UPDATE ON THE CLINICAL UTILITY AND COMPARATIVE EFFECTIVENESS TASK FORCE

DR. WILLIAMS: Thank you and thanks for the opportunity to present today.

(Slide.)

I also want to thank the task force members who are listed here for all their contributions.

(Slide.)

Our charge was to determine which issues, if any, SACGHS should explore in the areas of clinical utility and comparative effectiveness research. And so our immediate focus was to try and access where things were at in terms of federal funding in CER that concerns genetics and genomics, and that's what I'm going to be talking about today.

(Slide.)

So in the American Recovery and Reinvestment Act of 2009 there was a billion dollars—I'm sorry, $1.2 billion—I have to do my math. $1.1 billion that was appropriated for comparative effectiveness research divvied up $400 million to the NIH, $300 million to AHRQ and $400 million to the Office of the Secretary of

the Department of Health and Human Services that were to be targeted for comparative effectiveness research.

The $400 million for the Secretary must be used to "conduct support or synthesize” comparative effectiveness research or to “encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data."

The act also required the Secretary to task the Institute of Medicine with a report recommending national priorities for CER funds appropriated to the Secretary and required the Secretary not only to consider the IOM recommendations but also recommendations from the Federal Coordinating Council for Comparative Effectiveness Research, which I will referring to subsequently as FCCCER for obvious reasons, and spending $400 million appropriated to the Office of the Secretary.

(Slide.)

So our strategy was to review the recommendations that emerged from IOM and FCCCER and identify those relating to genetics and genomics, to

assess the degree to which these projects—the projects that were funded by NIH and AHRQ with their CER funds--satisfied recommendations and identify recommended studies or projects that are not yet funded inasmuch as we could.

And then it led to the opportunity then that we could potentially recommend to the Office of the Secretary directions for the funding that could support projects that were recommended either by IOM or FCCCER but were not funded, at least currently, through NIH and AHRQ.

The FCCCER is composed of senior federal officials, most of whom are physicians with responsibilities for health related programs. They issued a report on June 30, 2009, that recognized FCCCER can promote personalized medicine by examining the effectiveness of interventions by patient subgroup. And what I'm going to be talking about here is really a synopsis that we did of the report that focused on genetics, genomics and personalized medicine, or the purview of that. And the written synopsis of this report and others is behind Tab 4.

Now, I also included a report by the Lewin Group that was produced for the Personalized Medicine Coalition that had assessed—they had provided input both to IOM and to FCCCER about how monies could be used for comparative effectiveness research. And the Lewin report, I think, does a very nice job of crystallizing how comparative effectiveness research and personalized medicine can complement one another.

(Slide.)

Now, the FCCCER recommended that the primary investment of the Secretary's funds be in creating data infrastructure for CER. So one example of that would be patient registries and, secondarily, recommended significant investments for dissemination and translation of CER, particularly those CER studies on priority populations, and priority types of interventions. And they defined priority populations as racial and ethnic minorities, persons with disabilities, multiple chronic conditions, elderly and children. And priority types of interventions could involve comparing different medical home models or comparing surgery versus medical management, et cetera.

(Slide.)

The report notes “As the Secretary develops HHS’s full portfolio of ARRA investments, it will be critical to consider both CER and health IT holistically.” As such, our committee may want to continue to encourage health IT policy that supports collection of genetic information useful for CER and barriers to genomic data sharing are also barriers to comparative effectiveness research, and we’re going to spend the afternoon obviously talking about some of these issues so I won’t go into any more detail.

(Slide.)

The IOM report was also issue on June 30, 2009, and they generated 100 prioritized research topics and 10 recommendations. Of the 100 research topics, there were two that explicitly mentioned genetics or genomics. One of them was a first quartile priority looking at effectiveness of genetic and biomarker testing with usual care in preventing and treating breast, colorectal, prostate, lung and ovarian cancer, and then the third quartile priority was to compare the effectiveness of biomarker information,

including genetic information with standard care in motivating behavior change and improving clinical outcomes. There were eight other prioritized research topics that could conceivably include genetics and genomics within scope but were not explicitly mentioned.

(Slide.)

