Tick Borne Disease Working Group
1:30 PM to 2:34 PM

>> John Aucott: So, let's -- Vanila Singh, present or absent? Present.

>> Vanila Singh: Present. Thank you.

>> John Aucott: Richard Horowitz. Absent. Ben Beard.

>> Ben Beard: Present.

>> John Aucott: Karen?

>> Karen Vanderhoof-Forschner: Present.

>> John Aucott: Scott?

>> Scott Cooper: Present.

>> John Aucott: Yeah. Wendy?

>> Wendy Adams: Present.

>> John Aucott: Allen?

>> Allen Richards: Present.

>> John Aucott: Lise?

>> Lise Nigrovic: Present.

>> John Aucott: Dennis?

>> Dennis Dixon: Present.

>> John Aucott: Patricia?

>> Patricia Smith: Present.

>> John Aucott: All right. We have a quorum.

>> Male Speaker: Just a minute. Yep.

>> John Aucott: All right. So, we're going to start out with a -- the agenda for this afternoon is were going to -- a) we're going to be efficient, because we need to get through a lot of stuff. So,

Rich is going to start with a time line and tasks to be completed. But I want to ask people specifically not to get into subcommittee issues, because that's the next agenda item. So, please don't -- hold all questions about the subcommittees. He's just presenting the time line. You know, because we have a product to deliver. And the product -- the deliverable requires that we meet our deadlines along the way for the product development. So, he's going to go over that. But please hold any questions about the subcommittee structure and how the subcommittees work because that's what we'll do next.

> Richard Wolitski: Thank you, John. And just a quick introduction. Debbie Seem from my office is sitting in Kristin's place. She had a meeting at the White House for an hour or so. She'll be back this afternoon. But she didn't change her look during lunch time. So, this is kind of our best first draft of a timeline. And we thought it would be good to introduce it now because it sort of brings out sort or how much there is to do and some of the steps that need to happen in a certain sequence in order to get us to the report submission in December of next year.

So, there may be some things that the committee modifies or changes as a result of discussion. But here's one version of what it might look like. So, December 11 and 12, first and second meeting. Done. We're anticipating, if the group decides to have subcommittees, we issue a call for subcommittee members no later than Monday of next week. That would be open until -- it would be open until January 30th -- is when -- that's January 1st, sorry. Not the 30th. January 1st is when it would close. And this date would be just to document the minutes from this group, the transcripts, presenters' slides, and things. We're aiming having this up before Christmas. We might be missing one or two pieces, but most of it will be up by then.

The call for subcommittee members closes January 1st. Then the working group members review the nominations that have been submitted and make selections. And I messed up something there. So, probably the week of January 17th to the 26th would be when we'd target for having our next meeting. The -- one idea, one potential way for doing it would be to have the full working group and all the subcommittee members meet together as one large body. So then, the process of doing the subcommittee work could be discussed together. And we'd kind of have one meeting that kind of gets everybody off to the right start with receiving all the same messages all at the same time.

And some of the subcommittee meeting activities that are anticipated -- and I'm putting this in just to kind of stimulate thinking and to have you recognize how much work there really probably is going to be. All the subcommittees are going to have public comment process, so they are informed by the stakeholders and by the patients. There will be literature review potentially. Inventory of federal activity -- one of the charges is to assess what's being done. And then, there's an analysis phase for the subcommittee to do when they're looking at the literature. Looking at what's being done. And saying what are the gaps? And then, looking for duplication of effort. And then, proposing potential solutions to improve the federal response. To address the gaps, to enhance activities, to introduce research advances and scientific advances into the program that aren't there.

And then, that's their work. And so, to do this we have to get the inventory developed. So, we have to develop a reporting form that we send out to the agencies. We're going to give them

probably 30 days to respond. Get the information back to us. So, that would put us -- and throughout this whole time the Chair, Vice Chair, and DFO will be monitoring progress in the groups. And then, the reports come in 30 days later from inter requests. Subcommittees review that. They get literature review information. They would submit a draft report from the subcommittee to the full working group. That would be due, probably, in May. And that would then allow the full working group to start discussion of the meetings and kind of have a meeting sometime in May, after those reports are turned in, for the subcommittees to discuss the reports with the full working group.

