a health and safety issue, there's a gap, and we think that the Secretary should interpret the enabling statute in that way.

I'm not sure sort of the authority of that, but that may be one path to go down or one roadmap to go down, so to speak.

The second thing is that if in fact there is no leeway in the FDA's enabling statute, then it would strike me that that is sort of the problem. Then that would, in a sense, be a recommendation for the Secretary to sort of engage in a legislative agenda to change the statutory authority of the FDA to get them engaged in that such that the FDA would clearly have jurisdiction over these issues, which I think is the sense of this committee, and would enable FTC and FDA to work -- so that the issue doesn't fall through the cracks.

DR. HOOK: In an immediate reply to that, I think that a way to communicate that is in the second portion of the first bullet, to explore the potential need and ways for the FDA to enhance the oversight. We're trying to expand their jurisdiction in that.

MR. DANNENFELSER: If it sounds like there's a general consensus that they should do this if they can do this, I would suggest not changing it to direct the Secretary to make a certain interpretation. That may not seem appropriate. But it certainly would be appropriate for him to ask the general counsel to explore what authority the FDA may already have, and if it's limited to then seek further legislative authority if that's necessary.

DR. HOOK: Joan, then Debra.

DR. MANSFIELD: In fact, it is a question of interpretation, what is a medical device, and our general counsel has pretty much come down, to my knowledge, that in-

house developed tests are not medical devices. They're services already. I believe the Secretary could probably affect that interpretation if he chose to, but currently that is the interpretation of general counsel.

DR. HANS: Is that an opinion that's been put out in the public that you could provide to the committee?

DR. MANSFIELD: Actually, I don't know.

DR. McCABE: We have been told in previous meetings that it was still under deliberation but that no opinion had been given. So if that has been an opinion that has been given, it would be helpful to this committee to have that provided to us.

DR. MANSFIELD: Well, perhaps I'm overstepping my bounds in saying that, but to my knowledge that is the interpretation that general counsel has made, and I will find out if that's available to the public.

MR. MILLER: But that's an important issue that really needs to be fleshed out as a starting point for this discussion and for the committee to understand where it needs to go.

DR. HOOK: Joan?

DR. REEDE: I think there are two points. One, I think fleshing this out as we go through our conversation here, this need to reflect the fact that these issues are getting fleshed out, that there are assumptions about what is marketing versus advertising versus direct selling, there are issues about what's the purview of this organization versus that organization, and I think the conclusions of this discussion are not reflected in here. It just leaves the next body to have the same set of questions being asked.

The second part is that I think a lot of what is driving some of this is the need to monitor or to know what's going on in terms of the testing, not the test kits per se, which the FDA is monitoring, but the testing. When I look at the whereases that leads to this, there's nothing that really reflects the fact that we don't have a current mechanism for monitoring what's going on with regards to these tests and the public health, and I think we need that background to lead to a bullet about CDC or anybody else doing that monitoring.

DR. HOOK: Debra? Kay?

DR. FELIX-AARON: In terms of listening to the conversation, I recognize the tension that was stated earlier between whether this committee is ready for a resolution or not. I would like to propose that the committee suggest that if not a resolution but a communication to the Secretary would be helpful. I certainly appreciate the reservation of the committee in thinking that whether the level of discussion is at resolution, but I think there is also value in communicating to the Secretary that those issues are coming up, that the committee is deliberating those issues and would prepare the Secretary for a future resolution if the committee did arrive at that resolution.

DR. HOOK: Deb, then Brad, then Emily.

DR. LEONARD: I am very concerned as a laboratorian who does laboratory-developed tests. We prefer that term instead of home brew, but we can't seem to get it out there. Laboratory-developed tests are regulated under CLIA. So I think we need to be very clear about what we're talking about. It's the direct-to-consumer marketing that's the issue on the table here and not general oversight of all laboratory-developed tests that may be done under CLIA, and that's not clearly differentiated when you make statements about ways the FDA can enhance the oversight of genetic tests offered as services, because my laboratory and many CLIA-certified laboratories offer genetic tests as services because they aren't done through FDA-cleared test kits, but they aren't marketed directly to consumers. They are used in ways that would not be questioned by this committee. They're ordered by health professionals on behalf of consumers to make a diagnosis, et cetera.

