Planning for June 2006 SACGHS Meeting and Concluding Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: Actually, by the way, we're going to wind up ending early, probably, but we'll see.

Did I catch you too quickly there, ma'am? We're going to just ask you to revisit very quickly -- we've got a technical emergency here. We're going to ask the committee to take a look at the priorities, and let's just go back and review that real quick.

Let's take the first one, which is genetic discrimination. By the way, the goal of this discussion that we're trying to get at here is based on what you just heard. We were asking the question of what is our bandwidth. What is the ability of the committee to juggle how many balls simultaneously. I want you to be looking at this list for not only what's on it but also any glaring errors of omission, making sure that we're not being ostrich-like with our head in the sand and are missing a major challenge that we want to start paying attention to.

So the genetic discrimination, we are pretty well moving forward. We've discussed that pretty much. I don't think there is -

DR. LEONARD: We're missing one of these overarching things down at the bottom.

DR. TUCKSON: We're going to scroll. Great.

So genetic discrimination. I don't think other than the committee having a couple of conference calls, this is not a major time constraint for staff and/or the full committee. The subcommittee's got a little work to do, but it's not overwhelming. Am I missing that?

MS. CARR: Well, you want to have a meeting of the Chamber, the Coalition, and -

DR. TUCKSON: But I'm saying those are conference calls, and that involves a couple of members of the committee but not the full committee.

MS. CARR: Yes, correct.

DR. TUCKSON: Although it does take staff time and I don't want to diminish it, it's not an overwhelming commitment.

MS. CARR: Right.

DR. TUCKSON: All right. So we're wrestling that one forward.

Number two is genetics education and training. That's sort of a consistent across the board for us, and again, Sarah, you'll check me but not involving a lot of time at all. It's part of just built into everything that we do.

By the way, that being said, let me be provocative on these as we go through. The committee has always identified the concern about how do you get the profession ramped up to be prepared to manage and handle this new era. Those of us that went to med school, we didn't even know what a gene was, darn near. It is still, by the experience I have, difficult to get clinicians to go to

continuing medical education programs for genetics unless it's very, very narrowly defined. It's still tough.

PARTICIPANT: Or in Barbados.

(Laughter.)

DR. TUCKSON: So one of the things that I don't know whether or not there ever needs to be, and I'm not calling for it but I want to raise the point, is should we ever take this off of the built into every stuff kind of deal and turn this into its own priority. I'm not advocating. I'm just raising it, especially trying to catch the new members of the committee up to sort of how we got to this list. We again decided not to make it its own thing but to build it into everything.

MS. AU: Reed, as part of this, did you include genetics training for genetics professionals? Because, obviously, we are starting to feel a pinch in that area.

DR. TUCKSON: Yes. Actually, that was a workforce concern, and it's a great point, Sylvia. We have alluded in numerous things, including in the coverage and reimbursement document, being concerned about the numbers of counselors. One of the things that we can supply for you is an awful lot of testimony on behalf of the genetics counseling community as well, who have been really leaning on this issue. So you've raised an important one.

Patents and access we have just discussed and are looking now to elevate that even more into what we're doing.

Oversight. This issue of oversight is one that I want to raise up for -- maybe what I'll do is go through them all but come back to the oversight one, and some of the members of the committee who have been around a while might want to also get ready to comment on this when we come back to it.

The original committee, the original SACGT, whatever it was back then -- what was it called? SACGT, the original one -- did spend a lot of time on this oversight issue, CLIA, the FDA, yadda yadda. So we've got it back on this list, and we did have some gentle review of it a couple of meetings ago. The question becomes, based on what we sort of heard, some testimony yesterday, do we want to revisit and look at any of that oversight stuff and see what's falling through the cracks a little more carefully. So I want to make sure that we decide one way or the other on that.

The vision statement is straightforward.

Coverage and reimbursement now out. The key thing on coverage and reimbursement is the dissemination.

Sarah, press release? Yes, no? Don't know?

MS. CARR: Don't know.

DR. TUCKSON: We have written a press release. It is beautiful. It's gorgeous. So if it never comes out, too bad. We can email it to you all and you can just marvel at how wonderful the press release was.