So, basically, they work together. They do their thing. They draft a report. And they submit it to the full working group for consideration. There'd be a meeting to discuss the reports. Ask questions. Have the subcommittees present information to the full working group. And then, that's when the potential writing could start, after that meeting, where people have already said "This is what we agree should be in the report." And we have some discussion around that. And then, -- Amy -- you know, they're basically giving us just like a month to do a first draft off of that information. And having -- wait -- I messed something up here.

Basically, yeah, so we have a draft report with recommendations around June. Then, there's discussion within the group about it. So, that there's a full document ready sometime around July that gets -- actually -- yeah, July. Then it goes to desktop publishing and gets ready to be released probably around mid-August, because we want to be able to release it for public comment. So, that everybody -- it would go out and anybody who wants to review, comment, on any aspect of it will have the opportunity to do that.

It will also go out at that time for agency review. So, that the federal agencies will have the opportunity to review the information. And raise comments, concerns, questions about anything they think is inaccurate, or not correct. And, after that whole process goes through -- we give that about a month for the review process. Then we get the agency comments and the review comments back.

It's going to take time then to process those. And we're expecting a lot of public comment. And so, it's going to take -- we're kind of giving this about a month, 30 days, to get all the public comment in, summarize it, analyze it, and then to start incorporating it into revision process. That would then give us a revised document. The working group would then review that. Approve it. Make any final changes so that we get it out December 18th. I didn't do the best possible job walking us through that, but it gives you kind of a sense of the pieces. Then we have hard copies coming for the members. I see you all writing furiously. That should be here in a little bit.

But it kind of -- basically, it gives -- I think it's about three to four months for the subcommittees to do their work. And then, it gives us time to discuss the report multiple times within the working group. Of course, additional meetings could be added virtually in here. And there's some decisions about what should be done in person or virtually. But this is kind of a -- and we can answer some questions about it now. But really, this is maybe just a brainstorm of a timeline that helps inform the further discussions about subcommittees and timelines for those and getting that set up. But I thought I'd put this up as a bit of context for the work.

So, John, I'm going to let you moderate any -- do you have any questions, first of all? Mr. Chair? Ms. Chairman, do you have anything?

> Patricia Smith: Yes, my question is, eventually at the -- when we get somewhere near the bottom line there the -- how will this come down the pipe? So, the working group will get the final review on this -- all this iteration and all this important so on and so forth. So, then they're will be some type of vote here on that report to accept it or not accept it? Okay. So, then what happens for example, we've talked about, you know, dissention. Are we going to have like a -- will there be like a minority opinion? And will that be like incorporated with some type of explanation? Or is it just going to be, you know, 10 yes and four no.

> Richard Wolitski: Well, of course it's up to the Chair and the working group all of this, but the way we'd been thinking about it was not a single vote on the whole report. So, for each recommendation, there'd be a vote. So, then there may be, you know, some recommendations where everybody's in consensus. Those go forward. There'd be other recommendations there there's disagreement about it. And that then can be noted that there was a minority opinion on that recommendation. And there would be the potential for including some text about that. I think that's going to be one of those things that as we kind of get down to the writing of it we can assist you by providing some formats and suggestions for handling that sort of thing. It may be that some of this is done as an appendix or supplement to it. Some of it may be done in the body of it. Part of it will depend on how much agreement and how much disagreement we have too. As to how, you know, it looks in the report.

> John Aucott: Other questions or comments? Okay.

> Richard Wolitski: Okay.

> John Aucott: Thank you.