So I think any communications have to be very clear that we're not moving into this area of oversight of laboratory-developed tests, which is regulated under CLIA.

MR. MARGUS: Mr. Chairman, I need to interrupt for just a second. I have to actually run to the airport, rush to the airport. Inasmuch as this is my last committee meeting -- I'm rotating off -- I wanted to interrupt and just say to everyone that I've appreciated being on the committee and I've been honored to be on the committee, and I've appreciated everyone's tolerance of my naivete over the last year on certain points. Many of you probably have never seen a professionally trained -- what do we call them? -- appropriately trained health care professional on genetics, but I think all of you should.

I'm now going to leave the committee and go read my horoscope and take action without any advice from a professionally trained advisor and maybe buy a beer without a professionally trained advisor, and maybe drive a motorcycle without a helmet and buy some prescription drugs on the Internet without any guidance from a professionally trained advisor.

But anyway, I have appreciated it. I'm sorry to interrupt, but I did very much appreciate this year. Thanks.

DR. McCABE: Brad, we very much appreciate your service on the committee as well.

MS. CARR: Before you go, Brad, I just wanted to say that we hope you come back to the October meeting. Both you and Kim, your appointments were expired officially in January, but you've been extended, and until we have a replacement for you, we hope you'll both come because, for one thing, you've got to get your certificate.

DR. McCABE: And just to point out, you've been chaired by also an expired Chair, because likewise my term as Chair was up. So just as I'm continuing to chair as you head off to the airport, we hope you'll come back.

MR. MARGUS: So I guess I'll hold off on all that decadent behavior after all.

(Laughter.)

MR. MARGUS: Thank you.

DR. McCABE: Thank you, and have a safe trip.

DR. HOOK: Emily?

DR. WINN-DEEN: It seems to me that what we need is we need to be very clear that what we maybe are asking for the Secretary to do is to clarify for all who or which agency has the authority to regulate false and misleading advertising and delivery of services to the public. We're not concerned about things delivered through the right health care channels, through CLIA-certified labs. This is my concern, that there are CLIA-certified labs that are also advertising things for which the clinical utility has not been established, for which many of us in this room might say they are making false and misleading claims, and I think we need to be really clear about who is the policeman for that, and I don't think anybody here knows.

We've had a discussion is it FDA if it's a health and safety issue? Should it be FDA? FDA, as a result of the SACGT recommendations, had a pretty clear re-look through their general counsel at what they believe is their statutory authority, and I think Steve Gutman has repeatedly said to this committee that the current belief within the FDA is as Elizabeth represented it today, that they don't believe they have the authority to regulate lab-delivered test results.

So who does have the ability to regulate that, and who should we turn to when there's an issue? I think that's one thing we have to ask the Secretary to clarify, and maybe the way they clarify it is by looking with their general counsel through all the different groups and find out if this is a loophole or if there is some group that just really hasn't been given this as a charge.

So I think that's one thing I'd like to get on the table. The other is that I think that in the paragraph that precedes the bullet points, that we really should pull out the bullet point which reads "SACGHS believes that genetic tests should not be sold directly to consumers without the informed guidance of an appropriately trained health care professional, at least at this time." We should make it very clear that that is our key recommendation, and the rest of the

things we're looking for some clarification, guidance, and data gathering. Who is the right group to do the data gathering? Is it CDC? Who is the right group to look out for the health and safety of the general public? Is it the FDA? We just need that very clear so that that can be communicated.

DR. McCABE: Judy has one comment.

I think you're volunteering to take this on, Judy? Is that right?

MS. YOST: Actually, my comment is different. I'm just agreeing with Emily and agreeing with Kay in that I think that this recommendation, or whatever you want to call it, this resolution, is too conclusive for what we know. So I think that you are, to me -- and this is my personal, not CMS, opinion -- that I think you're interfering with individuals' and the public's freedom of choice here without having enough information to determine that. So I think that the most we can do is what Kay had suggested, send some kind of preliminary statement to the Secretary about our concerns and that what we suggest could be done, including explore whose responsibility this is sort of thing.

But I think that that is way far too definitive for where we are. I don't think we have enough information to stop the public's access to information on the Internet, which is something that's kind of broad. I think the point is --

DR. WINN-DEEN: No, I wasn't suggesting we stop their access to information. It was the delivery of health care results to them directly.