The point is that I feel a very heavy responsibility to this committee, and I feel like I have to advocate and fight for my committee, and the fight that I have to have for you is that if you put that much energy into that report, everybody in America needs to read it. So I am basically saying to Sarah and the team that I expect us to do everything in our power to try to get the government to put pressure so at least everybody knows about the report and can go online and get it. Now, there may be a lot of rules why we can't, so I'm just going to tell you that I'm going to irritate people to the point where I lose the battle. But if you're going to put in months and months and months and months of work on this thing, we're going to get people to look at it. I'm not interested in doing reports for shelves. Otherwise I don't have any point in being here, and I'm sure you feel the same way.

I also need you to, again, assign yourselves accountability for disseminating the report. Meanwhile the staff has done a good job. We've got 8 zillion people who are going to get it. So as far as I'm concerned, coverage and reimbursement is moving forward. We'll get the report out there. We will have, I'm sure, Sarah, a report back. You'll help me with that.

Who is our subcommittee chair? At some point I think you might want to be assigned responsibility for sort of seeing what was the reception of the report, did it get out there, do we have some way to monitor what the effect was, if any, so that we will know if we need to come back and revisit it and do some other refreshment of the issue. Okay? But basically, by and large, for practical purposes, coverage and reimbursement is off the table for us pretty much now and has got a life of its own. It's out there making its way as our child.

Large population studies. We've had a lot of discussion about that and we clearly do have more work to do there. The subcommittee will need to meet as a committee shortly to determine the next steps in terms of the timing of it. We're particularly waiting to hear some guidance from Dr. Zerhouni, which we are waiting to hear. We've queried him since this meeting is going on and waiting to get an opinion back. We are not going to try to rush a public study out into the hands of the public. You've got 12 hours, public, to respond, and we're going to write that up as an official report. I think we've made the sober determination that we have never violated our integrity with the public in soliciting mature comment, and we're not about to start now to try to just ad hoc something out there just for the sake of ad hocing it. It's not right, it's not fair, and we're not going to do it.

So at the end of the day we are going to determine what the timetable is for legitimate weighing in and what we might reasonably do, and our subcommittee is going to come back and advise us. So large pop is on the table, and there is work that we will be engaged in, so we need to put that in our workload.

The pharmacogenomics. Who wants to describe what you think the workload is for pharmacogenomics going forward?

DR. WINN-DEEN: I think what we need to do is to take all of the discussion that we had and come back and translate that into potential recommendations for us to discuss as real recommendations at the June meeting. The task force report, where we have an outside group helping us with the actual writing, we'll have as a draft May 1. So I think we should have a reasonably complete first draft of the work product at the June meeting. Then I guess after the June meeting it would probably go through the normal finalization of that draft, public comments, and then finalization after public comments. So it could still be some time, but hopefully at the end of 2006 we could potentially have it out. I think that's sort of what we're aiming for right now.

So there will be work for the task force between this meeting and the next one, and then there will be work which will include staff, and then between the June meeting and the fall meeting there will be a lot of staff involvement to get the public comments and then organize them and digest them into something that we can deal with at the fall meeting.

DR. TUCKSON: So a significant bolus of work. This is a major priority, and it took a lot of effort. So that's one that's going to occupy a lot of energy, and our receptor sites will be saturated.

DTC marketing. I continue to be very excited, and I want the committee to be excited by the fact that here was a great example, at least at an early stage, and we've got more work to do on it, where we called the question, organized government, challenged government, government reorganized itself, new relationships, new synergies between agencies who are now tackling the problem.

I think that's good. I think we ought to count that in our win column as being good.

DR. LEONARD: Given that it looks like they will have certain actions coming out, could we ask for an update on that from that group at the June meeting?

MS. CARR: You might want to also hear from the group that the CDC is heading up, which is developing some plans for assessing the public health impact as well.

Linda, do you think CDC might be ready to report out in June?

DR. BRADLEY: (Inaudible.)

DR. WINN-DEEN: I think Steve said that they're going to have their advice to consumers letter written between now and then. Is that what you mean by letter 206 DTC marketing?

MS. CARR: No. The consumer alert is something that's in development. That's a letter we wrote already.

DR. WINN-DEEN: We probably should have something up there that that's the next deliverable, the joint FDA-FTC consumer alert. That's sort of what we're looking for.

MS. CARR: But do you think of that as our deliverable?

DR. LEONARD: We can have an update.

MS. CARR: Oh, an update. Yes.

DR. LEONARD: From FDA-FTC.

MS. CARR: Yes, but remember there are two groups that use (inaudible), really, that one and the one that CDC is -- so hearing from both might be a good thing.

