Committee Discussion

DR. TUCKSON: Well, thank you, all three of you, for your involvement.

Dr. Berg, I'm going to try to catch you up real quick in 10 seconds on some important conversations that occurred prior to your joining us. Earlier today, the Secretary of Health's office gave us a specific challenge to respond to some specific and relevant questions regarding oversight. One of those actually was very relevant to your point, and that was to provide some guidance on how tests are selected by providers as part of our oversight responsibility. I think that you've sort of spoken to those issues in some ways today.

Again, because I'm the chair, I get to be the bad guy to ask all the terrible requests. It's kind of like if you haven't given enough. We have our advisory committee, and that advisory committee is chaired by Andrea who asked you to join in today, all three of you. And it also has Cynthia Berry and now Dr. Marc Williams. I would like to ask all three of you -- and you don't have to say yes or no today because you may not want to and you don't want to do it in public -- to join the committee. And also, by the way, Dr. Willey, if you are still here, I'm going to ask you to join the committee, and I think we're going to probably ask Dr. Burke to join as well. I think we're starting to get a terrific team together.

So I'm going to ask you all to see if you would be willing. Again, like I say, I don't want to put you on the spot -- ha, ha -- today. But if you would join in with us and we'll sort of ask you to help us to think about these issues because the work will go like lightning because of you.

Then in the interest of time, not to take up the time of the committee today, I think each of you made very wonderful presentations. The point I think, because it wasn't your assignment to do, is to point out what's missing, what are the gaps, what needs to be done that you're not doing.

Secondly, I don't know whether or not, as proud as you are of each of the components that you presented, if you really became designated in our schemata as the deal for your part of it, could you actually sustain the work. Do you have enough scale? Can CAP actually scale this -- but I just want to make sure that as part of the committee, you speak to the issue of sustainability at scale going forward.

So I think the two things I would sort of challenge you with are you've told us all the wonderful things. Now tell us what's not wonderful, what's missing. And secondly, for the parts that you are responsible for that you are so legitimately proud of, can you sustain in scale? And then would you join the committee? I think that's what I would sort of look forward to.

DR. FERREIRA-GONZALEZ: Any other questions?

(No response.)

DR. FERREIRA-GONZALEZ: I have a question for Dr. Vance. Earlier in the day, we had a public comment from the Genetics and Public Policy Center which states that two-thirds of the laboratories are involved in PT testing and a third is not. You presented some data from 700 molecular pathology laboratories, and the most frequent deficiency on the PT program accounted to 3.9 percent of the laboratories. I'm still trying to figure out the discrepancy for this.

DR. VANCE: What I can say is not all labs adhere to CAP. It's a voluntary program and not everyone enlists in the CAP accreditation program. So I think that's where the commentary comes from.

The other thing that you need to remember, though, is that number, as I told you earlier, is a dynamic number. It's a moving target. There are labs being gobbled up by larger labs. There are new labs coming out in the market all the time. So I think it's very difficult, number one, to keep tabs on all those laboratories, but also to make sure that those laboratories are involved either in a CLIA inspection process or a CAP inspection process.

DR. BERG: If I may make one comment.

DR. FERREIRA-GONZALEZ: Who is that? Oh, Dr. Berg, go ahead.

DR. BERG: Just a quick comment that a number of the tests that are out there and are being promoted are single source tests, which presents problems not only in that many of the data that might be relevant to the issue of their usefulness in practice are proprietary. Secondly, a further result is that there's very little in the peer-reviewed literature that allows us to look at them. It also means that these tests are not subject to the proficiency testing kinds of mechanisms that we have in place for other kinds of tests. So this particular domain has some special challenges in helping laboratories do a good job because of the nature of the tests and who is providing them.

DR. FERREIRA-GONZALEZ: Any other questions for the speakers?

