**Development of Final Recommendations**
***Facilitators: Reed V. Tuckson, M.D. and Andrea Ferreira-Gonzalez, Ph.D.***

DR. TEUTSCH: Is Kimberly Layton here? With the weather she is probably stuck somewhere because she comes from Virginia. We will give her another chance if she is able to get here later.

Let's move on to the main task of the day. As all of you know, what we have to do is get to our set of final recommendations and get to approval today. So I will turn the gavel, as it were, back to Andrea and to Reed.

Reed somehow ended up way down there. Can you see us down there, Reed?

DR. TUCKSON: Hello. When you are gone, you are gone.

DR. TEUTSCH: You get the corner spot.

So we are going to start off where we left yesterday in the discussions on the recommendations for Chapter 4.

DR. FERREIRA-GONZALEZ: After you all left, we stayed here and continued to muddle through. We have come up with an alternative version for Recommendation 4. I'm going to give you some time to read this recommendation. Actually, I could read it. Let me go ahead and read it.

"The Committee is concerned by the gap in oversight related to clinical validity. The Committee believes that it is imperative for this gap to be closed as expeditiously as possible. To this end, the Committee makes the following recommendations:

"All high-risk LDTs should be reviewed by the FDA in a manner that takes advantage of its current experience in evaluating laboratory-developed tests. In order to accomplish this recommendation, the Committee recommends convening a multi-stakeholder public and private sector group to determine the criteria for risk stratification and a process for systematically applying these criteria.

"The multi-stakeholder group should also explicitly address and seek to eliminate duplicative oversight procedures.

"For all other tests, this multi-stakeholder group is also charged with the development of a review process that meets the needs of protection of the public. This group should also consider existing regulatory models and data sources, e.g. New York State, and responsibility for overseeing this review process should be defined by this group.

"To expedite and facilitate the review process, the Committee recommends the establishment of a registry as noted in Recommendation 3."

Yes, sir.

DR. FITZGERALD: I know we are trying to get these recommendations to evolve in a more precise way. My concern is that we have in Part A, a term that we then say we don't know what it means and we need to define it. So "all high-risk LDTs," and then later on we say we are not quite sure what high-risk is and we don't define it in the report.

Now I'm worried just about the logic of saying these should be reviewed but we don't know what they are. In the end, when we do get the stratification, we may think that all moderate and high risk need to be reviewed.

I know we went from "complexity." We said yesterday "high complexity," which was not clear, either. I guess we are still struggling to figure out exactly how we want to categorize this, but I don't want to use a term that we then have no standards for. Not in the recommendation.

DR. TUCKSON: What do you suggest?

DR. FERREIRA-GONZALEZ: So move the bullet as Part A and where they convene to determine what is high risk.

DR. FITZGERALD: Exactly.

DR. FERREIRA-GONZALEZ: And then what high risk is then has to go through the FDA review.

DR. FITZGERALD: Right. So what we are saying is, regardless of what they come up with. We don't know what high risk is.

DR. FERREIRA-GONZALEZ: Well, there is some definition today of what high risk is. We might not fully agree to that definition of high risk. Steve?

DR. GUTMAN: Implicit here is the fact, as I said yesterday, we have been classifying products according to risk for 32 years. The original classification system was recommended by the FDA but it actually all went to advisory panels. FDA actually isn't responsible for final risk determination on anything except the fundamentally new products that went around in the late '70s or early '80s. We tended to follow the precedent set in the late '70s or early '80s.

So I guess I have either a concern, or maybe not a concern but certainly an issue to put on the table, which is, is there a proposal that there be one set of risks for commercial IVDs made by Abbott and Roche and BD and Beckman Dickinson and then we will have a different but special risk system for LDTs? If that is the case, then this would be a very effective way of accomplishing a two-tiered risk system, one that now exists and has been used for 30 years and one that you would put prospectively because of the unique status of LDTs.

That wouldn't create parity and it might create confusion and chaos for everyone to make LDTs, but it would be an option.

DR. BILLINGS: Can I ask a point of clarification to that, Steve? Are you saying that a small lab in the Midwest who develops markets or produces a test for inflammatory disease is aware of the FDA risk system and knows that you might classify that as a type I or Class 1 or Class 2 risk?

DR. GUTMAN: No, I doubt that a small lab would be aware of the risk system.

DR. BILLINGS: Right. So despite --

DR. GUTMAN: That is a communication issue.

DR. BILLINGS: Well, it is a functional issue of how FDA has decided to use its enforcement.

DR. FERREIRA-GONZALEZ: So let's go back to what we currently have on the table. In Bullet C, we said for all other tests this multi-stakeholder group is also charged with the development and review process that meets the needs and protections of the public. Maybe also, to get to some of these points, here we might be creating a parallel system. I think it is okay the way we have defined it here.

The notion that maybe we can have C be the first one, where this stakeholders group develops or evaluates to develop a review process that is appropriate for this type of testing that meets the protection of the public, which is underlined. Unless they look at models of data sources that maybe we can also evaluate new models. I think Mara brought up some of the issues yesterday that maybe they need to be considered for this.

We can say that maybe, in the meantime, as this process moves forward, the high risks, as they are classified today, have to go through FDA review.

DR. GUTMAN: We certainly would prefer the ability to move forward on a risk base and go after the high risk. The proposal which is still emerging is one that would take, I think, existing risk products that are currently certainly not high risk but perhaps moderate or some of the higher low risk. I don't know that it would actually change their risk but it would change our review practice, a very major emphasis that I don't think was clear. I don't think there was time on the slides we have seen yet on the proposal, so I don't know if it has been submitted yet to this group or not.

But a critical issue wasn't changing the risk, it was assuming that the risk was okay. It was suggesting that perhaps for certain risk products we would change our approach to how to handle them. I would actually argue that BUN might not be such a low risk product. You are not going to do a mastectomy or a prostatectomy based on a BUN, but you are going to be making decisions.

But the controls that they were suggesting, because it is a well established analyte, was that it may be -- I'm suggesting this -- exempt from pre-market review and it be captured by the quality system regs.

So from my perspective, God forbid, I do think we could refine our risk system. I hate this recommendation because it strikes me as exactly whoever said, "Gee, if you recommend you go to a committee to decide how to recommend, you are not going to get anything done for three years." So I actually hate Recommendation A. I think FDA ought to be allowed to use its work and consult and expand.

We are not even sure the registry is legal in terms of what FDA statutory authority currently exists, but if the registry was done, frankly, at Westinghouse or at GE or at the McDonald's, the point I was trying to make yesterday was that it has to be credible. If it doesn't have pre-market controls, then it has to have strong post-market controls.

DR. FERREIRA-GONZALEZ: It seems to me that you are currently undergoing a process of gathering information about other models of the process of review. What you just mentioned goes in line with Recommendation C here, at least, where we have convened multi-stakeholders to develop a review process that meets the needs of protection of the public.

DR. GUTMAN: I don't object.

DR. FERREIRA-GONZALEZ: They need to look ta the current models that exist there and maybe look at new models there. That could be a recommendation. But there is still a concern in the public about the high risk. Muin, Mara, Jim.