DR. TUCKSON: And I think the expectation would be that we would expect government to coordinate its presentation so that there is a sense of a relationship between the two, and by simply asking it to be done that way, perhaps that is a small -- although they don't need us to do it

because they're mature people -- but a subtle way of suggesting that they are actually going to talk to each other.

MS. CARR: And there's a lot of overlap between those two groups.

PARTICIPANT: They talk to each other frequently.

DR. TUCKSON: So the explicit assumption/expectation is you will bring together a combined report that will speak to how you're trying to solve a problem and all the tools in HHS and how they're coordinated to solve the problem. That's essentially what we're looking for. Okay, great. Done. So that's not going to take a lot of the committee's time. It's government working but not subcommittees of us and doesn't thereby completely overwhelm our team.

Access is built into everything we're doing, and we'll leave it that way, I think.

Then public awareness and understanding built in, but I raise that issue the same way I raised earlier the question about the physician education and health professional education across the board. I'm not necessarily calling for it, but do we recognize a need for any special activity? We've thought about that long and hard when we captured these priorities, and it did not make the list as the top couple of things, but again build it into everything. I have no reason to suggest it should change today, but I want to highlight it for the new members of the committee.

Please, Tim.

MR. LESHAN: Can I just put in a plug for DNA Day? I know that Joann Boughman mentioned it, but April 25 is DNA Day, and there's a bunch of information on genome.gov if you want to figure out how you might participate in DNA Day. It's a way to get the word out about genetics and genomics to the public.

DR. TUCKSON: So, let's see, that's important. By the way, we do have a history of support for little terrific and brilliant initiatives, like the family history Thanksgiving deal, which we really got behind.

When is DNA Day again?

MR. LESHAN: April 25 is the exact date, but there are activities all through April on that. But that will be the day when people will be going out -

DR. TUCKSON: That's like tomorrow.

MR. LESHAN: No. April.

DR. TUCKSON: Where am I now?

MR. LESHAN: It's March.

DR. TUCKSON: April is next week.

MR. LESHAN: But April 25 is the day.

DR. TUCKSON: I'm already through April in my schedule.

MR. LESHAN: I know the feeling.

But we will be having a web cast on our webpage, there will be interactive activities for students, and then a lot of genetics professionals are going out into the community to talk about genetics and genomics at high schools. So we welcome the participation of everybody.

DR. TUCKSON: Terrific. I think what we're going to do, by the way -- we'd like to hear back from you. We'll charge you, Tim, at the next meeting to give us a brief update on how DNA Day went, lessons learned, which I think would be important for us to know. So let us know lessons learned from DNA Day, and that way we can get ahead of the curve for next year.

MR. LESHAN: Be glad to.

DR. TUCKSON: So let me come back to another issue I wanted to raise, which is oversight. I think, based on what happened today and the amount of stuff that's on our agenda, I'm not sure that I have a lot of appetite to go much further on oversight. But let me just raise it and see if anybody else has any interest on that.

DR. LEONARD: I do think we need to nudge significantly CLIAC or CLIA or whoever to CMS to get the genetic part of the CLIA regulations out. It's been missing in action for way too long, and I don't know if that's done by a letter. I mean, I don't know whether we want to go to the Secretary and down through CMS, or whether we can encourage CMS to bring us an update on CLIA with the specific timeline that we can then keep track of at the next meeting or something. But I don't think we're doing our monitoring function of the oversight of genetic testing if we're not sort of making sure that's happening in a timely fashion.

DR. TUCKSON: Sherrie, you had your hand up?

DR. HANS: Just that it can be very helpful to have CMS, as Debra just said, to have them come present to the committee and let you know what's going on. That tends to be an effective forum for it.

DR. LEONARD: And I think we should give them equal time because I know I've been asking Steve to come and give us FDA monitoring updates on a regular basis. So we ought to ask CMS to do the same. Really, they're both in that same category.

DR. TUCKSON: Could I ask you or Debra, for the members of the committee that are new, and even though they've read every word of every committee meeting prior to their arriving, could you just give me an update on what actually is it that we are concerned about and what's the impact of those things not being out, those regs? What's the problem?

DR. LEONARD: This started back with SACGT, and even before that with, I think, ELSI, that they were concerned that there are genetic tests being performed that are not reviewed for the quality of the testing, the accuracy of the testing, et cetera. This was a major issue for SACGT. SACGT moved to ask the FDA to provide oversight of genetic testing, which the FDA looked into, and basically I think in the interim between SACGT and SACGHS they got a ruling from their legal department. I don't mean to misquote Steve, so make sure that I'm -- oh, he's not paying attention. That's good, so I can say whatever I want.