DR. TUCKSON: Dr. Berg, I would also make one other request of you. One of the things just to think about on a go-forward basis, if in fact you are willing to go forward on a basis with us, is we are interested in the idea of sort of developing some case studies that allow us to sort of see in the continuum of activities from analytic and clinical validity and clinical utility, all the way through to how tests are chosen for clinical use by a clinician. If you sort of think about a whole longitudinal chain of events, we're trying to think about some of those kinds of test cases, and I just want you to think about maybe using your CYP450 example as one. So if you were to sort of start at the end of the chain where a patient actually gets the test and work your way all the back to clinical utility and validity, yada, yada, and the oversight of those steps along the way, that might serve as a pretty interesting one of our examples that we might use. It may not be the best one, but I just want to get your brain to kicking around the idea if you were to look at all the steps along the continuum from clinical application all the way back through, you know, does the test actually do what it's supposed to do for the people that's supposed to do oversight, sort of how you might think that through. But I appreciate your offering an example.

Again, your presentation seemed to really predict much of our discussion.

DR. BERG: Sounds very interesting. Thank you.

DR. FERREIRA-GONZALEZ: I have one more question for Dr. Vance. With enacting CLIA, Congress also directed the Secretary to make the results of proficiency testing performance available to the public. Is the College of American Pathologists taking any steps to have this actually happen, or if that's not possible, can we as a group have some of those results?

DR. VANCE: I know that the college renders its proficiency testing results to CLIA, but I don't know if they would render them to the public. I can't speak on behalf of that.

DR. FERREIRA-GONZALEZ: So CMS has results of the proficiency testing.

DR. VANCE: Yes, they do. Yes, they are reported to CMS.

DR. FERREIRA-GONZALEZ: The other question I have -- and then Muin goes after me -- is that you have showed a diagram of the different laboratories that perform a proficiency testing program and when they fail, what you're supposed to do or not do.

DR. VANCE: Right.

DR. FERREIRA-GONZALEZ: Now, who is responsible for checking that laboratories that fail the proficiency program actually follow the steps that they have to follow? Is it up to the laboratories, or is the CAP keeping a tally on this?

DR. VANCE: That's a very good question. Actually CAP has gotten much more involved in that and has recently spent about $9 million to bolster its accreditation program particularly with monitoring and has created an entire new council called the Council on Accreditation. One of the subcommittees of this council is called the CCC, or a continuous monitoring committee. It is the responsibility of that committee then to monitor the PT results.

So it's a two-pronged review: one, to make sure that we're reviewing the laboratory testing menus to see that the laboratories are, in fact, enrolled, as they're required to, in appropriate PT; and then the other part of that is to make sure that they're performing adequately or successfully in the PT.

The other thing that I might mention in that regard -- so the Continuous Compliance Committee does monitor, and they're the ones that send the cease testing letter. Then they, again, follow that algorithm.

The other part of that is then the inspector too, when that inspection process comes along every other year, will have the PT results of that laboratory for the last two years as well. So the inspector will then be able to target their PT results and look at the evidence for their PT results and also their plan of action, if they have been unsuccessful previously.

DR. FERREIRA-GONZALEZ: Muin and then Steve.

DR. KHOURY: I don't have a particular question in mind but I'm taking this opportunity to thank Dr. Berg for his leadership in moving EGAPP forward. EGAPP has been a process that came out as sort of the product of the previous advice of different committees that came out in the '90s, the NIH/DOE Task Force, and then SACGT. I think, for the first time, we're beginning to see a little bit of a road map for how we can move forward. I think EGAPP and the EGAPP Working Group -- by the way, many of them are here, Sue and Steve Teutsch -- and did I miss anybody? And Deb Leonard has been on it -- have provided us with a really good leadership model to evaluate how we can move forward with this.

And I would like to acknowledge too that EGAPP is not only a CDC process. We have a very tight partnership with AHRQ. Gurvaneet has provided a lot of the raw material, so to speak, and the use of the evidence practice centers to do some of our work. We have an amazing steering committee that has FDA, NIH, and a whole lot of other partners. Obviously, nothing would happen without Linda Bradley, our secret weapon, who's sitting back in the audience.

(Laughter.)