The NIH reviewed all of the 100 recommended study topics and concluded that most of the 100 IOM study topics are already being studied through ongoing NIH research projects.

The review by our task force did identify numerous funded projects in the genetics and personalized medicine space. So I think that there is good progress relating to this, particularly in that first quartile priority of cancer.

Of the 10 recommendations there were two that we thought were of particular relevance to the committee.

Number 7: HHS should devote sufficient resources to research innovation in the methods of CER and so we would posit that beyond CER we also need

innovation around how we look at clinical utility, as we already heard in the discussion about affordable genome.

And Number 8: HHS should help develop large scale clinical and administrative data networks for use in CER. Now, this goal obviously raises privacy and informed consent issues, and that will likely overlap with issues that are raised by genomic data sharing and it does reflect ongoing efforts to create such data networks. The recommendation also implies that we need to collect clinical level data.

So, in some ways, what we're going to be discussing around meaningful use will also relate to this issue because if we are not representing some of this in meaningful use we are not going to be able to collect it.

(Slide.)

Now, I did get a chance to play around--and thank you to Mike Lauer for helping me with searches on this--to look at the NIH ARRA funded CER grants, and there were several funded projects that are going to directly relate to genetics issues that the IOM

recommended. Twenty-four of these were specifically funded under the comparative effectiveness research monies, and I have detailed those under Tab 4. There are many others and I did not—I was exhausted but I didn't do an exhaustive search, so if you want to parse it, but there's probably at least 50 to possibly hundreds that address genomic and personalized medicine issues that are not directly related to the IOM top 100 and there seems to be very good coverage across a broad range of conditions, and some of these funded studies are using the methods of comparative effectiveness research even though they are not specifically funded by the CER-designated funds.

I think that many of these funded projects will also serve as investments in data infrastructure and in dissemination and translation of CER findings which would be consistent with the FCCCER's recommendations.

(Slide.)

Now, we don't have much information yet on the AHRQ CER-funded grants. Gerberding (sic) did provide me some information that two of the

announcements, the CHOICE and iADAPT are closed, and the rough estimate of applicants is about 118 and 91, respectively. The titles indicate that a small proportion will have a focus on genomics but detailed reading of the applications may reveal others.

The PROSPECT and the EDM announcements are still open. And Gerberding was estimating that perhaps 10 percent of the these may have something to do with genomics, which would be a substantial number. All of these grants will be reviewed, funding decisions and awards will be done before close of the fiscal year 2010; that is September.

(Slide.)

So if we are to look at gaps in terms of what actually is happening, I think that there were three that could reasonably be characterized as such. The first is definition of adequate evidentiary standards for different applications; the second is this third quartile IOM priority healthcare delivery systems; and the third the coordination of efforts, And I'm going to briefly talk about each of these.

(Slide.)

I thank Steve for allowing me to borrow his slides. Some of you have seen these in another context but this slide overlays Muin's T-1 to T-4 translational efforts against when do evidence-based guidelines actually come out. This sort of represents what might be considered sort of an ideal model with everything in balance where our evidence-based guidelines are occurring before we go into health practice.

The problem, of course, is we really don't know where that evidence bar should be and if we lower the threshold for translation into practice then we may have things moving into practice that have little evidence on clinical validity, utility that may impact their coverage. There's a potential for increased harms and also the potential for increased benefits for moving things out that actually work. Usually we're relying on expert opinion at this level but this type of evidence bar would stimulate innovation.

(Slide.)

In contrast, if we move the evidence bar way to the other side, we are likely to have very good and useful tests that emerge with good prospects for

reimbursement but there’s lower incentives for innovation because of the cost of developing the evidence. We do reduce the likelihood of harms but by the same token we may diminish the benefits because we’re having some treatments that never make it into the clinical arena that are beneficial where we just can't generate sufficient evidence.

(Slide.)

Now I am not going to go through this decision factor matrix but this is something that has been discussed at least superficially at the eGAP working group about the different ways that we can think about where we would need best evidence.

(Slide.)