(Laughter.)

DR. GUTMAN: No, actually I am.

(Laughter.)

DR. TUCKSON: He's writing every word down.

(Laughter.)

DR. GUTMAN: Ruling is probably too strong.

DR. LEONARD: A suggestion.

DR. GUTMAN: There actually hasn't been a definitive policy statement. But it would be fair to say that we did signal this group that there was not enthusiasm for pursuing regulation of home brews. So the issue has been tabled, and the agency right now is actually focused predominantly on clarifying the regulation of analyte-specific reagents and demonstrating that they're not as scary as they might have been thought to be, and hoping that with a stick and a carrot we might be able to encourage people to standardize and bring products to us.

DR. LEONARD: But I think the SACGT efforts weren't without effect in that the CAP, at least, which is one of the laboratory inspection bodies that has deemed status under CLIA, did add to their molecular pathology checklist, which is laboratories that do molecular DNA-based testing of all types, including genetic tests, I think it's about 12 questions, because I think I wrote them, that address how a test is validated so that when a laboratory is inspected, any test that's been brought online as a laboratory-developed test since the last inspection will be reviewed by the inspector, and there are also molecular-specific inspectors who are supposed to be inspecting molecular pathology laboratories.

One of the reasons I'm interested in hearing about the CLIA regulations is that CAP did this. This isn't required in the CLIA regs at all. So it would be nice if CLIA also adopted some of that language or questions or standards such that there is some review of laboratory-developed tests in the CLIA review process. I think there's one question, which is what there was previously in the CLIA regulations. But maybe to expand that, as CAP had, so that when laboratories say they are performing tests under CLIA that they developed in their laboratories, that has some teeth to it.

So that's basically -- I think Judy Yost came and spoke to the committee about CLIA and how it works, but right now there isn't a genetic component specifically addressing genetic-specific issues within the CLIA regs. So that's why I'm interested in seeing those. They had been drafted, they went out for comment, they got comments back, but then nothing ever appeared to move those forward into new standards or regulations or whatever they're called. Some of the things that were in those initial regs were kind of scary, and labs and professional organizations did provide comments back to CLIA and CMS.

So where the final version would be, I don't know, but that's kind of the overview of what's been going on with oversight. I hope I didn't misstate too much.

DR. TUCKSON: So the issue ultimately, as so well defined there, is I think the issue we're worried about is that there are things that can fall through the cracks. I got this when the coverage and reimbursement policy document went out. People were sort of saying what about this issue? I mean, you're providing coverage and reimbursement for things that are not being approved, and how is that supposed to be handled?

How do we bring that to the committee? Who do we ask?

MS. CARR: Well, Dr. Rollins, we can certainly contact Judy Yost and see if she could come, or would you want to do that?

DR. ROLLINS: What? Contacting Judy Yost?

MS. CARR: Yes.

DR. ROLLINS: You can contact Judy Yost.

MS. CARR: Okay.

DR. ROLLINS: I don't even know who Judy Yost is.

MS. CARR: Oh, she's the head of the CLIA program.

DR. ROLLINS: I don't know her.

MS. CARR: Okay. You'll meet her at the meeting.

DR. TUCKSON: So with the comments of Debra and Emily, that will help phrase what we want them to do.

I think that I would ask, though -- and, Sarah, you can tackle me on this and just say that the staff doesn't have time because they've got a lot to do. So let me just ask this question, and then you give me your input as to what's possible.

In preparation for that presentation, it would be useful if we could develop a simple chart that laid out where the authority is today for oversight of genetic tests, where it is and where it ain't, what's missing, so that everybody can sort of just have a nice little map that sort of says, okay, here's who's got authority over these things, who's got authority over those things, and here's where the question mark is, so that when we listen to this presentation, especially for those who are new to the issue, that you're not floundering around trying to figure it out.

DR. HANS: I might just suggest that you add to that also, since there are a lot of new faces and this does extend back to the previous committee and to NBAC, maybe a little timeline on what CLIA had said they were going to do when and what progress they have made over that period of time so that we can all remember.

DR. TUCKSON: Good. That's a very helpful amendment.

