
Roundtable Discussion with Personal Genome Service Providers

MS. AU: Can I ask all the panel members to come up to the front? We are going to have 30 minutes for the Committee to ask questions of the panel. I ask that you keep your questions concise and single questions so that everyone can have a turn, or else Yvette will be on you.

I think Kevin had his hand up.

DR. FITZGERALD: I thought I would be way down the list. First of all, thank you all very much for your presentations. I'm limited to one question. However, I didn't hear any limit to the number of comments I could make. No, I'm only kidding.

[Laughter.]

MS. AU: You heard the "concise" part.

DR. FITZGERALD: First of all, let me thank you for hearing over and over again a desire on your part to be engaged in a conversation. One caveat, though, which I think is important to acknowledge on both sides is in any conversation there is always the possibility, and with this group the probability, that you will hear something you don't want to hear or that you don't like to hear. But that is part of being in a conversation.

So the idea I think in the end is that we are all hopefully on the same page and that is, as many of you have mentioned, to try to improve health care, to get much of this to the public in a way that the public can use this information to better improve their health and their lives.

To that end, I would like to make one suggestion to Professor Church. On the slide you used where you have all the various researchers and people who are involved in this because of personal influences in their own family, their children or themselves, with the disease, it might help to achieve that balance that Secretary Leavitt was mentioning if you also include a picture that came from a Wall Street Journal story on December 15th, 2007, about a father who is giving his seven-year-old son who has cancer 44 pills a day, most of which are not prescribed by the doctor, because he is using this very information that is available on the Internet.

So it does work both ways. I'm not saying that you stop something just because someone can abuse it. On the other hand, you don't do something just because you can because there has to be that balance.

On that end, a question. Many of you are involved in for-profit enterprises. I am not against for-profit enterprises per se. However, this is health care. This is not selling cars. So my question to all of you is, would you sacrifice your fiscal bottom line of your company in order to achieve the goals that you say that you have, which is improving the health care of all people, particularly in the area of access to your services?

MS. PHELAN: I would answer that from DNA Direct very clearly. From an investors' perspective, we have always sacrificed the bottom line. I believe that that is true because we are constantly thinking about how to provide a quality service in a responsible manner, and that is not always about an ROI.

SACGHS Meeting Transcript
July 8, 2008

MS. AVEY: From the 23andMe perspective, that was something very important early on when Ann and I started the company. We felt very strongly that we needed to stay in control of the company. For that reason we didn't take the typical venture capital investment. We were lucky to have supporters like Google and Genentech come forward and give us more of a strategic investment as opposed to them wanting to control anything we were doing. They really support what we do, but they don't have short-term objectives as far as financial reward. Obviously they are doing very well

So it is good for us because it gives us the control. It is only Ann and myself and Esther Dyson on our board. We control the company. We feel very strongly that we need the runway and the time to do this right. We don't have to have short-term objectives coming at us from other investors.

As I mentioned yesterday, we did consider trying to have a not-for-profit arm of the company to do things in parallel with what we are doing on the for-profit side, but you do find when you try to explore that, first of all, it is very hard from a tax perspective to have two different companies or two different sides of a company. It is also hard when you want to do research in a very big, global way to try to separate out the two.

So we did think long and hard about that, and so I do feel very strongly that we are going to have a social mission. We want to do continuing research. We are going to look for funding to help people pay that can't afford it.

I think there is a lot of that incentive and that drive within the company, but we also have to hire engineers and they won't come to work for a not-for-profit, typically. That is our challenge.

DR. GULCHER: We are involved in a publicly funded project where we are doing the genotyping at cost with a 1 million-chip array for several hundred individuals in a cardiovascular project. That hasn't been announced yet. But we are also providing back to the participants their deCODEme results on a voluntary basis because the researcher thought it would be very useful to give something back that would profile these patients beyond the research aspects of the study, which are unrelated to deCODEme.