DR. KHOURY: So thank you, all, for your hard work.

DR. FERREIRA-GONZALEZ: Steve?

DR. TEUTSCH: While we have Al on the phone, you've talked a lot about getting guidelines out. One of the issues, of course, is then getting guidelines into practice and all the quality improvement and translational things on that end. I'm not sure if that's going to be within the scope of some of the things that we're going to be having to deal with as part of the oversight, but it's, it seems to me, one of the real issues that goes beyond sort of how do you get from the laboratory to recommendations.

And I wonder if you've had any reflections about the complexity of getting this translated into practice beyond sort of what we've talked about with a health information infrastructure and decision support.

DR. BERG: Well, when talking about the Preventive Services Task Force, I often make the comment that the work that the task force does is the easy part. Although working through the methods and the science of these kinds of tests can be complicated and tedious, in the end, it's not rocket science. It's fairly straightforward when you're evaluating evidence against established standards. The real challenge comes exactly as you state: when the recommendation is out there and it's available, how do you get it into practice?

Those of us in primary care are extremely happy to see the NIH Roadmap leading towards the CTSAs and the T2 translation which is moving things. T1 is bench to bedside, and T2 is bedside to the community. And there are a lot of us very interested in that particular translational step, moving things from things like clinical guidelines and clinical trials into actual practice into the hinterlands of Alaska that I outlined on the slide.

So it's an excellent question. The EGAPP panel isn't likely to address that, but we hope that other groups will be able to help with that.

DR. FERREIRA-GONZALEZ: James?

DR. ROLLINS: I have a question for the EGAPP committee members, as well as Dr. Berg. We talk a lot about analytic as well as clinical validity, and then we also talk about clinical utility. But from an insurer's perspective, in terms of making sure that a particular test does have some desirable outcome for the population, or from a population perspective, for some reason it seems like there's not much emphasis being placed on clinical utility.

Now, earlier Reed asked you about a case where you might start from the beginning and go to the very end. As an insurer, as I say, how can I be sure that this EGAPP initiative, in terms of some genetic test, is going to result in certain outcomes at the population level or result in decreased cost or better management of patients?

DR. BERG: Well, I would encourage others to respond. But I would not want to be misunderstood that EGAPP is not interested in clinical utility. In fact, we've spent a huge amount of time trying to figure out how to take the methods of, for example, the Preventive Services Task Force in the community guide, which are ultimately focused on utility and apply them in genetic testing where there's so much more emphasis on analytic validity. In the Preventive Service Task Force, we almost never examined issues of the analytic validity of measuring blood pressure, for example, or measuring hematocrit. Those aren't issues. In genetics, it's a huge issue.

So the panel is absolutely committed to saying as much as we can about clinical utility because that's where clinicians live, that's where patients live, that's where insurers live, that's where employers who pay for insurance live. So we're absolutely committed to go there, if we can, recognizing that the evidence probably will fall short in an unfortunate number of cases.

DR. FERREIRA-GONZALEZ: Correct me if I'm wrong too, but a member of the EGAPP Working Group is a member of the Blue Cross/Blue Shield Technology Assessment Group. So then you'll have that component of the third party insurer into that group. But I think it makes a very key component to that work group to address the specific issues you're bringing up.

DR. BERG: That's correct. Maggie Piper is a wonderful addition to the group.

DR. FERREIRA-GONZALEZ: We have no other questions. We all put on our thinking caps, and we're going to move forward. Before we do, I will thank the speakers for very thoughtful presentations and hope that we can count on some of you joining our committee. So maybe we'll go from two to expanding significantly.

DR. TUCKSON: Not some of them. We're hoping that all of them will.

(Applause.)

DR. FERREIRA-GONZALEZ: But before we move into our discussion, I would like to close some of the issues that Reed brought earlier from our November meeting on oversight. We had requested CLIAC to provide a report back about their discussions with CMS about the specialty. In our package, in tab number 5, there is a summary of the committee meetings that occur in February, and I'm only going to read part of these just to have closure from our discussions in November.