And then finally on this assignment, I think I'm not sure what Steve said in terms of FDA made some decision not to do something. So again, that would be helpful in our map if we knew what it was that they were going to do, what it is that they ain't gonna do, and what gap does that leave exposed, which is I think really what I think the issue is, which is where are the gaps. I appreciate the staff taking the leadership in getting that done.

Well, with that, I think we did decide to do something about oversight, and that's terrific. I feel a lot better and I can sleep a lot better at night.

Would you, Sarah, conclude our meeting with a summary again, just take us through what we did in this meeting? We've already covered a lot of those issues, but take us through.

MS. CARR: Sure. Regarding the large population studies report, as a result of the discussion with the task force at lunch, there was a slight revision of the timetable. As Reed said, the group decided that it would be important to allow for a longer public comment period. So the staff will work on revising and augmenting the draft report in April, reflecting the deliberations of the committee today, and get a solicitation out through various vehicles. We'll use the official Federal Register, as well as some others, our listserv and website, and we'll want the task force input on this but maybe make a special effort to reach out to a broader range of scientific communities, as well as the general public and patient communities. This is what we're waiting to get some clarification from Dr. Zerhouni on, as to whether it would be important for the committee to write a letter to the Secretary before the next meeting, or right after it, to let the Secretary know where the committee is on this issue, and that letter might, if we did decide to do it, would provide an update on the status of our draft report and the solicitation of public comments, the policy issues that have been identified so far, and we'd discuss the importance of seeking broad scientific and public input concerning the potential large population study or resource. I guess we haven't figured out what to call it ourselves.

This last bullet is somewhat tentative, I'd say. If it's decided that it's important for the full final report to be transmitted to the Secretary before the next meeting of the committee after June, which is November, we could convene a special meeting of the committee on teleconference, and it would be important obviously to make the public aware of that and allow participation in that, but there is a way to do that. So we can consider doing that in June.

Emily?

DR. WINN-DEEN: Is there a way to get the survey data that might pertain to this in terms of people's interest and -

MS. CARR: The Cogent data?

DR. WINN-DEEN: Yes.

MS. CARR: Yes, we were intending to do that, definitely to follow up on that.

DR. WINN-DEEN: I just don't see that as a bullet up there.

MS. CARR: It isn't. You're right. We'll add that. I'll add that as soon as we're done.

On pharmacogenomics, Emily, if there needs to be any augmentation here, let me know. But I think it was agreed that the task force would further develop the recommendations or find them reflecting the committee's deliberations and discussion, and that you would be preparing, with the great help of ASPE, the Assistant Secretary for Planning and Evaluation and their contractor, prepare the draft report for the committee's consideration in June, and that would include the revised recommendations.

Then if the committee were comfortable with that report, it would go out for public comment after the June meeting, and it would probably be another 60-day comment period. We'd be ready probably by November for a final report if all goes well.

Then on genetic discrimination, the committee decided to write a letter to the Secretary that would urge the Secretary to request a meeting of the White House Domestic Policy Office that would include the Coalition for Genetic Fairness, the Chamber of Commerce, the National Association of Manufacturers, and possibly, if it's appropriate, relevant House committee chairs, or if necessary that would be done at a subsequent meeting, to discuss the unresolved concerns about the pending federal legislation to prohibit genetic discrimination in employment and health insurance.

This letter would also express our concerns about the effect of the fear of genetic discrimination on research, and this is especially important given the new research projects related to genes and environment, and possibly even the large population study, if it were to go forward. This would include Cogent's data as well, and we would also ask the Secretary to send our compendium of public comments and the DVD to the House committee chairs.

Then as preparatory to this letter, the task force itself would need to meet with those three groups, the Coalition, the Chamber, and the manufacturer's group. We will also provide additional copies of the compendium to the Coalition for their use on their visits to the Hill. Then we were also going to augment or revise the large pop draft to point out the need for federal legislation, that that might be a possible approach.

On patents, I think it was decided that the task force would reconvene and consider the committee's discussion today, revisit the proposed approaches for a way forward, further study, and then come back to the committee in June. I guess this would involve a sort of investigation and consultation about what data is possible to obtain about cost and effects on access, and we would organize an informational session in June that would bring the committee up to an even playing field, especially for new members who haven't really been as steeped in this issue as others have.