And you could imagine, you know, saying in each of these bars, you know, what evidence do we have around efficacy for regulation, we’ve got to get good evidence there, we’ve got reasonable evidence and feasibility, we’ve got no evidence on cost or these type of things. You can fill that out and use that in some type of decision-making process.

(Slide.)

So, I think this is an area where we have heard about this before at this Committee. We have definitely heard about it even this morning about where does that evidence bar have to be, and we think that this is something where the Committee could potentially play a role in helping to determine this.

I would also mention, though not in Tab 4 but in another part of the packet, there's a comment of the CMS MEDCAC that was recently surveyed on what type of evidence do you really need to make a coverage decision, and there are some interesting findings from that that I think support the same issue. You know, we are really struggling to say what is the evidence bar that we really need?

(Slide.)

The second gap is this third quartile priority, which is to compare the effective of biomarker information, including genetic information in standard care, in motivating behavior change and improving clinical outcomes. There are very few of the funded projects that I reviewed that specifically address these critical issues. There may be more of

these that emerge in the AHRQ projects. But this would be something where I think it would be a fair point of discussion for our committee as to whether this should be point of emphasis for the Secretary. I think particularly related to the issue of behavioral changes, both for providers and for patients.

(Slide.)

And then the third thing is coordination. There are all of these different projects. They are all collecting information and they're creating a lot of registries but are we really using standardized data representation and storage? Is this going to impair our ability to share findings across projects? So could we learn something about the genomics in one condition associated with risks for another condition that's associated with risk for another condition and we could combine that information?

I used psoriasis and coronary artery disease just because this is something that came up in our own institution where I was contacted by a psoriasis researcher that said, you know, "I'm looking for a larger control group for psoriasis. Do you have

genotyped individuals?" I said, "Well, we've got a big pool of them in our cardiovascular research group but they're consented to only be used for cardiovascular disease research." He says, "Well, did you know that psoriasis is a huge independent risk predictor of risk for coronary artery?"

Well, I didn't know that and it turns out none of our cardiologists knew that. Now they are very excited about working together. So I think that this is something where there could be a lot of opportunity for synergy if there were some type of coordination overlay and so that was something that we were thinking about as a possible role for the Secretary.

(Slide.)

At present, the Secretary's funding decisions are unknown. The Secretary was required to send operating plans to Congress in July and November of 2009 concerning funding decisions but that report is not as yet publicly available.

(Slide.)

I almost took this slide out because I was depressed. There was a bill that was introduced into

the senate, I believe, that--an independent bill indicating that studies should take into account molecular and genetic subtypes. So that basically codified this type of work.

That bill was folded into the overall healthcare reform bill and was, in fact, represented in both the house and senate versions that were passed but, as we all know, the status of that right now is unclear. So whether this particular bill will be extracted from healthcare reform and brought up independently or not, I just wanted you to know that there are some things at the legislative level that may also impact what it is we are going to do.

(Slide.)

So here are some potential next steps for the task force. One is to try and get a handle on these evidentiary standards for the use of genomic tests, outlines for considering adjusting an evidentiary bar. So, for example, if we have something like a Warfarin pharmacogenomics where we're potentially going to be applying this to hundreds of thousands of individuals a year, we probably need pretty strong evidence this is

going to work. On the other hand, if we have a situation where we have two treatments that are in therapeutic equipoise, and it’s a coin flip in terms of whether you do A or B, then perhaps we don't need as much evidence to say, well, we think that there's some genomic information that would distinguish between going with therapy A or B, it may be reasonable in that type of situation to move forward with a lower degree of evidence since right now we are essentially equal.

(Slide.)

There are other entities that have begun to address this issue. This was one of the major areas of focus at the initial gap meeting that took place last fall. It may be that the Secretary could charge this entity with taking ownership of this particular issue but it's one that we thought was quite important.

We could create an inventory or clearing house of genomic CER projects with identification of prioritization of gaps in the CER agenda which could inform how money should be distributed, again potentially with this special attention to the healthcare delivery system point.

We also thought about the possibility of having an informational workshop on this issue for the June meeting. We need to continue to monitor the health IT issues that continually arise and, in particular, reviewing the meaningful use rules, which we will be doing.