DR. KHOURY: I'm getting a bit confused here. I know we did this as a result of the discussion yesterday, but if I look at this cold, which I tend to do in the morning, it just doesn't make sense to me. What are we saying here? Why can't we be more direct? We recommend that FDA does something. Or, we recommend HHS does something.

This looks like it is all written in a torturous way. The Committee makes the following recommendations. It seems to me it ought to be the other way around. All LDTs should be reviewed by the FDA. The FDA should do something. What is it we are recommending the FDA to do? Is the FDA convening the stakeholder group?

DR. FERREIRA-GONZALEZ: No, we can say HHS. We can say HHS should take the lead. We can add that the HHS convene the stakeholders.

DR. KHOURY: Going back to the framework here, I'm a bit confused. Is this preamble only concerned with the clinical validity of tests? This is all a registry of clinical validity or a registry of safety?

DR. FERREIRA-GONZALEZ: No, this is not the registry.

DR. TUCKSON: The registry is another recommendation.

DR. FERREIRA-GONZALEZ: This is just clinical validity and the review of those tests. When we go to the registry, again we are going to have to figure out what we put in there.

DR. KHOURY: But why can't we be a bit more explicit about what we are asking the FDA to do? We are saying do this. The multi-stakeholder group should do something. So we have one group here, a stakeholder group. You have the FDA, you have all the agencies. It is not clear what we are asking.

DR. TUCKSON: If you start out then with the firm recommendation, the recommendation is that all high-risk LDTs should be reviewed by the FDA, and they ought to do it being informed by what they currently do, whatever the adequacy or inadequacy. Boom, done.

Now, the only point that the next point was is to say we aren't in a position, unless Kevin is, to say what is the definition of high risk. Let me just ask, are we in a position to say what the definition of high risk is? Do we have criteria for that?

DR. TEUTSCH: No, not right now.

DR. TUCKSON: So if we don't, all we are simply saying is then there needs to be some process urgently undertaken to define what is high risk. Now, do we want to be more directive than that? How much more directive can we be about high risk?

DR. KHOURY: Remember, Reed, in SACGT we spent almost a year under Riley Burke's able taskforce trying to define high risk and low risk. I think at that time we didn't succeed very well.

DR. TUCKSON: So, what is your guidance?

DR. KHOURY: Let the FDA do its thing.

DR. TUCKSON: Let the FDA go forward. Let them figure it out without having to create a committee.

DR. FERREIRA-GONZALEZ: Steve, what is your definition of high risk?

DR. GUTMAN: High risk is like life-threatening. It is actually in the reg. I don't have the reg with me. But high risk is making cancer decisions, mastectomies or not mastectomies, intervening in cardiac care. I would argue that there are many things that people would construe as high risk that we would call moderate risk. Glucose, which I think is actually a very high risk that you are going to dose insulin, we call that moderate risk.

So our risk classification systems tends to actually err on the side on the side of gentleness.

DR. TUCKSON: Let's be real clear, then. The first decision here is do we leave it up to the FDA alone to determine what they consider to be high risk and they then go and review. All you should be saying now is, either you want the FDA to be given the authority to do it or you feel like there needs to be a multi-stakeholder committee to advise on the definition of high risk. Which is it?

DR. WILLIAMS: I have two specific comments related directly to that issue, which is right on. The first is that we are not being responsive to the public comment that we have received on this if we say just let's continue with the way things are currently working with risk stratification.

We have had numerous public comments that have said there are issues with trying to apply risk stratification as it is currently done to LDTs. Therefore, we think it is appropriate, and the reason we incorporated this recommendation, that we need to bring the stakeholders together, which I think could be done in a very short period of time, to say what tweaks do we need to make to this system to actually make it work.

I understand Muin's concern about the SACGT spending a year on this, but that was Reed's point. This isn't the group to do the risk stratification.

DR. TUCKSON: Now, is there anyone who agrees with Muin's point that you do not want to go to the extra step of having a convening group to talk about it, just turn it to the FDA and let them do their thing? Is there anybody that wants to support Muin's point?

DR. FERREIRA-GONZALEZ: I don't see the problem of convening a group. If FDA had deliberations with the group, they might come up to the final decision that yes, that is the way to do it, and then we are okay.

DR. TUCKSON: I'm looking for supporters of Muin only. We already know the other point is on the table. Sylvia.

MS. AU: I think we are discussing why don't we have them go ahead with what FDA uses for risk stratification while the group is seeing if that is the correct one or we have to add on so that then the high risk, once defined by the FDA, must really be high risk and they should be doing something.

DR. TUCKSON: So a simultaneous strategy.

MS. AU: Yes.

DR. TUCKSON: So we have two options on the table. I only want you to speak to the options on the table. Or make a different option. You can add a new option.

DR. FERREIRA-GONZALEZ: I have Mara first, who has waited for a while, Kevin, and then Jim.

MS. ASPINALL: I think the two options are, or maybe there are three: convene the group; don't convene the group, just have the FDA do it; and do it simultaneously. Let the FDA do what it is doing now and convene the group.

I would speak against the simultaneous approach. One is I think it creates confusion in the market. For LDTs, which are being potentially newly regulated, you would say between February and May we are going with this definition and the group is coming together and may change the definition. I think that is very hard for laboratories. First of all, it gives you a disincentive to get involved soon because the rules might change. So you will say, I will just wait it out.

And I think that human nature being the way it is, if we convene a committee and they are already doing it one way, I think it gives the committee less incentive to get it done quickly. So I like Proposition A, which Marc spoke about, which is getting the stakeholders together, getting it done, but I'm going to come back later today to put a timeline on it so it doesn't go a long time.

DR. TUCKSON: Any other comments need to be just that clear. Is there anybody that has another point of view? Because otherwise we are going to take a poll.

DR. FERREIRA-GONZALEZ: Anybody with a different point of view?

DR. FITZGERALD: So in the meantime, Mara, what happens? Nothing?

MS. ASPINALL: In the meantime, there is draft guidance out now, which I don't know if this is finalized, but that we put this in quickly, the stakeholders get together within a period of -- I don't know if we can manage weeks but certainly not more than a few months, and we get clarity and we have something that sticks, not something that we have another interim period, which I think creates confusion and awkwardness.

I believe that many companies will game the system pro or con in a way that doesn't serve the best interest. We should put in the system and go forward so laboratories get the clarity of where we are going.

DR. FITZGERALD: May I respond to that? Here is my concern. I understand your concern. Looking at it from the flip side, if one looks at the experience of trying to wrestle with this issue up to this point, as Muin pointed out, this is not something that is easily determined. So you might be able to force a complex group of stakeholders together, tell them at the end of six months you want an answer, and not get a good answer in that period of time.

I'm just saying that is a possibility. If that were to occur, you have put all your eggs in one basket. So my concern is to say why not let FDA do what FDA is doing. I don't know if we want to call it "simultaneously" or "in parallel" or whatever. I would just throw out "in order to accomplish this recommendation," that phrase, from that little bullet point.

So A, FDA reviews high-risk LDTs according to your current standards. B, the Committee recommends convening a multi-stakeholder public group. Then the other B just folds into that because that is the same multi-stakeholder group.