That is one example where we are doing it at cost and providing that information and looking, regardless of whether or not the patients have the ability to pay, to see is this an interesting demonstration of how people might use this information in parallel with the research aspects of the contract.

DR. STEPHAN: I have been working in the academic, nonprofit space for the last 15 years doing research to identify the genetic drivers of disease. Implementing genotyping as a service just doesn't fit within the academic, nonprofit model, for the most part.

I would throw back across the fence to you what proportion of the service-based medical infrastructure is not for profit. Physicians operate on for-profit models. All diagnostic companies operate on for-profit models. I wouldn't say that that is a negative per se associated with this space.

MS. AU: The next question is from Julio.

DR. LICINIO: I have a question to do with not really the accuracy. I'm in a medical school. You teach people and you use whatever research is out there towards health care. This type of

SACGHS Meeting Transcript
July 8, 2008

information is coming from whole genome association studies and genes that we didn't even know existed before these studies, like one of the obesity genes that came in Science last year. These things come up, and it is interesting but it is not yet something that we apply in health care.

Then you have the direct-to-consumer information. The paper is out there in Science. We had a discussion about this yesterday. There are even things that come out in Science, Nature, and the New England Journal of Medicine with a lot of known replication.

When the microarray data that came out was on the cover of Nature, the best microarray for cancer identified in different profiles, there was the same type of work in New England and not a single gene overlapped. There were different profiles. Sometimes, even when the work is replicated, the relative risk is often different in the different populations.

So it is very interesting and kind of a cutting edge science, but is it really that relevant to health care? You can come up with examples that can be very compelling. Because of, maybe, a smaller risk you look at people more closely and then you find something. But very often in medicine, and we know from the CT scans, you find little things and then you look and look and look, and the person goes through a lot of procedures, and there was nothing to begin with. They go through a lot of unnecessary procedures. Overall, there may not be a positive balance.

This information that you all put on the websites is for a person's informational use only. It is very disclaimed in the deCODEme site and any of the other sites that it is only for your own information and this should not delay anything you are going to do with your doctor or interfere with anything you are going to do with your doctor.

So, is this really ready for consumer-based health care, and do people understand the difference between provision of information and actually what is important for their medical care?

DR. GULCHER: You hit a lot of points there. When you talk about the validation and the replication, I think most of our companies are putting things on that have been widely replicated. We are not just talking about "Why do you say that?"

Take the atrial fibrillation genes. There are 12 different populations now where those have been replicated, just to take one example. That is not just us discovering these. In the first publication that we published we had to replicate in four other populations, and then since then other groups have independently done it.

The point is, they have already been replicated in multiple independent populations, which is the new standard for publication in some of those journals.

So I can't speak to microarray data, but at least in human genetics Dr. Collins and others have set standards, or suggested standards, that finally the editors are abiding by for replication, because of that major problem that you brought up.

When it comes to what is the relative risk level that needs to be achieved to be clinically useful, that is really up to the physicians themselves. By the way, we are not saying that this is just personalized information that is just for recreation. We emphasize in every other paragraph that you should talk to your physician about this information. All the companies do offer genetic counselors, so clearly we are not just doing this for recreational purposes.

But the disclaimers are this is not a diagnostic. This does not mean you are going to get atrial fibrillation. It is a risk diagnostic. People need to be aware of that. Consumers need to be aware of that, and physicians as well. They are not determinative. That is why you see all that language that says this is not a diagnostic, it is a risk diagnostic or a risk genetic test, or whatever you want to call it.

When it comes to relative risk, at what level do you achieve a particular threshold for one of the guidelines? Take breast cancer, for example. The late-onset form. Let's not talk about the early-onset form. The late-onset form of breast cancer. When you have a lifetime risk of 20 percent or greater the ACS has suggested that you do MRI screening in addition to mammography. That is a risk that is defined not specific to treatment. It is simply a lifetime risk. This is one of the additional risk factors that can contribute to lifetime risk beyond just family history.

So I think we are feeding into risk, which then feeds into established professional guidelines.