Just to review the other topics that got added just now, Reed, we sort of went through some of our priorities today, and you certainly walked through them. We had talked about possibly doing that in June with the idea of considering other issues that aren't on our strategic plan, and I know, and I think we've mentioned, that AHRQ has some ideas about what else this committee might do, and perhaps we could either do that in a comprehensive way or just ask AHRQ for its explanation of what it wants the committee to do.

DR. TUCKSON: First of all, I think what we did today was important. We spent a lot of time on it, and I'm trying to signal to the committee that I want to make sure that your ideas, your issues, your concerns, your observations have a chance to be floated and to be reflected in the committee. I also want to be sure that we're not stuck in the mud and, as I said, missing something that's important.

Having said that, I think we clearly identified that we've got a lot on our plate now, so we're not absent things to do. Having said that, I think I just would keep it as an open-ended invitation for the individual members of the committee and our ex officios and AHRQ to bring things to our attention that they think are important and give the committee a chance to determine whether or not it's more important than some other things and to bump some things.

As I saw that analysis, Sarah, in my mind, some real heavy bolus stuff that's in the process that you can't do anything about. You've got to follow through. I saw some stuff that's sort of in the middle, just sort of flopping around, lesser committed but important. Then I see some things that are just built in to everything that we do. So if there's something urgent that AHRQ brings, we

can put it in and deliberate it. But as far as I'm concerned, we've done that, but the invitation is open to AHRQ to bring it, just as it's open to anybody to bring anything to us.

MS. CARR: Well, you know, the other thing we were thinking of doing in the context of that kind of session was to hear from the Academy about the genomics roundtable that's being formed. Lyla Hernandez is here today. I don't know if, Reed, you would want the committee to hear a little bit more about that now or in June, either way. As I understand their timetable, June would be good.

She's right behind you if you turn to your right.

DR. TUCKSON: I just want to be sure that we end exactly on time, but we do have seven minutes, and we've completed your report, so we actually don't have anything else other than to let the committee members decide what they want to talk about for six minutes.

Can you give us a quick tease on it? Please, and we appreciate your being here. Thank you.

MS. HERNANDEZ: Hello. The Institute of Medicine, in cooperation with the Division of Earth and Life Sciences at the Academy, is convening a roundtable. A roundtable is an activity that is very different from the kinds of committee studies, a report of which you heard today. Roundtables never issue recommendations. They bring together people who would not normally be able to serve together on an Academy committee because they would be perceived as having conflict and bias.

So, for example, the roundtable could bring together NIH, FDA, pharmaceutical companies, genetic technology companies to sit in a room, talk about things, have those conversations be off the record and not open to the public, and the way we can do that is to not issue recommendations.

So this roundtable is going to be focused on translating genomic-based research for health. I think you have a description in your packet about the kinds of topics that we might address, some of which you have been talking about today and are concerned about, clinical utility, validation of clinical tests, education of providers, the workforce issues, ELSI issues.

We're very interested in making sure that we don't duplicate or in any way cause problems for the Secretary's Advisory Committee. We're very much in contact with Sarah and hope to continue to work with you.

That's kind of generally an overview. It's probably not as much as you'd like to hear.

DR. TUCKSON: First of all, thank you, and thanks for being here and sitting through the whole meeting. Can you send us some background stuff that can be distributed with our next mailings to our committee?

MS. HERNANDEZ: Absolutely, yes.

DR. TUCKSON: So that we can see it and see the chart or the charge? Who is the chair?

MS. HERNANDEZ: The chair is Wylie Burke.

DR. TUCKSON: My gosh, formerly from our original committee and ubiquitously wonderful.

MS. HERNANDEZ: So far she's the only member.

(Laughter.)

DR. TUCKSON: And there's great disagreement among the committee.

(Laughter.)

MS. HERNANDEZ: The members will be -- those who sit on the roundtable are those who contribute to the sponsorship. So, for example, Affymetrix, UnitedHealth Care, GSK, FDA, Human Genome, VA, CDC, Genomic Health have all agreed to sponsor, so they'll all have a seat on the roundtable, and we're continuing to contact others.

DR. TUCKSON: Thank you very much.

Let me, before we close out, ask the members, this is your committee, is there any issue that has not been discussed, any observations, anything that anybody on the committee wants to state? We have time. So does anybody have anything on their mind at all that you want to raise?

(No response.)

DR. TUCKSON: I think they want to go home.

Listen, thank you all, and Sarah and team, you guys are terrific. Great staff support. Thank you all. See you next time.

(Whereupon, at 3:27 p.m., the meeting was adjourned.)