So an update on the committee on the outcomes of the CLIAC meeting in February. At our November meeting, we learned that CLIAC was meeting in February to discuss CMS decisions not to go forward with the notice of proposed rulemaking for genetic testing specialty under CLIA. Given the complexity of the oversight issue and the questions that remained for us as a committee, we felt it was important to get an update from CLIAC after they held their discussion.

I want to thank CLIAC chair, Dr. Lou Turner, and Joe Boone, Associate Director for Science in the Division of Public Health Partnership of CDC, for providing us with a summary of their deliberations. Again, a copy of that is in your tab number 6. Let me just highlight the main points of the meeting, and the rest, please go back to tab 6 for the complete report.

"Judy Yost shared CMS's plans for strengthening genetic testing oversight, which were the plans she presented to us in November, that is, improving their website, providing technical training to surveyors on genetic testing, and collaborating with CDC to publish educational materials. CLIAC members expressed support for CMS's efforts to improve its website, provide technical training to surveyors, and collaborate with CDC to disseminate information.

"However, several members of the committee disagreed with CMS's decision not to go forward with establishing a genetic specialty under CLIA. These members questioned the agency's rationale and pointed to concerns in the genetic testing community about laboratory quality, particularly regarding the qualifications of laboratory personnel and the interpretation of genetic test results, two important measures of quality that are not being captured in CMS survey data because CMS surveys are not routinely inspecting genetic testing laboratories."

There's a number of other key points, again, that are in your tab number 6 that I would recommend you go back and check.

DR. TUCKSON: I was trying to make sure that Kathy Hudson she was hearing what was being said as well. Let me just try to see if we can nail this issue down here because I'm a little confused, and I appreciate this.

So this issue was teed up by public testimony from Kathy Hudson who was pretty specific about a number of these issues. And I'm trying to understand where we are.

So what you just read was from -- who was that from?

DR. FERREIRA-GONZALEZ: CLIAC.

DR. TUCKSON: That was from CLIAC. And it specifically addressed this issue of why the decision was made by CMS not to do a specialty. And they concluded at the end of the day -- what was their conclusion again? That it was okay?

DR. FERREIRA-GONZALEZ: They "expressed support for CMS's efforts to improve its website, provide technical training to surveyors, and collaborate with CDC to disseminate information." So they were in agreement with CMS that those are the plans for strengthening genetic testing oversight.

DR. TUCKSON: And I think I want to just restate it again. Again, you're trying to report not justify. I'm just trying to make sure.

So do you get the sense that as a result of the discussion that CLIAC said we are okay with CMS not doing a specialty and that their strategy of these other tools is acceptable? Or did they say that the other tools are good, but you also need to deal with the specialty issue? I'm trying to make sure which. Are they completely endorsing the whole strategy and saying it's okay not to have the specialty issue?

DR. FERREIRA-GONZALEZ: That's my understanding, but I don't know if Joe Boone is in the room to further confirm this. I mean, there was an endorsement of the activities that CMS has decided to put in place to strengthen the genetic oversight. There were some concerns among some members of the committee that it was not sufficient.

DR. TUCKSON: I see Steve has got his hand up.

DR. GUTMAN: Yes. I was present at that meeting. It was certainly my sense of the meeting that the package that Judy put on the table as the surrogate for the genetic specialty sold, and I'm not sure it was unanimous, but that the sense of the committee was that this would be an acceptable substitute.

DR. TUCKSON: Well, let me ask then of Andrea and your committee, Andrea, as you go forward.

First of all, I think Judy Yost and the CMS people are terrific people, and they're hard-working and well-meaning to get after what they're trying to do.

I don't know what to do with some of the testimony that we heard earlier from Johns Hopkins, in that they were very specific about some points regarding the relationship between the specialty designation and the proficiency testing. I'm somewhat concerned about one-fourth. Again, I don't think that the presentation from Hopkins was designed to say this is a definitive probability of .008, New England Journal of Medicine study. They didn't oversell their presentation. But I think they made an observation that in one review, one-fourth of the labs are not doing proficiency testing as perhaps they should be doing. I think there were some issues raised around analytical errors that may be resulting.