DR. LICINIO: I would like to just say something. Trust me, I am as much for this type of information as a person can be. I'm not using this to attack the area. But the website says the genetic product is for informational purposes only. It is not medical advice and it is not a substitute for professional medical advice, genetic counseling, diagnosis, or treatment. You must seek the advice of your physician or other qualified health provider with any questions you may have regarding the genetic aspects of a medical matter, and you must not disregard professional medical advice or delay in seeking it because of the results of a genetic scan or anything you have read on the deCODEme site.

The website also states that deCODEme is an anonymous information service. It is not a medical service, not a genetic test, and it is not designed for medical decision-making. Therefore, it is not covered by health insurance companies.

That is what I find a little confusing.

DR. GULCHER: It is not reimbursed, certainly. It is not a substitute for your physician or a genetic counselor. A lot of those are self-evident things. But it is very important to inform the consumer that we are not making a diagnosis for them.

Just because they are at lower risk of atrial fibrillation and they have palpitations or have a stroke, that doesn't mean that they should not be evaluated for atrial fibrillation. I think that is the major point.

DR. KHOURY: First, thank you. This is a wonderful beginning of conversation. I want to quote something that Kari Stefansson said in April in one of the newspapers. He said that "Every college-educated person in the U.S. should have this test within the next five years. We cannot afford not to." That seems to be a little bit different from the kind of thinking we are talking about here.

But the idea behind all of this is that I think this information is not ready for primetime. I think part of the problem is the concept of lost in translation. When you talk about validation, you mean replication. When I talk about clinical validity, that is a very different concept. It is the ability to predict the health outcomes that we are trying to predict here, whether it is risk factors or diagnostic tests, predictive value, clinical sensitivity or specificity.

SACGHS Meeting Transcript
July 8, 2008

When you talk about value to consumers, I talk about clinical utility, I talk about the balance of harms and benefits. In order to do that, we need research. When I heard Linda just talk now, I thought she was a research enterprise, not somebody who is selling me a test for a thousand bucks.

That is the kind of stuff we need to do. We need to figure out what this information means for clinical validity and how it is going to improve health outcomes without providing harms.

Your own personal example is a powerful anecdote. It is a hypothesis-generating anecdote. It doesn't prove clinical utility. It means that we need a clinical trial to show whether we follow up a hundred people like you or not, whether the deployment of a prostate cancer-specific test would do more good than harm on a population level.

I think we have a problem in lost in translation. We need to get together to speak the same language of what we mean by clinical validity and utility. In order to do that, I think the dialogue has just begun.

So, no question for me. Thank you.

MS. AVEY: I would just comment to Muin that that is exactly why we wanted to start this company. I think this year has been different than what I was experiencing when I was with Perlegen where we just couldn't find cohorts large enough to study. It was so hard. We went to multiple centers. You would have to do a consortium self-study. Then you would have different diagnostic criteria used in each one, so you never quite knew do we really have the same phenotype in all these groups.

[We need] to have a centralized way to collect all of this information. Eventually, if people are willing through maybe Cleveland Clinic, who has now partnered with Google Health, we can start pulling in this phenotypic information through a health record that is very standardized across many, many people and across many different, diverse groups. We are really hoping that merging that now with genetic information in a Web 2.0 environment is going to be very powerful. That is the goal, but we need to work with all the organizations to make it happen.

MS. AU: We have Rochelle, Marc, Mara, Jim, Kevin, Paul Miller, Mike, Gurvaneet, and Francis on the list. So, Rochelle.

MS. DREYFUSS: I think my question is short and I think it is mainly aimed at George. It is back to the question of costs. I'm curious whether you are affected by patents on any of the things that you are investigating. When you do the whole genome sequence I assume you go through the BRCA gene alleles as well. How much does the cost of licensing add to the total cost?