DR. FERREIRA-GONZALEZ: This is critical. It might hamper access to certain testing because laboratories don't know what is coming down the pike.

DR. FITZGERALD: Right.

DR. FERREIRA-GONZALEZ: So I concur with Mara that we have to have, maybe, the stakeholders convene in a very short time and then come up with a decision before they go through this continued high risk. If I have a high risk and I know that there is another group that is going to be coming up with a different definition of high risk, I'm just not going to put it through.

DR. TUCKSON: One last comment and then we are going to poll the sense of the Committee to get a consensus here.

DR. BILLINGS: Just to Kevin, if nothing happens, we still have that very complex framework that the Lewin Group presented yesterday that is in existence. FDA has been acting to do its regulatory thing with that framework in place. So if the Committee takes nine months or six months to figure out what a high risk thing is, it is not like there is nothing left. So I don't think we have to fear a great deal of the absence of any oversight.

DR. TUCKSON: Now, let's just start to see if we can't push to a quick consensus here because we really do have to move this. You have a couple of options on the table, and it boils down to how many of you think that we ought to define the FDA as moving forward in this field now and not worry about the convening of other body, that the FDA should do this, they have the authority to move forward, and that is what happens? How many of you are of that posture?

[Show of hands.]

DR. TUCKSON: Did I see four? Oh, yes, the other side. Ex officios. Everybody is on this. This is not a formal vote. This is a consensus. So, four. We have four altogether.

Now, how many of you believe that the FDA ought to move forward, because they already are. You can't stop them. They exist, as Paul's point was made. They are doing their jobs, getting paid by the citizens. While that is happening, urgent convening of a group that will recommend as we have here? So the convening of a group occurs and that will then ultimately inform the process. How many of you are in favor of that strategy?

[Show of hands.]

DR. TUCKSON: That is the overwhelming majority. All right. I think you have a pretty clear sense, so I think that you have declared where you really are. Yes, Joe.

DR. TELFAIR: My question is in terms of the turnaround on this. There is more than one type of methodology for convening a multi-stakeholder group in terms of convening. There is more than one strategy. There is a rapid strategy or there is the more traditional strategy. Since I don't know what is it you all were discussing, I'm just wondering is that something that could also be a recommendation as a strategy that actually speeds the process a little bit more?

DR. FERREIRA-GONZALEZ: We have Jim and then Mara.

DR. EVANS: Two things. I think we get sidetracked by this whole issue of finding high complexity or high risk. Correct me if I'm wrong; it seems to me that the reason you even bring up high risk is a real-world constraint and a necessity to triage FDA's limited resources and approach this huge universe of LDTs.

I think that what we can say is that FDA needs to tackle this, that the bottom line is that all LDTs must be safe and must be sufficiently regulated, and that we can tell them there are gaps here and this needs to be done posthaste.

As far as triaging which ones they feel are most in urgent need of oversight, that is something the FDA has been doing for a long time, I imagine, figuring out what they need to tackle first. There is nothing wrong with us saying that this has to be done quickly and maybe a very blatant statement that all LDTs need to be addressed by FDA.

DR. TUCKSON: Jim, I think you are speaking to the sense of what we have as a consensus. You are adding specific stuff around urgency. Mara had a point about urgency. I think we all recognize that. So the writing can capture the urgency words in here. Everybody is talking about not playing around.

You might want to have the subcommittee, as you capture the final language, get to Muin's point a bit by just stressing in the body of the narrative that the point is that the FDA is doing what it is doing, move forward. FDA should not be screwing around waiting, sitting on its hands for nine months until some committee [meets.] I think the sense of the Committee is pretty clear on those points. Muin didn't get everything he wanted, but he got a lot of it.

So the consensus is there. Let's move to the only other issue that you didn't describe. There was a throw-out from Steve which I think people need to deal with quickly, and that was this issue of these parallel programs for LDTs versus IVD/IVDMIAs.

I don't know if I understood it. Anybody else understand whether or not we have created a single system or two different systems? Steve, do you want to explain that real quick, what we just did just now in terms of the consensus?

DR. GUTMAN: I'm not sure I can. I'm not sure I'm following because I'm hearing different things.

The current risk system, whatever else you can say about FDA's risk system, whether you swear by it or swear at it, is highly public. Even our interest in IVDMIAs isn't exactly a state secret. So everything we are interested in and the direction we are going, the current classification, our initial foray into future regulations, it is just all open.

DR. TUCKSON: So Steve, the consensus is that you will keep doing what you are doing. Now, having said that, did we say anything else that creates a parallel universe, or is it one?

DR. GUTMAN: That is not what I thought the vote actually came out. That is what we would like, but in all honesty, I wasn't sure that that was the direction that I was getting.

DR. TUCKSON: Mara.

MS. ASPINALL: I think Reed's comment and Steve's comment may be sort of crossing. I think there were two issues. One is, I thought the last vote said, which I agree, have a multi-stakeholder group in an urgent manner, and deals with Joe's issue. I would say it is too prescriptive to say the details of how they do it, but rather give them the timeline.

To Kevin's issue, they may not come up with the perfect example, but work expands to the time allotted. It may not be perfect in six months, but it may not be perfect in three months, so let's give them a short period of time and get it done to emphasize the urgency.

But I think that was the sense of the Committee on that issue. Your question, Reed, to me is a different one, which is, is there a different system for IVDs than there is for LDTs. I don't think we have discussed that, so I don't think there is a consensus or a proposal. Well, maybe there is a proposal, but I don't think we have discussed that formally.

DR. FERREIRA-GONZALEZ: I think we did in the text of the report. We made a distinction between the product and the LDTs that we consider services. So already in the report we are bringing out that there are differences between these two.

MS. ASPINALL: I would like to suggest that we continue to recommend that there are differences. In reality, there are important differences both in what is done by the laboratory, the number of laboratories doing it on any one piece of data or analyte, as well as the volume that is typical of the average LDT versus the average IVD.

That was one of the very important things we saw in the public comments. It is just, quite frankly, infeasible for many LDTs to go through the exact same process an IVD might go through because of the relative numbers of putting together the data and the relative resources. We heard a lot of that from the university laboratories as well. It is not feasible to go forward and therefore it becomes an access issue.

DR. FERREIRA-GONZALEZ: Marc, do you have a comment?

DR. WILLIAMS: We are obviously all hearing different things. I heard Jim very clearly state that his recommendation was that basically to avoid parallelism that all LDTs and all IVDMIAs undergo a triage process by FDA using their currently available standards, so that we basically eliminate this avoidance of FDA oversight.

We would also then look at this multi-stakeholder group to address some of these other issues so that if we can refine the process to address this, that that would be the way to move forward to try and facilitate that.

Again, I think you don't say to FDA "You don't do this." I think the point is that we really want to be directive but if we are really concerned about the end user, the public, then you have to say we can't allow tests to come out where we have no data about anything relating to clinical application of the test. That is just not acceptable.

DR. TUCKSON: Let's get our philosophies straight, then. We have been struggling with this dichotomy forever. The poor small folk, we can't overwhelm them with a whole bunch of regulations. Yet everybody, we have also said, has to be regulated. At some level, you can't have anybody slipping through the cracks, so we are closing the crack.