So I just think that I would ask us to tighten down -- if we could sort of take that testimony that we've got there from Kathy Hudson and sort of look at these issues carefully. If the CLIAC people have reviewed this thoroughly and, as Steve has said, they have bought off on it, I'd just like to sure I know what parts of Kathy Hudson's presentation they have bought off on. And if it doesn't need to be redone and if I'm doing something to add to bureaucracy and stagnation and redundancy, then please overrule me quickly at the beginning of your next meeting.

DR. WILLIAMS: I mean, I think the presentations we heard today present a prima facie case that there is a need, and the reason is that all of these people that presented would not be spending the time, money, and effort that they're spending if there wasn't a need to do oversight. I think we wouldn't even be having an argument about whether it's needed or not if people had not taken the ball and run with it to say, well, we think we need to do this.

And if the College of American Pathology and the American College of Medical Genetics hadn't created their guidelines and their proficiency testing, I think we would be in a terrible morass regarding having any standards. And I think there would be a huge hue and cry. So in some sense, there's an ability to not take ownership in the sense that so many people are doing it voluntarily that we are being prevented from the scope of a problem that could be much larger. But ultimately the problem comes down to that this is all being done voluntarily, and as a consequence, there's the ability to opt out.

DR. TUCKSON: First of all, well stated and well articulated.

Just to drill a little deeper, in terms of what I'm trying to get at, because your comments are right on, it's the specific part around the specialty determination because I think what I'm curious -- that issue was apparently clearly presented then to the CLIAC around this need for a specialty determination and it decided that it wasn't necessary. Kathy raises the issue, if I understand her testimony, about the relationship between that and the proficiency testing. And I'd like to just make sure that the subcategory of proficiency testing is actually going on and that the CLIAC committee's discussion, if it did not explicitly deal with the frequency of proficiency testing, then let's add to that. That's just my subcomment within the overall framework.

DR. FERREIRA-GONZALEZ: Well, this is something that we can take and look at what CLIAC, which is an advisory group to the Secretary, made the decisions and what these other individuals presenting today have brought to our attention.

DR. TUCKSON: The other thing, by the way, just to complete the thought -- I apologize -- is I also want to make sure that the committee explicitly nails down this question of -- Congress had directed the Secretary to make the results of the proficiency testing performance available to the public. Apparently this may not have been -- and I note the careful use of the words -- "apparently may not have been done." I just think we need to look into this and see whether or not this is an issue that needs to be addressed. It's like once a committee like ours has been

informed of these concerns, it is not easy for the committee to ignore them. And we just need to, without saying yes, just check into it and make sure everything is cool.

DR. ROLLINS: A quick comment? Representing CMS, I think that because of the conversation which took place this morning in terms of possible deficiencies on CMS's part, I do think, as I said, some type of dialogue or some type of meeting should take place between the representatives of Johns Hopkins, as well as CLIA representative Judy Yost.

Number two, in terms of, I guess, some follow-up, since we're talking about CMS, some of the recommendations which were made in terms of things that this committee wanted CMS to perform, essentially the recommendations have been reviewed by the different divisions of CMS. Most of those recommendations are feasible and favorable. Some of the recommendations there will be some more discussion on, but in terms of specifics, because the document has not been cleared, we couldn't present it today, but by the time this committee will meet again, that document will be cleared so that we can, as I say, address the recommendations made by this committee.

DR. TUCKSON: Let me just note then -- and I want to be careful here since I'm the one that raised all these things. I'm trying to walk a very deliberate and a very transparent and a very public fine line. So, number one, again, I want to be very careful on this.

I am trying very hard not to be critical or put CMS in a defensive or negative posture here. It's very important to not do that. So we are not going to be, at least as far as this chairman has anything to do with, attacking or putting CMS in a negative posture.