By the same token, I think we could say that our work here is done, that there's really enough happening, and maybe there isn't a role for the task force to move forward. So that would be a potential next step.

And some of you may come up with brilliant ideas that I haven't thought of, in which case we could consider other options.

(Slide.)

So, with that, I will end and we can have discussion.

Wayne?

DR. RANDHAWA: Thank you, Marc.

I would not suggest to dissolve the task force. I think we are just beginning to do the work.

I think CER, when it's all said and done, is

sort of a good sort of medium by which this committee and other groups can tackle the so-called issues of clinical utility. I mean, it's a way to address the clinical utility in the real world. Whether CER will live or die in congressional language, I think the issues that it has raised are real and they are already on the table.

Just by the way of clarification and just additional information, I was looking at the 24 projects you identified from the NIH list. Many of them have nothing to do with CER or genetics but they were coded as such. I'm wondering if you have issues on that but let me just finish my thoughts.

As part of my other hat, I have two jobs, one of them is an NIH job and I spend so much time at the NCI, we actually from the NCI perspective funded seven out of these 24. They are part of a network of CER and genomic and personalized medicine. We had our first meeting with the grantees in January and we have connected those groups with both GAPNET and eGAP. And they are going to—and I'm hoping we can find across all of NIH other worthy projects that can actually join

that network from a non-cancer perspective because I think cancer is sort of the dominant field in CER right now and the IOM, I guess, priorities reflected that breast cancer, ovarian cancer, et cetera, but I think there are other worthy areas other than cancer. So I think if this committee actually keeps shining a light on CER from what its true meaning is, for clinical utility in the real world, have a discussion and inventory, and then work with the other groups and develop some kind of report to the Secretary with specific encouragement or recommendations, I think it's a good way of spending the time because it's a window, it's an opportunity to shine the light on so-called clinical utility issues.

Thank you.

CHAIRMAN TEUTSCH: Let me just expand on the on the issue of what are talking about on clinical utility, and sometimes that’s a fairly defined thing that we know about in harms and benefits in health terms. But the decision factor matrix that you put up, Marc, talks about how different people make different decisions and context is very important. And FDA has a

specific set of regulatory requirements of how it makes decisions, safety and efficacy; payers have other criteria; patients have a different set of criteria.

So you can think about all of these things not just as sort of clinical utility but I think we can add real value perhaps saying how do we help get the information necessary for decision-making, which the clinical is one, and I would suggest that patients and clinicians think about these things rather differently than a regulatory agency or even a payer but different people need different information, and help people understand that and the information that's needed and where they get it so that they can be making better decisions is one of the pieces that I think should come out of the slide you showed.

Jim?

DR. EVANS: I just wanted to put a plug in for--you highlight something in your synopsis early on that I think we should make a conscious effort to address and counter, and that is the kind of bizarre accusations that you hear a lot that somehow comparative effectiveness research is antithetical to

personalized medicine and I think that Gurvan and Steve's commentary beautifully articulates why that's not the case. But I think because you hear that a lot that should be high on our radar screen to counter because it's just simply not antithetical.

CHAIRMAN TEUTSCH: This group is rarely at a loss for words.

Mara?

MS. ASPINALL: Just for fun I will say I very much agree with Jim. I think that you continue to hear that about comparative effectiveness and I think the issue around comparative effectiveness looking more broadly than just against the standard of care today is the key change to that perspective because there was misinformation, I think, at the beginning that it was only looking at the current standard. And that brought about some of the concerns that personalized medicine was not always in comparison to the current standard and, therefore, by changing, it would not be appropriately viewed.

But in both the report and other work, the broader definition of comparative effectiveness has

done that but I do think that misinformation and perception is very much still out there.

CHAIRMAN TEUTSCH: Gwen?

MS. DARIEN: I think it plays into a lot of emotional fears. It's the same thing as a lot of the genetic discrimination fears and the fear is that it is going to lead to health rationing. So I think than Jim and Mara are really correct it has to be very, very clearly articulated and taken out of an emotional context.

DR. WILLIAMS: You know, it's interesting that you mentioned the R word since the funding, the ARRA funding, specifically articulated that you couldn't include that in the research, which, you know, for most of us sort of said, "That's really tying our hands to some degree."