> Richard Wolitski: [affirmative]

> John Aucott: So, now we're really going to get down to some work. I'm going to pass around the Act. The actual Cures Act that is the foundational document. I'm sure you've all read it through many times and know it by heart. But just in case you didn't, I brought a copy for you. And the reason this is so important is because this is really what drives our product. Okay? And so, what I've taken the liberty of doing is highlighting in here -- it was in color originally. And the light highlights are kind of the content areas that the act lays out. And we'll be discussing those soon. And, of course, this is a matrix of the contents areas with the pathogens. Now, I'm sure you can already do the two by two table and it's a 10 by 20 table, right? So, we're not going to fill in every cell of 20 pathogens by 10 content areas. In other words, the diagnosis of 20 different pathogens. That would be a whole group there. So, just let's start by, you know, kind of recognizing that we can't accomplish 20 pathogens by 10 content areas. But that's the universe of what's in the actual Act. Okay?

So, that's okay. What we're going to do is though is kind of work that as a starting point.

Always going back to what's in the Act. Okay? So, the -- and so I want to reiterate a few things that Rich said. The key part of our product is having a document. It's going to require subgroups, we think. But we have to vote on that and decide that we agree on having subcommittees because that's our decision. But, I'm going to throw out there as a starting place that we should consider forming subcommittees so that we can break this down in to manageable bite sized pieces. Okay?

So, what I'd like to do now is kind of think out loud with you all. Now, that you have this document that you've reviewed in three minutes. But, you know, we've -- I've sent out before some ideas about what content areas might be. And so, we've had a chance to think about that. So, let's just open it up for thoughts. But always looking at this document for what the contents areas -- and let's start with the content areas first, because I think we're going to have to obviously say that some of the areas are going to just start with Lyme Disease, you know, as a beginning place. And again, we're not going to do every organism or every content area.

So, I just wanted to open it up now for ideas about what some possible content areas would be. And I think you know in -- and I'll also just through this out as a manageable number. We're not looking at 20. Subcommittees. We're not looking at two subcommittees. We're looking somewhere, you know, five-ish subcommittees. So, I know that ties our hands a little bit, because of everybody's just great ideas about all of the things we can do. But again, we have to deliver a product here. And part of that is going to be in having a manageable number of subcommittees. So, let's just for purposes of a starting place, think about this as maybe five subcommittees. Pat?

>> Patricia Smith: Well, I think that since once of the primarily obstacles, I would say, to patients at this point in time in getting diagnosed and treated is getting diagnosed. [laughs] So, I think that there should be definitively a committee that focuses on that area.

>> John Aucott: On testing and diagnosis?

>> Patricia Smith: Correct.

>> John Aucott: And I think that fits with the Act and the Charter. The testing and diagnosis are there. So, Pat's suggesting testing and diagnosis and that's certainly in the Act. Allen, your mic, yeah?

>> Allen Richards: So, would clinical diagnosis be separate then? Or are you doing diagnosis -- both laboratory and clinical together? Or --

>> John Aucott: The Act does call for, you know, clinical research. But it doesn't necessary split diagnosis into clinical and laboratory diagnosis. I mean, as a clinician, I'd make the case that those have to go hand in hand anyway. So, I wasn't necessarily thinking we would have to split out clinical from laboratory diagnostics.

>> Allen Richards: Okay. So, it's just diagnosis.

> John Aucott: Yeah.

> Karen Vanderhoof-Forschner: I see it as five subcommittees. One is diagnosis. One is pathogenesis. One would be transmission. One would be testing, and one would be vector focused. Vector range.

> John Aucott: Okay. So, let's pull those apart and kind of pick one to start with. So, vectors. Say your vector comment again? You said vectors.

> Karen Vanderhoof-Forschner: Right. Vector range.

> John Aucott: So, let's talk about that as a committee. That's certainly in the charter as well, is vectors. What -- let's hear some thoughts about vectors and if that's an important thing to do.

> Patricia Smith: I definitely think we have to. As Jill Aurbach -- I don't know if she's still in the audience. But it's the ticks.