DR. CHURCH: I think the effects of patents are certainly there, not so much in the instrumentation yet. I think some of the chip manufacturers have stayed away from certain IP issues. It has been somewhat limiting. Hopefully we will be able to get this straightened out. Maybe one of the other panelists can [speak to this.]

MS. DREYFUSS: How about on the sequences themselves?

SACGHS Meeting Transcript
July 8, 2008

DR. CHURCH: I think that is the only place where I see any limitations [unless] a large screen of the whole genome results in you going and getting a confirmed, CLIA-approved test on a very specific allele.

For example, if you did a PGP or 23andMe and then it went to Ryan's DNA Direct to get a myriad BRCA1 test, that would not be threatening because that would actually increase their market. I have talked to them about that, and they seem to be comfortable with it right now.

So far I don't see it as a huge barrier, and there is certainly an incentive to develop sequences and technology that is presented by the patent process which I think is very positive. It could become a problem, but it isn't right now.

MS. AU: Marc, are you there?

DR. WILLIAMS: Yes, I'm here. I wish I could say I was on top of Ensign Peak because I have been there and it is a wonderful place to look out and think.

A couple of comments and then one question. The first one is that we have been talking a lot about new knowledge and the research. Muin very nicely summarized that point. I think the issue that I would raise is that the model that we are looking at here is really the potential of funding research on the issues of how important these things are using clinical revenue.

That is certainly not something new. We have danced around this before. But I think we at least need to be honest about the fact that we are looking at non-traditional research funding mechanisms to be able to learn about things that we don't currently know about, and some of that is now coming directly from the consumer. I think that we just need to be up front about that.

The second point is that there have been comments made in the presentations and in the responses to the questions that risk information is linking to establish professional guidelines. While that is true, I think we have to realize that what we are talking about here is clinical plausibility, not validity or utility in the sense of really understanding that there is an evidence base that suggests that this genetic information that is associated with other risk factors, family history, environment, et cetera, in fact does impact risk and in fact does argue for different modalities.

We can say that we think if we got people on Warfarin because of their genetic risk for atrial fibrillation that that would save a billion dollars a year for the healthcare system. That is all well and good, but it is completely assumption-based.

The reality is, if we put a lot of people on Warfarin and it doesn't work, we are going to add cost to the system related to the complications of using a medication that, even if we used pharmacogenomic information to better dose it, is still going to result in people with thrombosis and bleeding.

So I have a question, and I apologize that, because I haven't been able to log into the Webcast, I'm not sure exactly who I'm directing it to. But it was the presenter that gave the personal anecdote relating to prostate cancer. Because it is a personal question, I think you can fairly say "I don't want to answer it."

But you mentioned in your presentation that you brought this information to your primary care physician, who then acted on the information. The question I have is, how much education did you need to do as an informed consumer to teach your primary care physician what to do?

SACGHS Meeting Transcript
July 8, 2008

Because I would hold that it would be extraordinarily unusual that your primary care physician was in fact positioned to be able to use that information.

DR. GULCHER: Before I answer that personal question, I did mention in the talk yesterday that we have a preventive cardiologist that recommends some of these individual tests for MI and type II diabetes in his preventive cardiology practice. For some patients he even recommends that they get deCODEme for all that, primarily for him to assess the cardiovascular aspects.

So he has a patient who comes in with a PSA of three whom he had been evaluating for other risk factors. He said, go to your urologist. I don't know anything beyond the heart. Most cardiologists will freely admit that, and they are proud of it.

But he goes to the urologist, who says, "I'm not going to do anything. You are 55 years old. You are in the normal range."

But then he gets his deCODEme report later and his cardiologist says, "Well, you don't see any increased risk for cardiovascular, but what about this prostate cancer?" He sends him back to the urologist, and the urologist goes ahead and does the ultrasound-guided biopsy. He has even more cancer and a higher grade than I have.

Once again, another anecdotal example, but here is an example where it is an incidental finding by a cardiologist who has no business thinking about cancer. But yet, it probably led to some useful intervention, which represents how, really, things should be if we could move from intervention to prevention.