Now the notion is, should the process coequal you regardless of whether you are an LDT or an IVDMIA folk. We have two different points of view on the table. One is saying yes, there should be a difference, and one is saying that there shouldn't.

Other than the people that have spoken, who is strongly in favor of one side of that equation or the other? Where are you on this issue? This is a big issue. Do you go easy or do you recognize a differential in these two populations?

MS. ASPINALL: Not necessarily easy.

DR. TUCKSON: Differential. One process or two. Kevin looks confused.

MS. ASPINALL: I just said not necessarily easy, just different.

DR. TUCKSON: So, where are you at? Confused, not sure? See it as a difference without a distinction?

DR. FERREIRA-GONZALEZ: We are asking in C for another group of multi-stakeholders to be charged with the development of a review process that meets the needs of protection of the public. Can that group wrestle with this notion?

DR. TUCKSON: It is a punt. So you want to punt. Muin doesn't want anybody punting anymore. He is tired of punters. Steve, would you again, just very quickly, say again what are your concerns about having parallel systems from an administrative point of view?

DR. GUTMAN: The concern about the parallel system is what Mara said. You need to be careful and like what you wish for, and I don't wish to chill technology and I don't wish to review 1,200 genetic tests, many of which may be very exotic and rare.

So that is a negative side. AdvaMed got a little bit truncated there, but I think they have a point. A lab test is a lab test. If I'm a patient, whether my lab test is graded by the Mayo Clinic, by Steve Gutman Lab of Rockville or by Genzyme, I want the damn thing to work and I want somebody to be responsible for it working.

So as a patient, whether it is FDA or CMS or HHS or AHRQ or CDC, the damn thing should [work.] Somebody has to stick up their hand and say "I'm taking responsibility that this has been quality controlled not by the sponsor."

DR. TUCKSON: Paul's hand is up, and I want to get there, but that sure resonated as clarity. Let me just make sure I know where you ended.

I think everybody is on board with you -- I'm watching the heads nod -- when you say the doggone thing should work, there should be an independent party that says it should work, and so forth and so on. Your first part of getting to that, do you say that you are prepared to accept from your experience two different mechanisms to get there?

DR. GUTMAN: I think if it is a rare test, whether it is made by Abbott or whether it is offered by the Mayo Clinic, it is a rare test and we have to be careful about what we wish for.

DR. TUCKSON: So, two different.

MS. ASPINALL: No, he's saying the same.

DR. TUCKSON: It's one? So one process.

DR. GUTMAN: Yes. Maybe it needs to be tampered with, it has to be fooled around with, but yes.

DR. TUCKSON: Clear. I stand corrected. I'm trying to hear. One. Paul.

DR. FERREIRA-GONZALEZ: You talked about a system, but you just said that you can't actually review all of them.

DR. GUTMAN: No, so I do think that the Department is faced with a challenge.

DR. FERREIRA-GONZALEZ: Exactly.

DR. TUCKSON: Everybody, Paul has his hand up.

MR. MILLER: I had better say something important and relevant.

[Laughter.]

MR. MILLER: It strikes me that in a sense the group is coalescing around some ideas but that there are different perspectives about that same idea. The way I see it is that there is a policy issue about what the process should be. Quite frankly, I'm hearing that there is quite a good deal of agreement about what the policy is. You have just stated that we have heard the heads nod.

Where the breakdown lies is in a sense how do we get to actually effectuating that policy. Does the reality work. I would submit that if we agree on the policy, and this is a policy body, that we frame it in a way back to HHS to say here is where the group is and this is what we think is the right thing to do. It is not incumbent upon this Committee to work out where the resources are or whatever. It is for this Committee to say here is what the right thing to do is, here is what our panel of experts says, and let's move forward and make that work.

DR. TUCKSON: So we have Julio and then James. With that, try to get us specifically on where you are on this specific thing.

DR. LICINO: My comment was a little broader than that. Just studying up some of the things that were discussed yesterday -- I wasn't here but I went through the materials as to what is being discussed now -- people were saying that this has to do even with freedom of information, just telling people who they are. It is just freedom of information and giving your genetic blueprint.

But if you are telling people that they have a risk of myocardial infarction, they are going to change their lifestyle. They can change their life dramatically one way. If it tells them that they have a risk of Alzheimer's, they may completely shift their whole entire lives in a different way.

So I think in a sense these tests are even more important and more in need of regulation than BUN and 057 or 120 or 130. We split the hair over the precise accuracy --

DR. TUCKSON: That is good, Julio. That is terrific. Jim, what I need you on is one or two systems. That is all I need to hear now.

DR. EVANS: You aren't going to get that from me.

[Laughter.]

DR. EVANS: I will be clear and tell you that I think we need to quit parsing. We are parsing on parallel and differentiating LDTs versus IVDMIAs. We are differentiating about high complexity, et cetera. That is not what we should be doing. We should be saying just what Steve said, that every test that a patient gets should be reliable. Number one. Number two, all that parsing is just code for the fact that real-world constraints make it difficult to implement, which is what Paul is saying.

So what we need to do is say all tests need to be reliable and that the FDA, it seems to me, has a long track record of looking at that. We should say to the Secretary this is a difficult issue because of the constraints and you have to figure out how to get this implemented, and it might mean advocating for more resources to do it. Because you have a flood of new tests that need to be evaluated.

DR. TUCKSON: Jim, let me just ask you. You are very clear. The only question I have for you is, do you feel like if that is what we did -- some people would put the phrase "if that is all that we did" -- that we would have then less than ambitious and thereby slowing the process down by not being more direct?

DR. EVANS: No, on the contrary, I think it is extraordinarily ambitious to say to the Secretary you need to be sure that every test has undergone scrutiny and it may mean figuring out how to get more resources to do that. I don't think it is more ambitious to make more committees.

DR. TUCKSON: So we all know where we are, we have already gotten one set of consensus there. I opened up this door because I wanted to make sure that people were not going to read this report, as we already can tell, as through a filter of whether or not we are saying there should be two different tracks, two different systems for LDTs and IVDMIAs.

Jim, I think you are sort of saying rise above that. I think Paul is saying rise above that debate and simply say, look, it is not important. Just you figure that out. What we are saying with great clarity is this is what the goal has to be.

DR. EVANS: I think there should be a bullet that says this is going to be a bigger and bigger problem. It is already a problem. It is going to be a bigger problem and you need to figure out how the resources are going to be devoted to this.

DR. TUCKSON: There may be an emerging consensus of that is what you mean to say. If there is somebody who feels strongly that this is not what you want to be associated with, you need to quickly and succinctly tell us that. I see Kevin's hand was up.

DR. FITZGERALD: No, I'm just going to make it happen.

DR. TUCKSON: You are a doer.

DR. MILLER: Rather than just stating the policy and giving it to the Secretary, give the Secretary at least some guidance into how to come out the other end in solving that.

DR. FERREIRA-GONZALEZ: That is what we have here.

DR. TUCKSON: Therefore, let's take the look now at what we have.

DR. FERREIRA-GONZALEZ: Mara and Kevin.