So there are a lot of issues and, of course, the other issue that we really haven't talked about that isn't specific to genetics and genomics is the whole idea of how we do the research is still up in the air as well. The FCCCER report spent a lot of time talking about alternative methodologies, you know,

methods that not traditionally assessed or scored well in NIH funded opportunities, perhaps a little bit less so in AHRQ, but the idea of, you know, adaptive trials and things that are really new types, new ways of doing research, doing research off of the clinical data that we are beginning to accumulate is going to be a critical piece of this. That emphasizes the need to be able to capture the data that is really critically important and some of that data is going to be genetic and genomic, which means we have to have the capability within our clinical information systems to pull that information out.

CHAIRMAN TEUTSCH: Andrea?

DR. FERREIRA-GONZALEZ: To add more to what Marc is saying, there's something that I find missing in the use of genomic and genetic information because these tests may be being performed maybe in research laboratories and we have to be very concerned about the quality of the test that is being performed. There are clear regulations that establish that even for research purposes that information transmitted for decision making should be done in a CLIA certified laboratory

and throughout here I didn't see anything about that.

The other issue is not only that the quality of the testing, it is how the results will be transmitted to healthcare providers or researchers. Being a practitioner, I know the challenges to really convey specific information, what you can test, what are the limitations of the test is and what you cannot do.

Also something that missing here that is very important is comparative methodology research. Her2neu, for example, and I can give you an example, you can have different technology to use to do the detection and make changes or decisions on your treatment. So that research is--I didn't see anything of that but I think it's critical that you add that part of the information.

To talk to Mike's reference materials, normal way to do proficiency tests, and also no part of anything that I have seen, I would like to maybe recommend the Secretary to create a clearinghouse for information similar to the clinicaltrial.gov website where this information is already put for clinical

trials. So there's already a model there that we can use or recommend the Secretary to use to put some of the comparative effectiveness research in publication.

And lastly is biobanking. I mean that as we continue to work through all the issues we talked in the previous session, and the current session, and session that is going to follow, the user and storage of specimens is well-annotated under quality control is critical not only for continued research, but then we can go back and do other testing with new methodology.

So these are issues that need also to be part of our discussions.

CHAIRMAN TEUTSCH: Marc, this is what you had put up first for us to think about but something tells me you are not totally agnostic about which of these we should be pursuing and when. Do you want to lay out what you think a reasonable agenda would be?

DR. WILLIAMS: I am not sure I can define a reasonable agenda.

CHAIRMAN TEUTSCH: An unreasonable agenda?

DR. WILLIAMS: I am much better at that. I think that from a practical perspective, the--you know,

some guidance on evidentiary standards is going to be critically important. Whether this is something that really could reasonably be expected to be completed by a task force of this committee or whether this is really something where we need to get an idea of who actually is in the game relating to this and say, okay, here are the people taking ownership of this, and this is something we need to support and hear back on, I just really don't know on that. Again, I think it would be beyond the scope of the task force to be able to create an inventory or a series of inventories but I think it's a critically important thing to do. So One thing the task force might reasonably do is to say we need a clearing house of information and we need it on these different issues and we would recommend that be created within some entity. Again that was something discussed at the initial GAPNET meeting. One thing GAPNET could do would be to have a clearing house of projects so that people know what actually is going on in the space.

In terms of the informational workshop, we already know we’re going to be having a workshop on

affordable genome so it may not be reasonable in June to have another informational workshop or it may be that people think we have heard enough from prior presentations that we don't really need to go there again. Certainly that would be something the task force could very reasonably take ownership of in terms of pulling that together.

That doesn't really answer your question all that well, I don't think, but that's—

CHAIRMAN TEUTSCH: Well, the good news is that Muin is raising his hand and since he's mixed up in almost all aspects of this, he can tell us what's going on with some of these other—with GAPNET, EGAP and assorted other nets.