> John Aucott: [affirmative]

> Patricia Smith: And so, I think we definitely -- but I would still ask -- and maybe when we get down the line it won't happen. But that testing and diagnostics kind of stay together. Only because I think we do have to at least look at other tick-borne diseases in some way. And so, maybe we need that to be a separate entity that looks at what are the other tick-borne diseases and the fact that there's not much -- at least from what I've seen -- not much government funded research on a lot of those. And perhaps not even a lot of diagnostics. So, maybe it could be like a general overall overview of those so that we are doing what is indicated in the Charter, which is talking about other tick-borne diseases.

> John Aucott: So, combining testing and diagnosis makes sense. And I think, again, we can start with the priorities which we might agree are Lyme disease. That's open to discussion. And that's a starting point. And then, prioritize other tick-borne pathogens under testing and diagnosis?

> Patricia Smith: Well, I was -- I mean, the committee can decide what they want to do about it. But I was more thinking about that if that were done, other tick-borne diseases as a separate entity because there are a lot of differences, obviously. And some of them don't even have --they don't have treatments, maybe diagnostic tests. Or maybe the CDC has the only testing and so on. I think that maybe it makes logical sense, since there's a lot less information about those. I mean, yes, there were rickettsial diseases thanks to people like, you know Richard over there.

> John Aucott: Yeah.

> Patricia Smith: And others. We do have some information on that. But I think a lot of the ehrlichia and the anaplasma -- and if indeed we're going to be looking at, you know, I don't know if you're going to include the alpha gal meat allergy or tick paralysis. Although technically, they're not diseases.

>> John Aucott: Yeah.

>> Patricia Smith: But they certainly are things that are caused by the tick bites.

>> John Aucott: Sure.

>> Patricia Smith: And we have a massive problem now with especially the alpha gal allergy from everything I hear --

>> John Aucott: Okay.

>> Patricia Smith: -- that is just spreading like wildfire.

>> John Aucott: So, I'm going to put alpha gal on a side bar for now because it's not really a tick pathogen. But's it's an important -- a really important thing. So, okay -- so we've got surveillance of ticks. We have testing and diagnosis, and Pat's calling out possibly for a second group for other pathogens for testing and diagnosis. Ben?

>> Ben Beard: Well, so for me I sort of see two issues related to diagnosis. One is diagnostics. Tests that are available and the need for tests for all the tick-borne diseases. And these are tests for, you know, it's a real-time test. Not simply a serologic test. So, there's that. But there's also -- if you talk about diagnosis then to me that kind of gets into the issue of physician recognition and training and training on what are your guidance to physicians and education, because you're enabling them to make a diagnosis. So, I'm not arguing one way or the other on that. But if you have a sub-committee on testing and diagnosis, that, to me, you know, covers -- or diagnosis and diagnostics or something like that. There's really two different issues. There's -- one is the practice of diagnosis and there's also the tests that are available for conducting diagnostics.

>> John Aucott: The technology?

>> Ben Beard: Yeah, the technology. And those are two important -- both of them are important.

>> Karen Vanderhoof-Forschner: I see the issues as being very large.

>> John Aucott: [affirmative]

>> Karen Vanderhoof-Forschner: The whole diagnosis issue is very large. With a different set of subcommittee members than you would necessarily see on the clinical side for disease presentation, which is not fully appreciated by physicians out there. And so, I see it as two different end results, two different missions. And I think Pat's right in the idea that we need to choose disease burden, which Lyme disease would be the first one. But also, you can either do additional by the next disease burden or you could do it by co-infection. And the most useful, I think -- Pat, you might agree -- is co-infection. In which case, those would be issues for the committee and have a different set of people on the committee itself. And the testing would be maybe more lab people. And the clinical diagnosis, the diagnosis would be more front-line

physician and published stuff.

>> John Aucott: And were going to get to membership of the committees later. So, I don't want to go down that path right now. But you're absolutely right. The membership of the committee's is a different issue which we're going to address later. Yeah. Lise?