MS. ASPINALL: I would agree with Paul and what Steve and I think Jim said. Making the fundamental statement that all tests, not IVDMIAs but LDTs and IVDs, have to be safe and effective and the FDA is involved, is a huge step.

DR. TUCKSON: Hold it right there, Mara. Hold it right there. I just want to make sure we get exactly what you are saying. Are you saying in A all --

MS. ASPINALL: No, this isn't even an A. This is really above A. I think it is what everybody was saying.

DR. TUCKSON: Do we want to use the words "all tests, LDTs, and IVDMIAs"? I just wanted to make sure I knew where you were headed.

MS. ASPINALL: With that, in answer to your comment, I think that is a huge step. Many of the stakeholders have said that CLIA alone is enough to have done that. So I want to recognize that this is a statement in a way that is not a small one and is a significant policy. Not all the public comment folks would agree with that because many say CLIA alone today is allowing these tests to be safe and effective.

But what I want to acknowledge, and Andrea mentioned it from my comment yesterday, and my concern and therefore support of two systems is not so much that we need two different systems but we need to acknowledge that tests are different from devices and that service tests are different from product tests.

I very much agree with that statement that all tests, regardless of what they are, because a patient doesn't know the difference on who is doing it or whether it is on a central lab or a decentralized lab. They don't need to know. That doesn't help them to know.

But what I'm concerned about is taking the square peg and putting it only a few holes that we have available. What I want to make sure, which is consistent with what I said yesterday, even if it means a bigger regulatory environment, is that we have something that is appropriate to both types of tests as they exist now.

DR. TUCKSON: Andrea has given a list of responders. As you respond to that list, you need to focus in on these two pages, A, B, C, and D, and what changes, if any, would you make, so we can bring this to closure.

DR. FERREIRA-GONZALEZ: Kevin, what do you have?

DR. FITZGERALD: Following up on this, we take "high risk" out of A. So we are going to say "all LDTs." Now, Steve, what do we say should be reviewed, evaluated, addressed? I don't want to get into a technological --

DR. GUTMAN: All tests.

DR. FITZGERALD: So all tests should be what, addressed?

DR. GUTMAN: Yes.

DR. FITZGERALD: "Addressed" is good? Okay. "Addressed by FDA in a manner." "Tests," yes. I'm sorry. "Should be addressed by FDA in a manner that takes advantage of its current experience in evaluating laboratory tests." "This should address." Don't say "review" it or "evaluate" it because that might be too technical.

"This step by HHS entails commitment of significant resources."

DR. FERREIRA-GONZALEZ: Where are you now?

DR. FITZGERALD: Right at the end. Just put that in. New sentence.

DR. FERREIRA-GONZALEZ: Here, above the bullet?

DR. FITZGERALD: I'm sorry. Yes. "This step by HHS will require commitment of significant resources in order to avoid potential harms," and then we could say "(e.g. patient and public health and stifling technological innovation.)" One of the potential harms is stifling technological innovation. So in other words, this has to be done right. Otherwise you get both bad effects.

DR. FERREIRA-GONZALEZ: Isn't it also stifling innovation but access to the testing?

DR. FITZGERALD: I'm sorry? You can add to the list if you want.

DR. FERREIRA-GONZALEZ: So the public harm will be also access to the test.

DR. FITZGERALD: Yes, access. Sure.

DR. EVANS: I was just going to say, one of the things that I have learned from Reed over the last couple of years is that it is easy to demand that more money be spent. In a way, this is demanding that more money be spent. I think that this is actually a case where it makes sense to demand that.

This may sound like wordsmithing, but because it is a big deal I do think it should be B. We don't want to come across that we are cavalier, that we can solve all these problems by throwing money at it. Just give them some money. When we do that, I think it should be deliberative and careful and it should not be a throw-away. I think it should be a point.

DR. BILLINGS: Kevin, can you clarify for me how your change picks up what Mara had said just before you about the bifurcation of service and product?

DR. FITZGERALD: My understanding currently is that is one of the areas that we are having difficulty parsing, and the idea of what we are talking about here for LDTs versus IVDs, IVDMIAs, all that sort of thing. By putting in just "tests," I thought we could be broad enough. That was the idea, to get above that particular distinction and say in place we have the possibility of addressing this situation via the FDA.

Now, that doesn't mean that the way things are currently is going to be sufficient do to that, but the template is there. That means you have to have the resources committed in order to step this up.

DR. TUCKSON: So, do we have consensus on this change, other than maybe moving this step to a sub-bullet?

MS. ASPINALL: I think we can deal with that later.

DR. TUCKSON: I think the other modification earlier, from the other discussion, was that we would eliminate "In order to accomplish this recommendation" and we would simply put "The Committee recommends."

DR. FERREIRA-GONZALEZ: Yes, "The Committee recommends."

DR. TUCKSON: So, do we have it? Yes, Mara.

MS. ASPINALL: I don't think Jim meant the same thing, but I think B is absolutely essential, that we address explicitly. I would get rid of "seek to" and I would say eliminate "duplicative oversight procedures." Can we go back? Just the word "seek to" and talk about being specific. None of the labs can exist over duplicative oversight for which you have two things to do that are against each other. You just can't do it.

DR. BILLINGS: There are actually three things. You will have FDA, CLIA, and state.

MS. ASPINALL: Which is even worse. But I would agree. So I would just say it is absolutely essential to get rid of the word "seek to."

DR. TUCKSON: You said should eliminate?

MS. ASPINALL: Eliminate "duplicative," however many there are.

DR. FERREIRA-GONZALEZ: "The multi-stakeholder groups should also explicitly address and eliminate."

MS. ASPINALL: That is good. "Address and eliminate."

DR. TUCKSON: Good. Anybody have any problem with that? I think that is straightforward. Moving quickly. Yes?

DR. KHOURY: "The Committee recommends convening a multi-stakeholder public and private sector group." Is that by HHS, by the Committee, or by FDA?

DR. TUCKSON: HHS. "Recommends that HHS convene a." Good pick-up. Last comment?

MR. DANNENFELSER: Are they going to have the authority to eliminate by themselves or they can only recommend that these duplicative procedures be eliminated?

DR. TUCKSON: To the extent that it is within the purview of HHS. They can't eliminate states.

MR. DANNENFELSER: It says "the multi-stakeholder group." That is why I'm just wondering. It is kind of the broader outside people and so on.

DR. TUCKSON: Again, the Committee is convened by HHS, so anything within HHS can be eliminated. It can't tell New York what to do, but it can certainly be informed by and try.

DR. TEUTSCH: Yes, the group itself can't actually eliminate it.

DR. FERREIRA-GONZALEZ: They will have to recommend how to.

DR. TUCKSON: Oh, I see what you are saying.

MS. ASPINALL: I think that is a detail. I would rather have the strength of the language that says "eliminate." It is really just New York and Washington, and there are a lot of relationships between there. I would rather have it as "eliminate."

DR. TUCKSON: Good. Let's proceed, please. Let's go to No. C. Anything there? Oh, go back to B.

MS. ASPINALL: There is no C now.

DR. TUCKSON: This, as I remember it, refers to the --

MS. ASPINALL: We don't have that anymore.

DR. TUCKSON: It goes away.

MS. ASPINALL: No, no, no. Just the phrase "for all other tests."