So from my own personal experience, I did have to show him the descriptions of what we put on our reports. As I showed you in one of my slides, we try to make it simple for the physician, emphasize these are risk factors, these are not Mendelian, determinative genetic factors. We give them a risk. We describe the bottom line stuff at the top. We give them the more detailed part of the bottom.

But we convert that into a lifetime risk. We show the assumptions of what we think the baseline risk is, and the big differences among the three companies actually are more on that, which we are simply quoting some contradictory literature out there in epidemiologic studies. But the relative risks themselves in some cases will lead to more intensive intervention. In other cases it will just be done the standard way, which is ignore the PSA.

So I did have to show him some of the reports and whatever, but I did not put a gun to his head to suggest that he send me to a urologist.

MS. AU: Mara.

MS. ASPINALL: Thank you. Let me first start by saying thank you all for your openness and transparency today and yesterday, and being willing to very freely be a part of this and engage in this discussion. I do think that this is, as is personalized health care, an industry in its adolescence. It is only through these types of discussions that we can get into adulthood, whatever that looks like.

I want to go back a little bit to I think it was about 18 months ago when the Secretary and HHS issued their report on personalized health care. It combined personalized medicine with the IT arena. The Secretary mentioned it today in terms of the electronic medical record. A lot of what

you all are talking about is both a healthcare company but fundamentally an IT company, a data-oriented company, that is focused on providing information.

So, two questions related to that. The first one is the fundamental one that hasn't come up yet. [Using] David's example from this morning, how do you reconcile the different results he got from different areas?

One of the biggest challenges that we have in diagnostics, and perceived probably throughout the healthcare environment but particularly scrutinized right now in diagnostics, is getting different results from different labs and ensuring that does not happen. So HER2 testing standards and ensuring that it doesn't matter what lab you go to, if you are getting the same test you will get the same result.

I will add I think critical for the respect and the recognition of the key role diagnostics play is a fundamental confidence in the system itself. It relates back to what this Committee did in terms of having standards and having regulations to ensure that a physician can choose and a consumer can choose to do the test or not, but to believe that no matter who they get it to is a reputable lab or a reputable genomics company and they will get the same result.

So my first question is how you reconcile David's experience and how important is that. I know you have talked about some industry-wide initiatives, but I would like to hear more about that.

Then, secondly, how does it relate to the electronic medical record. Does the consumer need to hold that and, five years later, remember that it happened? Are the healthcare systems, not individual physicians but the systems, ready to take this data so when you get a test five years from now you can get your metabolism score and say -- and I don't know if you all do metabolism -- "I don't want to prescribe this at this dose because the system gives me a clue that says we have to do it differently"? Or, is that burden today on the consumer?

It is those two pieces but very much, I think, related to the issue of data and validity of the data.

DR. GULCHER: Just to be clear, when David Duncan was going through his results, whatever overlap there was in terms of the actual testing of what he called the raw genetic data, there was no discrepancy, at least with respect to the three services. Is that right, David? The actual genotype calls. Did you find any errors among the three companies? Were there any errors?

MR. DUNCAN: No.

DR. GULCHER: No differences.

I'm just putting that out there. We seem to be able to measure things correctly. Now the question is can we actually annotate them correctly.

There are different ways of converting from odds ratio to relative risk. Dietrich does it differently than we do it, a little bit. In some cases that leads to a different result. In many cases it doesn't matter. He thinks of the control populations as being super controls, I think, and we think of it as being more population controls in terms of our own studies and other things.

We will get together on that. We have been brought together by Ed from the PMC, and I think we can agree, especially with some of your input, on what those standards should be in terms of annotation and combining the markers together. I think we would welcome that feedback. I

SACGHS Meeting Transcript
July 8, 2008

think that would give greater clarity, with or without a Good Housekeeping Stamp of Approval. I think that would certainly go a long way to addressing that because I think that is the vast majority of the variation among what you saw in terms of the annotations.