Let the record state the ex officio from CMS has leaped to a cooperative posture and a willingness to engage in conversation to clarify these issues. And that's an important principle that I think we want to acknowledge and underscore.

The ex officios are not members of the subcommittee that we're creating, but I'm sure that they'll be called in to be supporters. No, the ex officios don't get to be on the subcommittee this time.

But anyway James Rollins has really stepped up and been really supportive of that. So I think that's important. Given the spirit of your comment, Dr. Rollins, whether you work with the Hopkins people or not, I think the real issue is more the generic issues that have been presented. It provides a certain focus to make sure that these are part of the work of the subcommittee, and whatever happens has to occur in that environment. And this is not an adversarial kind of thing. It's trying to understand it.

So I hope there's no difference of opinion where I am. This is all on the high road, high ground, trying to accomplish things which everybody has the same interests, and that is to do right by the public. There are no bad guys here. There are no enemies. There are no adversaries. We're just working on behalf of the American people, and let's keep it right there.

DR. FERREIRA-GONZALEZ: Now, with that comment in mind, looking at these issues, maybe we can put back up again the framing of the questions that were put forward to us this morning. There were seven questions.

As we go through those seven questions, there's another set of questions at the oversight task force we came up with. It's a framework for moving forward, and you can find them in your document under tab number 5. There are actually six questions there.

So maybe we can actually discuss these more in detail. As Reed was saying this morning, we can look at the questions that the Secretary has put forward and see what we want to add or want to delete from these.

Now, we can use these six questions that the task force has come up with to see where are commonalties and where we have moved forward and even actually add or delete some of these.

Any comments from anybody?

(No response.)

DR. FERREIRA-GONZALEZ: If you look at our the task force's question number 5, I think there is an issue here. I will read that for everybody. "What would be the impact of these solutions on the accuracy and quality of genetic testing; investment and innovation; availability and cost of genetic tests; and patient/consumer health and health care decisionmaking? How might these effects vary for different categories of genetic tests, for example, direct-to-consumer, predictive, diagnostic, pharmacogenomics? What would be the effects of leaving the system as it is?"

So what we were trying to look at in the work group at this point is to see what are the consequences of some of these issues. And I think we need to look at these, and I would like to add this into the area where the Secretary has added.

Any comment from any members?

(No response.)

DR. FERREIRA-GONZALEZ: So the idea will be to -- Joe?

DR. TELFAIR: Let me just make a general statement about the questions. There are a lot of compound questions that you have in terms of the way they're written. So if you were looking at how you're going to assess or get the answer to a specific one, I would recommend actually for your committee that you consider is there a way that you look for comment as across the questions, or do you look at a way to demarcate the questions to be more discrete? It just is going to make your process a lot easier because you do have questions where you can answer the question, but you're not quite sure what element of the question you're answering. It's just that it's hard to follow, as a committee member, when you have this. That's a general comment.

Specifically for this one, it seems something was mentioned earlier by the CDC. Is there an evidence base already to answer some of the parts of this question in terms of can you review what is already written or can you get it through other sources and then address that issue? I would say maybe that could be something that you could do as a task force, and then you have it open-ended. I know that's the process we engaged in when we were doing the large scale testing issue, and in another committee that I sit on, it was the same thing. What can we answer with the existing information, and then what can we not answer?

So an approach -- I guess what my contribution would be because I'm not a laboratory person -- would be to consider looking at that question because it's a good set of questions. So to repeat, one is to make them a little bit more discrete. Secondly, to look at existing information that you can gather from the experts themselves, and then look for the holes, and maybe there are other sources. That's just a recommendation.

DR. FERREIRA-GONZALEZ: Thank you.

Any other comments? Is there anything that we want to add to the seven questions that were posed to us this morning?

(No response.)

DR. FERREIRA-GONZALEZ: One of the things that struck me today, one of the public comments from Gentris Corporation, was the use of controls and the FDA/CLIA controls. So maybe when we look at the proficiency testing materials, we can also add about controls for the testing. That's something where we can address some of the concerns of from the public comment.