>> Lise Nigrovic: One other subcommittee to consider would be prevention. Both tick-based and vaccine.

>> John Aucott: [affirmative] So, can prevention go with surveillance or is it a standalone group is one question I have for the group? I mean, trying to lump things together. Can we lump prevention with surveillance?

>> Lise Nigrovic: I'm a lumper, not a splitter. They're different but we could put them together.

>> Wendy Adams: Yes, we can. I mean, I think that makes the most sense.

>> Lise Nigrovic: Yeah.

>> Wendy Adams: And it certainly runs across -- from an agency basis it would also be consistent with keeping --

>> John Aucott: Prevention and surveillance? Ben?

>> Ben Beard: Yeah. I guess I would just wonder what the subcommittee -- what direction they're going with surveillance, because if it's going back to, you know, what the law says in terms of what's being done today and what the gaps are and what the needs are, that can be pretty readily addressed. I mean, there's one agency that's really responsible for that, in terms of what's being done. But, the key thing is that surveillance is not a responsibility of the federal government. It's the responsibility of the states. And so, if we're making recommendations to the HHS Secretary and to Congress on something that the federal government is not chiefly responsible for, what are we to do about it? And, I mean, you can check the constitution.

I mean, we struggle with this all the time. We work to coordinate it. We don't do it. And it's reported to us. So, it's just something to keep in mind. I'm not -- I mean, surveillance is critically important to us. But there are something's that you're put in charge of and some things that you simply assist and coordinate. And --

>> John Aucott: That's a really important clarification. I thank you for that. And I would also just add as a comment, you know, surveillance is being transformed by the use of electronic medical record systems. And there's, you know, some really exciting projects and research being done on surveillance -- or are being done that will probably change the way that surveillance is done as well. But thanks for that important point.

>> Patricia Smith: John, I'd like to comment on that. And I've had discussions with Ben on this in the past. And my feeling is that we need to look at surveillance. And the reason we need to is

we're supposed to be uncovering the problems. You know, we're not supposed to necessarily be solving them. Right? But we're supposed to be uncovering them. So, the problem, as I see it, and I've seen it for a while because I do look into surveillance a lot, because it prevents so many of our patients from getting diagnosed and treated in many regions of the country. So, I think we have an obligation to look at surveillance. Now, whether it is that this type of set up that we have for surveillance is not meeting the needs, at least as far as Lyme -- I can't speak to the other diseases, and something else need to be done about that, well, they would need -- you know, whoever the "they" are; Congress, probably, most likely -- would need to address that issue. And so, I think we do need surveillance. But I think it may be able to be included in a prevention thing and maybe not all by itself, perhaps. I don't know, because there's a lot of interplay, I think, between surveillance and prevention, because obviously, when you have surveillance you're going to have your now what's called high incidence states. And those maybe looked at differently for prevention strategies perhaps than low incidence states. But I think they are connected.

>> John Aucott: Okay. All right. I want to make sure everybody is involved here. Other comments too?

>> Wendy Adams: I highly support the -- looking at surveillance. It plays a huge part in California in a negative way. So, I would -- from that, from a regional standpoint, I think it's really important to balance out the federal government's knowledge of what happens in other regions of the country besides the northeast and mid-Atlantic states.

>> John Aucott: Okay.

>> Dennis Dixon: I think it makes logical sense --

>> John Aucott: One at a time, please. Dennis?

>> Dennis Dixon: Yeah. And Ben, is there something in here that could work to your advantage? If there's an issue that you feel should be done, and you're not able to do it. I agree with Pat that we're not supposed to be solving the problems. We're supposed to be doing an overview of what's being done and what's not being done. Could that play to your advantage?

>> Ben Beard: Yes. Surveillance needs to be approved. I don't have a problem with it. I just wanted to make this -- you know there are things that you control and things that you don't. And I just wanted to make sure that people were aware of that. That where these recommendations go and what can be done about it at the federal level. But certainly, I'm -- anything that is going to strengthen surveillance, I'm completely supportive of that.