DR. TEUTSCH: We are going to need to wrap this up very soon, so I ask the next few folks to ask very succinct questions, and I'm looking for very succinct responses.

MS. AU: Can I just follow up? Electronic medical records, are they integrated? Are the systems ready to do that?

MS. AVEY: I think, at least the way we are envisioning it, that we will look to companies like Google and Microsoft, who are doing the heavy lifting of merging or creating PHRs that will sit on top of the MRs. They have already announced partnerships. I think Kaiser is working with Microsoft and Cleveland Clinic has announced an arrangement with Google. They will become the standard of an individual. If they say "I want my PHR. I want my own personal health record," they would be able to draw that up through their clinical center if there is a partnership there.

Then they are also working with places like Long's and Walgreen's. You can pull up all your prescription information as well and store it in one place where you control it.

We don't think genetic data itself makes sense to transfer into a PHR. It is more about what is a report that could sit on top of that data that would be easily transferable into that record. Then the patient would have the decision to say "I want to port this back over to my doctor."

We envision someday a two-way communication going on from genetic information to PHR to EMR. Something like that we think is pretty workable, but obviously it is very much in the early stages.

MS. AU: I'm sorry. We are just going to take two more questions, one from Paul and one from Francis, because he gets the honor of asking questions.

[Laughter.]

MR. MILLER: I don't know why I'm getting to ask a question.

I want to briefly go back to this research enterprise aspect because I'm really interested in that and particularly, Linda, your focus on that. How you communicate information with your customers I think is interesting, and your next steps that you are trying to do.

My question is, because you are communicating this kind of information and doing these studies through your database, are you subjected to federal human subjects regulations? Do you have IRBs and informed consents, and should you? Or is it simply we are going to look at your data and then we will send you an Email back and tell you what we found. How does that play out?

MS. AVEY: Luckily, when I was at Perlegen I had to manage all of the OHRP work that we did and all of the oversight that we had as a company, so I was very familiar with IRBs. I had to go crack the whip to get all the scientists to go through the training. I went through the training.

We have implemented the same thing at 23andMe, where we have all of our scientists going through OHRP training. We have it all put away in a booklet. Everybody has to do that before

SACGHS Meeting Transcript
July 8, 2008

they can even look at any customer's data, which is all de-identified. They don't have any means to really find out who these people really are.

We have talked to an IRB. We do have a consent form, so all of our customers do go through this consent, whether or not they read it. With some of the stuff, we bullet it out and put it in bigger letters so they read the really important parts that we think they should see.

We have talked to a commercial IRB, and this is a new model for them, just like for you and for the world. They need to really sit and think about it. Because we don't have a protocol necessarily that is well defined, it is hard for them to get their heads around what exactly we are doing.

But it is going to be an ongoing discussion like we have with you, and we are eager to see if we can move that along. We have every intention of doing that. George can comment on how long it took him to get his consent form through the IRBs that he has worked with.

DR. CHURCH: It was one year to get the initial IRB in and 3.5 years to get the scaled-up version. I think that is reasonable considering the changes going on here.

MS. AU: Francis gets the last question.

DR. COLLINS: Thank you for that great opportunity.

[Laughter.]

DR. COLLINS: It will be quick. It follows up on a comment that Jeff made in his presentation and then came up already in the discussion. By the way, this has been a very useful panel. Thank you all for coming and talking about what your own plans, hopes, and dreams are.

Jeff, the thing I'm concerned about with regard to the follow-up of findings is not only a circumstance where you have to educate the healthcare provider to take action but the concern where the healthcare provider takes unnecessary actions on the basis of not quite knowing what this means, perhaps having some trouble understanding risk factors in a quantitative sense, and as always, worrying about possible litigation if they don't then order every possible test.

In addition to your two anecdotes, one of them being yourself, where a prostate cancer genetic test resulted in some valuable information, one worries about how many other biopsies got done that were really not indicated on people whose PSA was very low, whose relative risk factor was quite small, and whose family history may have been negative, and who may have been 42 years old at the time.