DR. TUCKSON: What is the difference there?

MS. ASPINALL: Yes. I don't think we need this.

DR. TUCKSON: Yes, it is over.

DR. FERREIRA-GONZALEZ: But I think we can also look at "consider existing regulatory models of data sources" also. We can consider new models, too.

DR. TUCKSON: But that is the committee.

DR. FERREIRA-GONZALEZ: No, no, no. Taking a portion of this and putting it back into A.

DR. TUCKSON: What portion would you put back?

DR. FERREIRA-GONZALEZ: I would like to put back that the group should also consider existing regulatory models, data sources, and new models of oversight.

DR. FITZGERALD: Wait, wait, wait. That bullet in A, that sub-bullet, I thought we were going to combine with B. It is all one thing that the multi-stakeholder group does. Otherwise we have two things on the multi-stakeholder group.

All you have to do, Cathy, is move the B in front of the bullet. That's right.

DR. TUCKSON: So the highlighted part before "responsibility." Right there.

MS. ASPINALL: But add the phrase "and new models." "Existing and new regulatory models."

DR. TUCKSON: Would you cut that and paste it into the earlier one?

MS. ASPINALL: And then put it where Kevin said.

DR. FOMOUS: You want it at the end of here; is that right? No?

MS. ASPINALL: Yes. What Kevin is suggesting is also put the B in front of the bullet point. So these would be the three things the Committee would do.

DR. FERREIRA-GONZALEZ: But we need to add "the current existing regulatory models and data sources and consider also new models."

DR. TUCKSON: So, "existing and new."

DR. FOMOUS: The sentence that is in B about explicitly addressing duplicative oversight procedures, where do you want that within this bullet paragraph? Do you want this sentence to come at the end of this?

DR. TUCKSON: I thought it was the third bullet.

DR. FERREIRA-GONZALEZ: We will have three bullets, I guess.

DR. TUCKSON: Basically, if you take Jim, you will have four bullets. Three bullets with Jim.

DR. FITZGERALD: Basically, Cathy, B is talking about the multi-stakeholder group. There are three things that the multi-stakeholder group is going to do within B, which actually is going to turn to C once Jim's sentence becomes B.

DR. EVANS: Well put.

DR. FITZGERALD: Thank you.

DR. TUCKSON: This is just now graphing here.

DR. FITZGERALD: We can figure that out later if you want.

DR. TUCKSON: I think we have the sense of it. Again, you have Jim's B about the money and then you have three bullets under C.

DR. FITZGERALD: And we will take care of that later.

DR. TUCKSON: So, you all got it? Move to the next issue. We didn't do D. You are eliminating C. C goes. Now you are left with D, which is an appropriate transition to start to talk about the registry, which is where we are headed.

DR. FERREIRA-GONZALEZ: Do we also want to talk about or say something that any system that comes up from the deliberation, there has to be some period that allows the laboratory industry and even the IVD manufacturers to step up to the part?

DR. FITZGERALD: No one is going to just immediately expect --

DR. FERREIRA-GONZALEZ: But we have to tell them that we might want to wait for two years before anything would change?

PARTICIPANTS: No.

DR. TUCKSON: No. Now Andrea is going to take us through a discussion on the registry because the last statement on this one is this process is going to be informed by this as yet undefined registry. So we need to go do the registry.

DR. FERREIRA-GONZALEZ: Recommendation No. 3. Recommendation 3 supports a mandatory system of genetic test registration that uses CLIA registration data as the foundation. This recommendation was significantly revised from the draft recommendation, which called for a voluntary system of registration through a public-private partnership.

During the discussions of this recommendation with the taskforce, we had agreement that registration should be mandatory, but the taskforce was split on where such a registry should be housed, either at CMS or FDA.

The public comments also did not offer a clear indication of which agency should house the registry. A few comments articulated a preference for CMS or FDA, but most remained silent on this issue or suggested registration with a government regulatory body or publicly supported website.

Based on the split decision regarding a home for the registry, SACGHS staff explored the issue with our ex officios from CMS and FDA. I would like to pause to thank Judy Yost, Steve Gutman, and Liz Manfield for their patience with our questions and making concerted efforts to seek answers within their respective agencies.

These discussions led to unanswered questions about the legal authority to gather and publicly display certain data elements. Because of this rather significant development, the steering group modified this recommendation, and this is something that you have here now.

Let me read this recommendation as you only recently received it and may not have time to review it.

Recommendation 3, which is the newest version, states that "There are considerable information gaps about the number and identity of laboratories performing genetic tests and the specific genetic tests being performed. To gain a better understanding of the genetic tests being offered as laboratory-developed tests and to enhance the transparency in this field, SACGHS reviewed proposals for a voluntary or mandatory test registry and considered the benefits and burdens of each type of system.

"The Committee decided that a mandatory, publicly available, Web-based registry that is well staffed to maintain an accurate and database will offer the best approach to address the information gaps.

"Since genetic tests are not unique from other laboratory tests for oversight purposes, the registry should include all LDTs.

"The Committee also discussed whether such a database should reside at CDC, CMS, or FDA. Based on the exploratory work, SACGHS concludes that the concept of a mandatory registry

offers promise but recognizes that there are unresolved issues, including practical and legal questions, that require further analysis before a final decision can be made about how and where to implement the registry.

"So with that preamble, in light of these unresolved issues, SACGHS recommends the following course of action:

"CDC, in collaboration with CMS and FDA, should convene a stakeholder meeting by September 2008 to determine the data elements to be included in the test registry. CDC should cast a wide net for a broad stakeholder representation, including representatives from the private sector who can represent a role for the public-private partnership in developing a registry.

"CDC, through this stakeholder effort, should assess the level of effort as well as the burden on the laboratory and the impact on the other key stakeholders such as patients, physicians, and payers, necessary to obtain each data element, including linking to reliable sources of existing information.

"HHS should perform the requisite legal analysis to determine what data elements, as determined by the CDC stakeholder group, can be required by CDC, CMS, and/or FDA. For example, if clinical validity is a required data element, the legal analysis should determine whether CDC, CMS, or FDA currently have the statutory authority to require reporting of this information for all LDTs.

"If these agencies do not currently have the necessary statutory authority, the legal analysis should identify specific statutory provisions that may be needed in order to effect the system of enhanced reporting requirements and a statutory authority should be sought.

"HHS should appoint and fund a lead agency to develop and maintain the mandatory registry for LDTs. The lead agency should work collaboratively with its sister agencies to create a comprehensive registry and minimize duplicative collection of registry information. The lead agency should have the qualified personnel who are experienced in developing and updating large databases in a timely and accurate manner.

"While awaiting completion of the above processes, HHS should use short-term voluntary approaches such as incentivizing laboratories to register with Gene Test and encouraging laboratories to make their test menu and clinical validity data for these tests publicly available on laboratory websites."

DR. BILLINGS: Andrea, we just decided, at least in the discussion we had before, that FDA is going to review all tests. So they are going to have information, presumably, on all tests. So aside from Bullet C, which basically says that the lead agency ought to be FDA and that they ought to work with other agencies to make sure that they are reviewing all tests, why do we need this registry? Except to make sure that the public has better access to test information.