Marc?

DR. WILLIAMS: I would just like to comment on that. This is something that has come up in the CETT process quite frequently. In the public testimony, they indicated that they had six cleared controls. We've seen evidence that there are 937 genetic tests that are currently being offered. I think the perspective is if we are going to move controls to the level of what are FDA-cleared, do we in fact have a system by which we will be able to have controls for all tests, even the ultra-rare disorders where we've essentially had to rely on patient samples, or whether there would be certain exemptions relating to that. So I just was struck that this was a relatively narrow view of the control issue when one looks at the broad perspective of testing.

DR. FERREIRA-GONZALEZ: I think this is an excellent point because not only is this a limited number of FDA-cleared controls from these two different companies, but at the same time, there's a cost associated with running these controls, and with the current reimbursement state, I mean, it becomes very difficult.

But at the same time, I think we might be able to have some kind of exception where we can still use already characterized specimens from patients which have been run with FDA-cleared testing, for example, to get the right result. But I think something that we can consider and look at different ways where we can actually look at these controls when there are FDA-cleared controls or not and so forth.

Thanks.

Dr. G., I guess.

DR. RANDHAWA: Thank you.

Just responding to your comment about is there anything else we can add potentially to this. In my reading of question number 5, there's a subpart B, which is investment and innovation. It's a fairly broad category. Again, I don't know if Steve will actually want to comment on this. We'll be hearing from him tomorrow about economic impact and looking at it more globally. But if you are going to be discussing investment in innovation and the economic aspects thereof, then do we also need to consider the downstream effects of the public health impact and the economics of that on the other side, so just to maintain the entire economics and not just only one part of it?

DR. FERREIRA-GONZALEZ: That is a very good comment. Thank you.

Does anybody else have any other comments?

(No response.)

DR. FERREIRA-GONZALEZ: Where's Reed? There are no other comments? They don't want to add anything else to what we currently have.

DR. TUCKSON: So you're saying that's it? We've got the charge to the committee? We're going to respond to the Secretary's requests as is? You just left all of them there. All right.

So here's the deal. We're going to break for dinner in about 10 seconds. Andrea, here's the deal. You've got to stop for a minute, Andrea, because I've got to say thank you.

(Laughter.)

DR. TUCKSON: You've got to get your award, your applause. The committee of Cindy and you put on -- first of all, clearly you identified the right people to be before us. I mean, it was just extraordinary. And we got all the stuff we needed done. You predicted what the Secretary was going to ask us and you had all the right people to answer all those questions. So can we get a round of applause to the committee?

DR. TUCKSON: Marc, thank you for, in addition to all the other things you're going to do, joining that. Let's go ahead and make sure that we get the other people that we asked. Let's do not lose anyone. Sylvia is joining? Steve is joining?

MS. CARR: Kevin.

DR. TUCKSON: We've got too many people now. All right. We've got a lot of people then.

MS. CARR: Kevin, Steve, Sylvia, and Marc.

DR. TUCKSON: Andrea, did you hear that? Kevin, Steve, Sylvia, and Marc, and then the external people that we are going to try to get.

MS. CARR: Ad hocs.

DR. TUCKSON: They're ad hocs. All right. So we've got a real good thing going forward. This is now a terrific issue.

There's a committee meeting tonight here. Who is that?

MS. CARR: The Task Force on Patents.

DR. TUCKSON: The Task Force on Patents is meeting here tonight. Everybody else, first of all, you're more than welcome to join them. And then the full committee comes back here at what time? 8 o'clock?

MS. CARR: 8:00 a.m.

DR. TUCKSON: And what time is breakfast?

MS. CARR: Before 8:00 a.m.

DR. TUCKSON: Before 8:00 a.m.

So gavel at 8 o'clock. You all really should feel good about a very productive day. Thank you very much.

(Whereupon, at 5:15 p.m., the meeting was recessed, to reconvene at 8:00 .a.m. on Tuesday, March 27, 2007.)