DR. McCABE: What I'm going to do, because our lunch is --

MS. YOST: But there are laws that do require that the public does have access to health-related information, like HIPAA. I mean, there's nothing wrong with encouraging that -- whatever term you want to use, caregiver, health care professional, whatever. You can certainly encourage that that happen, that there be an interface between that public and a health care professional. But I don't believe that you can just recommend stoppage completely of this kind of service, because there is, as you suggest, a hierarchy there. There are perfectly legitimate tests, and we don't have enough information to say whether or not they should include the intervention of a health care professional directly or not.

So since we don't have that hierarchy, I think to do a blanket statement is way too, to me, very strong at this time. That doesn't mean that maybe if we have further data or information that indicates so, that we shouldn't proceed. But I think this is way too preliminary at this point.

DR. HOOK: A quick reply from Sherrie, Joan has a comment, and then I'm going to turn it back over to the Chair.

DR. HANS: Just quickly, reflecting on this discussion and not the previous meeting but the one before where you were discussing with the FTC these issues, it seems that the grave concern and the concern for immediate action that brought you into this discussion really was the false and misleading advertising, and there are many other issues that have sort of come out here that I think the committee intends to pursue much further over the next year or so.

So perhaps what you simply want to do at this time is to just focus on the false and misleading part and encourage the Secretary to work with the FTC or the Secretary to direct the appropriate HHS agencies to work with FTC on that piece of it, and let him know that you'll be coming back with various other issues, because that's also where you actually have an oversight mechanism right now. In access you have no mechanism to begin to address. You can say that folks shouldn't be directly accessing these tests without an intervening health professional, but there is no regulatory/statutory mechanism that you have at this time to get at that, and that doesn't really provide the Secretary at this time with any idea of how to proceed since there's no regulatory hook, if you will.

So my suggestion is that you just focus on the very narrow concern that really raised this issue as something you wanted to deal with immediately at this time.

DR. REEDE: My comments are along the same line. As I've listened to more

and more of the discussion, I'm at a point where there are more questions here than there are answers. I think for us to try to draw conclusions with these questions out there and a lack of clarity among all of us I think is premature. So I think, again, being able to follow up on this, the issues are around the sort of false advertising, et cetera, being able to speak directly to that.

I think there is a place to say we need to collect more data, more information about the extend of this or how it might be impacting the public. But to go beyond that, I really feel uncomfortable because there are too many issues that have been opened that I don't understand the ramifications of.

DR. McCABE: Well, thank you, Chris.

The sense I have of the committee is that what we -- and I'm going to make a proposal and then see if this is acceptable. Rather than taking this as a resolution, take it as a letter to the Secretary informing the Secretary that we have had this information presented to us, that we are concerned about false and misleading advertising, that that is the issue, that our concern is that it's not in the public's benefit and perhaps to the detriment of the public's health, that we will be gathering more information, that we would like to have the Secretary identify ways that agencies under his jurisdiction can begin to work to identify what the impact of this is, and suggest that the Secretary also needs to have agencies work with the FTC to deal with the issue of false and misleading advertising.

Is that acceptable? Is there anyone who disagrees with that approach?

(No response.)

DR. McCABE: So we'll use some of the background from the resolution, but of the resolved parts we will only deal with the single bullet concerning false and misleading advertising.

Yes, Chris?

DR. HOOK: Well, to the extent I think a number of very valuable suggestions and observations have been brought up today, that we could bullet as clarification information gathering recommendations and a whole variety of actions that will be necessary for our subsequent deliberations. But we ought to at least put forward the request for that now in very clear terms based upon just the areas that need to be resolved from our own discussion this morning.

DR. McCABE: I think what I would ask staff to do is take the discussion and help to inform us, but we'll leave that in the letter to the fact that we're planning to do an in-depth study and include those as aspects of the in-depth study. We'll inform the Secretary that we're planning to do the in-depth study. Is that okay? Is there anyone who disagrees or has any comments on that approach before we break for a very brief time to gather our lunch?

(No response.)

DR. McCABE: If not, then I will consider that the silence is empowering us to write that letter to the Secretary, and I will send it out before the next meeting.

Thank you very much, Chris and the task force members, for helping to move us forward on this very important area.