DR. FERREIRA-GONZALEZ: I don't know that we are recommending that FDA will review all tests. We are recommending FDA look at everything but not necessarily actually physically reviewing low-risk and so forth. They might be using different mechanisms for this.

DR. BILLINGS: Well, if they have information on all the tests, why can't --

DR. FERREIRA-GONZALEZ: They might not get all the information for all the tests. Mara, Muin, and Kevin.

MS. ASPINALL: I think, Paul, to your question, we recommended that the FDA in overview has responsibility for all tests but that doesn't necessarily mean pre-market review and it doesn't mean that there is an easy-to-find directory. One of the public speakers mentioned it. You can't get a list of all the CLIA labs today.

I think what we want as we talk about public health and transparency is the ability to get a comprehensive and complete list of tests that are available and what the specifications are. As we heard for Gene Tests from several people, as effective as it is, it is not comprehensive. I think that that, to me, is dangerous because people look at it as if it is comprehensive and may make certain conclusions based on it.

So I think this works very well with the other recommendation, and we should have the transparency for the public but also physicians to be able to keep up with the rapidly changing and increasing number of tests to say what is there, who does it, what are the basics about these tests. We could debate what is on the registry, but I think this is a very important point that we have a window of opportunity to recommend. It would be a wonderful statement a year from now that we have the ability to look up all tests that exist in the U.S. that are available to physicians and patients.

DR. FERREIRA-GONZALEZ: I think what we have recommended is that the FDA look at all the tests but not that they are physically going to go and review all the tests. That is what the specific recommendation say.

Now, in the meantime, as this process evolves, this registry can provide important information to the consumers. As this registry evolves even faster, it can be developed, but then the FDA can look at what is already in there and necessary to be reviewed or not from there. Muin.

DR. KHOURY: Can we go back to just the beginning of this? Recommendation A. For those of you that have been at this table for many, many years, my friend Elliott Hillback from Genzyme used to serve on the SACGHT. I have this running joke, Muin and Elliott always saying we need to inform the public and the providers what we know and what we don't know about the genetic tests at any given point in time. It has to be authoritative and updated. We don't have that right now.

I think we have pockets of this through Gene Test, through the SEP process, through EGAPP, and it is not only about clinical validity. It is about the whole package, the whole package from analytic validity to proficiency testing, to clinical validity, to clinical utility. Whatever data are available out there so that providers and the public can make the right decisions about the use of these tests, and also for these things to be reimbursed.

So I view the registry as a vital concept to go through this morass here of trying to pool all the information together.

Now, Recommendation 4 was a breakthrough recommendation because you just asked the FDA to do something, which I think is profound, and you just created a stakeholder group to help with that process. Now, how many stakeholder groups do we want to create between now and September to create the registry?

I would maintain to you that you keep this as a high level recommendation and you task HHS to create the registry but not discuss the data elements. We know what they are: analytic validity, clinical validity, clinical utility. Let's not go through this granularity of saying we need to do A and B and C. Basically, you are asking HHS to implement the concept, and you can give them some guidance.

DR. FERREIRA-GONZALEZ: I still think it is very important to engage the stakeholders. You say we know what the data elements that we need are, but how much data and how much in-depth? That is very important. It goes to the key of how successful it is. So you still need to engage the stakeholders to really see the burden of all this.

DR. KHOURY: I think there is a vital distinction between what you are saying and what I'm saying. The recommendation is to create the registry. In the process of the creation of the registry, things have to happen, including evaluating authorities, legal authority of collecting data, engaging stakeholders. But, just basically, create the registry. Give it to HHS to implement. The groups, CMS, CDC, NIH, will get together.

DR. FERREIRA-GONZALEZ: What you are saying is add to this saying HHS should create a registry.

DR. KHOURY: Exactly.

DR. FERREIRA-GONZALEZ: Then we can leave CDC in collaboration because that is the process.

DR. KHOURY: Right now, what you are giving us is sort of A, B, and C, which seem to be a bit confusing. HHS should appoint and fund a lead agency. That is No. C. You are putting the cart before the horse. If the lead agency is NIH, then NIH should do the convening function of the data elements. Why should we give CDC something to do before HHS acts on the lead agency?

DR. FERREIRA-GONZALEZ: But if you don't know the data elements, how would you do the legal analysis?

DR. KHOURY: The lead agency, in collaboration with all the others, will figure out the data elements. But you are giving recommendations to HHS to do something.

DR. FERREIRA-GONZALEZ: I think we are okay with saying you have to create a registry.

DR. TEUTSCH: What I'm hearing Muin say is we are creating a registry which contains up-to-date information available to the public on analytic validity, clinical validity, clinical utility, and availability of the tests. That is what I'm hearing. That is what we are asking them to do. Now we just talk about how to get there. But that is the recommendation.

One point of clarification. Since we put "tests" in No. 4, are we just putting "tests" here or are we putting LDTs? "Tests," right? "Tests."

MS. ASPINALL: I would suggest, again, this should be "tests." I just can't say enough that this is a historic moment. It is the only part of the healthcare system we don't have the ability to get everything that exists. So I like what Muin added, and I think this is a key area that addresses lots of the stakeholders and lots of the public comments of stakeholders to say we want transparency inside the medical community and outside the medical community. This does it.

DR. KHOURY: One more thing. Just like you did with the FDA, you have to put resources behind this. Right now, the creation of the registry involves --

DR. FERREIRA-GONZALEZ: That is what we said in the recommendation. We will fund it, Web-based, accessible. We have some language.

So, the idea is to add a new A.

DR. KHOURY: Switch C to A. "HHS will appoint the lead agency," and then that would be who is doing the convening. If it is NIH, fine. If it is CDC, fine. Or we can keep it going at the HHS level for a while. But don't ask CDC to do something in a vacuum. I think we all want to work together because this is complicated. It is not going to be done by just one agency.

DR. TUCKSON: Andrea, let me just make one comment. You keep driving the train here. Sarah, if staff could tally from everything we have done so far in terms of recommendations to this point and each time we make a new one. We need to put up a slide at break that shows how many committees we have commissioned and how many of them have money associated with it.

So that, when we come back at the end of our discussion and start to really fine-tune before we close this whole thing off today, we will know whether or not we have committed too many committees and too much money.

Sarah, if you could just [do that.] Please continue the discussion, Andrea, but I just want to make sure we have that list.

DR. FERREIRA-GONZALEZ: Paul Wise.

DR. WISE: I hesitate a little bit to bring this up at this point, but I'm new to the Committee and maybe you could help me a little bit with this process.

I'm increasingly uncomfortable that this is the proper forum to hash out these kinds of issues. I feel that in some ways the time pressure to get this out is forcing a lack of serious consideration of things that may be extremely important in the end.

I could use some guidance. If this is the way it always works and every report goes through this kind of detailed conversation among the Committee at not quite the last moment but somewhat near the last moment, then fine. But if this isn't typical, then is there a larger question about whether this should go back to the committee for more detailed conversations, talking more with some of the people who represent the different agencies in the government.