DR. KHOURY: Okay. So, yeah, there's just an alphabet soup out there but here's what's going on, and I suggest that this committee can actually weigh in towards the end of the year, maybe after June. The reason why I say that is for a couple reasons. One, the projects that are actually being funded now, in the 24 plus or minus 10, I think, are doing the work, plus getting together and trying to develop that number one,

and the roadmap type issues, and they are going to have maybe joint meetings with an IOM roundtable on genomic translation that’s chaired by Wylie Burke and also the IOM forum on the cancer forum. So that discussion is already occurring in the background.

Of course, GAPNET will try to have the clearing house of projects and maybe even knowledge base on the genomic applications. AHRQ is doing all kinds of things this year and Gurvaneet can tell you more about that. So I think waiting a little bit until the end of the calendar year and then having just another session to figure out really what's going on could inform this committee as to what the next steps should be, just waiting and seeing what the other groups are doing. So there is really no need to rush immediately because the work is being done, and maybe if we put the place holder maybe at the June or the October meeting for a quick update on the various efforts by NIH, CDC, Gurvaneet, AHRQ and the IOM roundtable could actually give us more information to play with because this is rapidly moving target this year.

CHAIRMAN TEUTSCH: Gurvaneet, do you see any gaps at the moment which others are not addressing or do you think we should just wait and see—

DR. RANDHAWA: I think there are gaps in all of these things obviously. Whether or not these other groups are going to address them fully is not clear. I would suggest that we work with them somewhat since many of us are involved in these things and wait to see towards the latter part of the year what kind of recommendations this committee wants to make to the Secretary. Now remember all of these other entities are doing it from various vantage points. I mean AHRQ is doing their thing, NIH is doing their thing but this is the committee that provides advice to the Secretary. So I think there is always a role for this group to weigh in and we shouldn't wait too long. I'm not suggesting to push it another year or two but maybe towards the October meeting we will be in better shape information-wise.

CHAIRMAN TEUTSCH: Andrea, and then Marc?

DR. FERREIRA-GONZALEZ: I agree with Muin that these issues may have to wait until the fall, but

I'm wondering if we can do something in the meantime. The issue of the CER where testing is being done, not only for genomics and genetics in research laboratories, and the information is being used to trigger patients, that needs to be done in a CLIA certified laboratory under rigorous quality control, if we need to bring that to the attention of Secretary or somebody in those areas.

CHAIRMAN TEUTSCH: Andrea, I am just wondering if that falls under this general rubric of clinical utility, and we've had the oversight report. We're clearly dealing with the genomic data sharing and the kinds of issues that we heard earlier.

DR. FERREIRA-GONZALEZ: But these grants are already being granted. They are granting the money and testing is being done so do we need to bring these issues up?

DR. WILLIAMS: Yes, I guess I would share the issue about whether that's something that this task force would be primarily tasked with because, as I hear about this it, really seems much more related to the work we have done in oversight and that. I am not

saying that we shouldn't and we probably as a committee should respond but I am not exactly sure of the best way to do it so I would defer to Steve on that.

I would certainly not disagree with what Muin has said. I think that there is some wisdom in that. I think there are two things that we can probably do as a task force even if we were relatively inactive. One would be to continue to monitor the Secretary's report so when that actually emerges into the light of day we can review that and see what are priorities that the Secretary has identified will be. The second thing would be is when we do actually have the information on the AHRQ funded projects, take a look at those from the perspective of how is genetics, genomics and personalized medicine represented in those, and that would give us a better idea of the overall scope of what's going on.

CHAIRMAN TEUTSCH: Let’s take two more quick comments from David and Mara, and then we’ll try and wrap this up.

DR. DALE: I was going to comment that I think probably the space for us to be in is in the

second two words in our name, health and society. That is, the patient's question often is does this information matter to me? Or the parent's question, is my child healthy? The piece we need, which really doesn't fit with the acute stimulus money, but is the long-term, that is information sets that provide the clinical information to link to genetic analysis. And so we need to encourage the government and other sources to invest in--people say registries but patient databases that allow for drawing good conclusions. Those are long-term investments. But I think of the huge value of the Framingham project in terms of what we have done with that because we made a long-term investment and looking for ways structurally to fund those kinds of projects, I think, is very important.

CHAIRMAN TEUTSCH: Mara?