>> Dennis Dixon: I think making your partners on this committee aware of that issue can help frame how the report is written such that it addresses and issue and points it to some other party for solution if appropriate.

>> Richard Horowitz: I agree that the surveillance is absolutely essential. In our area we had four cases of Powassan just in Duchess Country recently, and above where we are. And when

you look at the ticks, I mean, the Powassan went from one to two percent to five to six percent over a couple of years. They are finding more of the relapsing fever, borrelia miyamotoi. They're going up. So, I think the act of surveillance is going to be essential, because the doctors, if they don't know what's in the ticks, they don't know what to look for in a lot of these cases.

>> John Aucott: Okay. So, I think we're getting somewhere about this. Good. Let's finish up with one more comment and then we'll move on to some other ideas.

>> Patricia Smith: Oh, this was on a different --

>> John Aucott: Okay, you have a new -- okay, go.

>> Patricia Smith: Please.

>> John Aucott: Go. Yes.

>> Patricia Smith: Yes.

>> John Aucott: Okay.

>> Patricia Smith: See John, you can actually tell me when to speak.

>> John Aucott: Yeah, this is good.

>> Patricia Smith: Don't tell my husband that. Okay. I think access to care is another area that is extremely important. And I think that we heard, over the last couple of days, and many of us have heard that for a really long time. Many tens of thousands of times. And so, I think that absolutely has to be a principle thing that we address.

>> John Aucott: Other thoughts on that? I mean, Kristin and I were talking about this and we were thinking about -- you know, one of the things in the Act is treatment and access to care. And we were thinking about kind of splitting those in a way because access to care is such a huge issue. And it's independent of the actual treatment. And so, I like that idea of talking about access of care as separate of actual treatment, because treatment really drives from pathogenesis. But access of care is universal. It doesn't matter what we're doing. So, that's -- that's a super idea.

>> Patricia Smith: [unintelligible]

>> John Aucott: Talk to the whole group. Talk to the whole group through your mic.

>> Patricia Smith: That would address the other pathogens in that also because access to care, in other words, would be all the tick-borne diseases. Access to care for all of them.

>> John Aucott: [affirmative]

>> Karen Vanderhoof-Forschner: So, are we broadening to include all the tick-borne diseases? Or all the ticks?

>> John Aucott: So, we're just -- right now we're just talking about content areas. Remember I kind of split this up, you know, for purposes of discussion. We're just talking about content areas. And then, the second half will be the 15 different pathogens. Right? So, we're just talking about content areas right now.

>> Richard Wolitski: I'm going to go ahead and just take some of what I took down as notes to put up on the screen so that people can see it, because some of us are more visual. And what I'll also try to do is put what I believe is in the Act in terms of content that has to be covered.

>> John Aucott: [affirmative]

>> Richard Wolitski: So, you and I can compare notes real quickly to make sure that we have the same lists.

>> John Aucott: [affirmative]

>> Richard Wolitski: And then, I'll put that one. I'll do two columns. One the required stuff that has to be covered somehow. And then, the terminology and what people are proposing and kind of have those two up together. So, it will be surveillance and prevention.

>> John Aucott: It comes from the charter. Yeah. Treatment is there?

[inaudible]

>> John Aucott: Short and long-term outcomes. Do you have that?

>> Richard Wolitski: Yeah.

>> John Aucott: That came from one of the two. Maybe not -- pathogens?

>> Richard Wolitski: Pathogens.

>> John Aucott: Yeah, you got that. And then, --

>> Richard Wolitski: No, actually this is the wording that is -- research --

>> John Aucott: Yeah. Research, surveillance, prevention.

>> Richard Wolitski: <unintelligible>

>> John Aucott: Okay

>> Richard Wolitski: Let's put it up and then we can continue the debate.

>> John Aucott: Yep.

>> Richard Wolitski: See if it's --

>> John Aucott: [affirmative]

[inaudible]

>> John Aucott: So, Rich is putting this up. Other thoughts on content areas while Rich is getting a visual up there?