DR. TUCKSON: Paul, thank you. It is a great point. I will just give you a little quick history. First of all, inevitably you will find in every report that we do an enormous tension and pressure around time and deadlines and that sort of thing. However, you often have the opportunity to postpone certain decisions if you are feeling an unreadiness.

In this case it is a little different because we have a request from the Secretary to deliver a product by a date. Therefore, we are under a little more unusual pressure in this case. That is why you are feeling it.

Be that as it may, you can imagine that, like most things in nature, it abhors a vacuum. You will fill up every second of every day and you will machinate and gnash teeth on every issue for every report. But this one is a little different because of the timeline.

DR. MILLER: We would love to have you on some of these subcommittees if you think that we are not having too many meetings.

[Laughter.]

DR. FERREIRA-GONZALEZ: The deadline for the recommendations is February 29, but the document is the end of April.

DR. EVANS: Sweet. The one thing I would second with Paul is that I do feel like we are doing a little bit more in the way of substantive discussion here than we usually do at this stage. I would just make the plea that we make sure that all of us do our jobs when we get the report. If we see things, don't just rubber-stamp it.

DR. FERREIRA-GONZALEZ: You have until February 20th on the report.

DR. TUCKSON: Not on the recommendations. The recommendations we have to have by the end of the day.

DR. FERREIRA-GONZALEZ: Now, the rest of the Committee realized that the steering committee that worked on this document plus the taskforce worked over the summer and the holidays, so I'm not feeling bad asking you to read this. It is all upon all of us to actually make sure that there is consistency in the language, that inaccuracies are brought up to Cathy, who is the designated keeper of this document, to make sure we all support a product that we are proud of.

Going back to Recommendation 3 on the registry, I'm feeling a bit uncomfortable on keeping the elements right now without really having an evaluation of what it means to say "clinical validity." Do you want a number for clinical validity? We need to be very careful what we are asking here.

DR. WILLIAMS: I'm not hearing Muin say that there isn't a role for convening a group to discuss what elements are needed. What I'm hearing Muin say is that that recommendation which is currently C needs to be A because HHS will make a determination of what the lead agency is and they will task the lead agency then to do the other things we are talking about. That will in fact include evaluation of the elements for what is necessary and then what is practical.

DR. FERREIRA-GONZALEZ: I just heard some elements given out here. That is why I'm bringing it up. I think what we are talking about is Recommendation C becoming A now, and then in A, we can change "CDC" to "The lead agency, in collaboration with the sister agencies."

DR. WILLIAMS: They will decide what they want to do.

DR. FERREIRA-GONZALEZ: There are data elements that are already being collected. Can we avoid duplicating. That is where I'm trying to go.

So we have now A, "Appoint and fund a lead agency." No. B becomes "The lead agency." I do want the collaboration. Instead of "CDC," "The lead agency."

DR. TEUTSCH: I think we know what the general content is, which were the things that we just talked about, analytic validity, clinical validity. How you measure them and the detailed metrics are not for us to work out and for the agency. We know what the general content of the registry is and probably need to say what that is. Not the detailed elements.

DR. FERREIRA-GONZALEZ: No, I think we still need to be convening the stakeholders to really see the ramification of what that data is, are we going to get that data, what will it take from the laboratories to obtain that data.

So what we have now as A is "HHS should appoint and fund a lead agency to develop and maintain the mandatory registry." B is "The lead agency, in collaboration with sister agencies, convene a group of stakeholders by September this year to determine the data elements to be included in the test registry."

Second slide. Let's go back.

DR. WILLIAMS: All the "CDC" in that has to change to "lead agency."

To speak to Steve's point, I think we can maybe solve this by saying in that first sentence, "To determine the data elements that address analytic validity, clinical validity, clinical utility," and what is the last? "Accessibility to be included."

DR. FERREIRA-GONZALEZ: Do we really want to tell --

DR. WILLIAMS: Yes, because the report basically says here are the gaps and here is why we need a registry. So yes, we need to specifically articulate that.

DR. FERREIRA-GONZALEZ: I would still argue to have the stakeholders get together and go over --

DR. WILLIAMS: No, we don't want the stakeholders saying we don't need to collect clinical utility. We are saying we have proven that we do need to collect it.

DR. FERREIRA-GONZALEZ: You are going to have stakeholders, the payers and other ones, there that might say that. So, I don't think so.

DR. KHOURY: I disagree wholly with you, Andrea. I think we need to lay out a little bit more.

DR. TUCKSON: Let's just deal with this, then. I think that there is, again, a clear dichotomy here. Let's just make sure we know where the Committee is. How many of you on this, just so we get a sense of you, think we ought to be very directive in saying that there should be a registry that includes the elements that we have described? How many of you think we need to be absolutely explicit and we say that there should be that, not leave that decision up to a multi-stakeholder group?

Let's start with the registry. The registry itself. There should be a registry and you don't leave that up to "Mother, May I?" with a committee.

[Show of hands.]

DR. TUCKSON: Who feels like there ought to be you leave up the determination of whether there should be a registry to a multi-stakeholder committee?

PARTICIPANTS: No, no, no.

DR. TUCKSON: I'm just asking to get it clear. I just want it piece by piece. We have it clearer than that.

Piece 2. Define the elements now.

DR. WILLIAMS: Basically, what I said was we don't need to drill down on the specifics, but the elements that need to be included have to address analytic validity, clinical validity, clinical utility, and accessibility of data.

DR. TUCKSON: Great. Those of you who feel that those elements should be in the registry, let us know by a show of hands.

[Show of hands.]

DR. TUCKSON: Those of you who feel like you ought not dictate but leave it to some committee, raise their hands.

[Show of hands.]

DR. TUCKSON: So we have a clear sense of the Committee. You have resolved this issue. Move forward.

DR. BILLINGS: Can I ask a question, Reed? Let's say we prescribe the set of elements for the registry and a test doesn't have adequate clinical utility. What does it matter?

DR. TEUTSCH: It is just blank.

DR. BILLINGS: It is blank. Fine.

DR. TUCKSON: Muin?

DR. KHOURY: As part of the EGAPP process, we have been spending a lot of time discussing data elements and breaking down analytic validity, clinical validity, clinical utility, and all of these things into a series of questions. I think by last count we probably had 45 or 50 questions. We don't have to hash them here today, but the broad elements are what can be put out there.

The fact that the test doesn't have clinical utility is not necessarily bad. It could be left blank. But the customer and the providers and the payers need to know.

DR. TUCKSON: So we have that issue resolved. Move on, Andrea.

DR. FERREIRA-GONZALEZ: Yes. So that is B. Now we have A, "Appoint a lead agency." Now we have C, which is in the meantime. Any comments or edits to this C?

[No response.]

DR. FERREIRA-GONZALEZ: Can we move forward to the next recommendation?

DR. TEUTSCH: We are already a half hour beyond our break time. Why don't we take a 15-minute break. First of all, is everybody in agreement with these recommendations? Okay. So, why don't we take a 15-minute break. Plan to come back at five minutes after the hour.

DR. FERREIRA-GONZALEZ: What do we have; Nos. 5 and 6?

DR. TEUTSCH: We have Nos. 5 and 6, and then of course we have to go back and review the overarching, and we need to go back to revisit some of the ones we did not finalize.