MS. ASPINALL: Well, maybe it's a good summary following up on Andrea's question. Are there some time-sensitive issues that need to be addressed in the short term? I understand Muin's comment about from October on there are other issues but, in the light of this set of grants now, are there comments, are there

summaries on what's been put together to date that need to be—to be useful and actionable need to get to people before the October timeframe so that to me is the key time-sensitive question because, as I understand the health questions, but I also focus on the relevance of this committee and want to ensure we are doing something that people need the information.

CHAIRMAN TEUTSCH: Well, I'm hearing that we should be monitoring those and looking at them—

MS. ASPINALL: I guess I'm—

CHAIRMAN TEUTSCH: --but what I'm also hearing is that we probably should defer until October to get a real presentation of what's going on with these other entities and then we can make a decision about what's going forward but we can do some--ask staff to monitor these and maybe provide us some information for June.

MS. ASPINALL: Well, and are there any implications for which there are action items that can be impacted by the Secretary's office for which our view of it, even if it's an initial look at the data, is relevant.

CHAIRMAN TEUTSCH: So maybe I could ask, Andrea and Mara, since you seem to have a good notion of this, and I don't, maybe you could coordinate a little bit with staff about what could be done in the interim and then we'll look to the fall to get an update on the other activities and decide where we can add some value.

DR. WILLIAMS: So if I understand this, the issue is, as I see it, that you're putting forward is in these funded research projects currently that are doing genomic testing there are concerns that you have about how the testing is being done and whether the results of that are going to actually represent the quality that needs to be--that we would need to have to actually draw conclusions.

DR. FERREIRA-GONZALEZ: Well, there is already a federal regulation that covers those types of testing. If you are going to make a clinical decision on how to treat a particular patient, even for research, it should be done in CLIA certified laboratory. So bringing to light to the agencies that there are these issues they need to be very mindful of.

DR. WILLIAMS: So is this really something that--since right now the primary funding is through NIH, I mean is this something that would need to go—this concern would go—rather than going to the Secretary would go more directly to NIH?

DR. FERRIERA-GONZALEZ: Whoever is funding this research.

MS. ASPINALL: My issue was just slightly different. It was really a question. Are there any decisions that are being made, less on the previously-granted grants, which Andrea has mentioned, but more on those coming up for which the analysis that we have done and that you, Marc, have done in conjunction with others and taking other pieces, is useful to get in front of the Secretary or others. So basically is the work that's been done so far useful to anyone in the granting of additional work between now and the end of the fiscal year?

DR. WILLIAMS: I think I can answer that question, which is right now everything--I don't think that there would be any way to insert anything into the AHRQ process would be my guess. And my understanding

is that the Secretary's report is actually also done. It's just under consideration. So I don't think for either of those two things, which are the other two pots of ARRA money that haven't actually been distributed that we would have an opportunity to sort of weigh in on that. I think it would really be going beyond that.

CHAIRMAN TEUTSCH: We really need to wind up this session.

MS. ASPINALL: That was my fundamental question. I'm happy to work with Andrea as well on other issues but that was the core of mine.

DR. KHOURY: So just to clarify, the scope for this committee or this task force was the ARRA CER but AHRQ has already been funding many projects in CER that predate this. Some of the issues that were raised by Andrea, the analytic validity of the tests and the performance of the tests, we actually have a methods report, which I will talk about tomorrow, which discusses some of the quality issues and looking at the evidence.

So there's also other grant projects like the

work on pharmacogenomics that was outside of this funding but it’s also coming to a close. I would suggest that if we wait it might be useful to get a lay of the land, and there are other things that were not discussed here that will also be part of the discussion.

Also, it's a fast-moving field in terms of what is comparative effectiveness research and some people have already started using the term “patient-centered health research” as a part of comparative effectiveness research. So I think if we stay true to what the overall goal of our project is, regardless of the label, we will have a more long-lasting impact.

CHAIRMAN TEUTSCH: All right.

DR. WILLIAMS: Yes.

CHAIRMAN TEUTSCH: Very good. So that brings us to a break. I know we are running a little late so if we could limit it to 10 minutes so we’ll start back 10 minutes from now.

Thank you, Marc.

Thanks, everyone.