To what extent, in your own thinking about how this all plays out as either a benefit or a risk to the public, is this an issue that there is going to be a tendency to follow up on modest risks by ordering more tests? I'm a physician, so I can say denigrating things about physicians, I guess, and denigrate myself at the same time. Oftentimes physicians, without being quite sure what to do, just figure, "Well, we had better look into it."

My professor in medical school way back when said all non-indicated tests will be abnormal.

[Laughter.]

SACGHS Meeting Transcript
July 8, 2008

DR. COLLINS: That is often said but a true story. Then you have to do more tests to follow up on that.

So, what are your thoughts about that specifically, Jeff, since you have gone into a very specific example?

DR. GULCHER: Right. I think that is why we try to emphasize these are clinical risk factors like other clinical risk factors. Family history is a clinical risk factor. Environment, other conventional cardiovascular risk factors, or whatever. Physicians are using them on the basis of what are those risks conferring to their particular patient in the context of the general population risk.

That is why we try to convert these to relative risks and emphasize if it has been demonstrated that these risk factors are indeed independent of other cardiovascular risk factors, the conventional ones, and independent of CRP and LPPLA2 and Lp(a), which has also been demonstrated in a cohort for cardiovascular markers.

If that is the case, you can do what physicians have been doing for a century: multiply independent risk factors together to define a composite risk. Then you act on that.

If that, for example, converts an intermediate risk patient based on ATP3 criteria and you multiply it by a risk factor of 1.3, if you are homozygous for 9P, some patients are going to get bumped up into the high-risk category. The LDL cholesterol level may be chosen by their physician, not by us but by their physician, to perhaps be at a lower level, 100 milligrams per deciliter instead of 130 milligrams per deciliter. That is one example of where it can potentially modify the risk factors up or down.

We are not saying that you are acting only on this genetic test. You are acting on that genetic test in the context of the other risk factors because this is just another clinical risk factor test.

DR. COLLINS: That would be true if every physician was thinking in exactly this kind of quantitative way. I guess what I'm wondering about is to what extent do you or do the other companies feel the responsibility to try to help physicians in that circumstance not overreact, even as you are promoting, of course, the value of this information. We all understand why you need to do that. How do you do so in such a way that doesn't cause healthcare providers to somehow attach even greater significance to these findings than they should and therefore to carry out a whole bunch of follow-up tests that are actually unnecessary?

DR. GULCHER: So you are concerned that a physician might act on a relative risk of 1.1, for example just because he says it is a little bit bigger.

DR. COLLINS: Yes.

DR. GULCHER: I think you are exactly right. We try to lead people through these risks and put it in context of other risk factors in our reports, but we don't come out and say "Don't do anything for this patient who has a relative risk of 1.1" because he may have other risk factors. The whole point is to emphasize combining this information to the other information that you are already routinely collecting on those patients. It is the sum total of that composite risk that I presume in many cases, not all cases, is guiding physicians in their practice.

SACGHS Meeting Transcript
July 8, 2008

I mean most physicians. I disagree with whoever mentioned that most physicians aren't using Framingham. They are using a Framingham score and using the ATP3 criteria to risk stratify. These primary care physicians are doing so.

I think it fits well into a paradigm that already exists. We are already using family history for common disease like prostate cancer and breast cancer. It is totally analogous to that but independent of family history.

DR. TEUTSCH: We need to wrap up the session. I would like to thank the panel and everyone for engaging in a very lively and open discussion.

As all of you are aware, we are running a bit behind.

[Laughter.]

DR. TEUTSCH: Which is fine because we have had good discussion this morning. We appreciate the extras that got added onto our schedule.

Just so you know, what we are going to do is we are going to hear from Kathy Hudson and then we are going to have a break for lunch. We are going to roll the discussion that we planned to have just among the Committee into the discussion on the priorities this afternoon with Paul.

Let us give a round of applause to all of our fine panelists.