>> Karen Vanderhoof-Forschner: I'm going to go back to pathogenesis.

>> John Aucott: Pathogenesis, sure.

>> Karen Vanderhoof-Forschner: And transmission. And I think pathogenesis will inform both treatment and diagnostic test.

>> John Aucott: I mean, pathogenesis is a big thing, right? So, I mean, that's the -- that's one of the core subjects that really drives a lot of the unknowns. And a lot of the, frankly, to be open about it, a lot of the controversy is centered around pathogenesis. So, that's a core area and -- that leads to those things. So --

>> Wendy Adams: I also think pathogenesis has had so much research that's come about in the, you know, last kind of two to four years that really needs to be examined for the federal government as opposed to -- since the last guidelines were written.

>> John Aucott: [affirmative]

>> Wendy Adams: So, I think it's important to call that out and really put some time and writing around what that research means for patient care going forward.

>> John Aucott: [affirmative]

>> Karen Vanderhoof-Forschner: And transmission, which would include transplants and donation of blood for the diseases.

>> John Aucott: [affirmative]

>> Karen Vanderhoof-Forschner: As you may know, Willie had taken EMRash on the leading edge and attached it to an animal model and was able to transmit the disease. So --

>> John Aucott: So, I think the transmission and pathogenesis can by lumped together. Good. Lise, any ideas at this point? Didn't mean to put you on the spot. It's just, you know --

>> Lise Nigrovic: I was asking the question before -- there's the topic areas and then there's research, public engagement, education. Are those sorts of domains within the topics? Or are they separate?

>> John Aucott: Well, they overlap them. If you really list out like every basic research clinical, you know, and add those to, you know -- you end up with about 10 or 12 different things.

>> Lise Nigrovic: That's the rows within each set of --

>> John Aucott: Yeah. Yeah. So, I'd like to get a little more discussion about pathogenesis and treatment being a group. What are people's thoughts about that? Because, you know, one of the issues that's kind of the -- you know, that is subtle but is important, is you know, treatment really is driven by pathogenesis and since, you know, we have to be a little bit agnostic against pathogenesis because part of our mission is to identify the gaps in what we don't know. So, until we know that pathogenesis, it's hard to say how that's driving specific treatment. Pathogenesis is a key area, because it's going to drive other things in the future.

>> Richard Horowitz: I agree. I mean, the fact that the work on biofilms, which when you were referring to the persisters and the biofilms, things that have come out in the last couple of years.

>> John Aucott: [affirmative]

>> Richard Horowitz: That definitely will inform treatment.

>> John Aucott: [affirmative]

>> Richard Horowitz: Because there's a lot of physician's that are now integrating those ideas into treatment protocols.

>> John Aucott: [affirmative]

>> Richard Horowitz: So, I think you can lump them together into treatment.

>> John Aucott: And then, again, being agnostic, there's also groups that think that, you know, triggered inflammatory states are a part of the pathogenesis. Again, I think we need to be fair and agnostic about what the answer is. We're here about identifying the gaps and identifying all the possible gaps. So, okay. Are we --

>> Vanila Singh: One point, John.

>> John Aucott: Okay.

>> Vanila Singh: Would be also -- pathogenesis would also drive help in regard to diagnosis as well, right? So, when our colleagues out there come to understand there's a variety of ways, perhaps, that this is -- that this process is being determined by -- you know, co-infections, different varieties of bacteria and whatnot. Then that also helps in terms of diagnosis and

picking up the not typical process, or the a-typical. I would also think that would be another arena.

>> John Aucott: Absolutely. Yep. All right. So, just to kind of summarize where we're at right now. We've talked about vectors and prevention with maybe the tag on of surveillance as part of that. We've talked about testing and diagnostic, possibly linked to education, as a second area. We've talked about pathogenesis and transmission liked to treatment and interventions as a third area. We've talked about access to services and affordable, accessible care as another area. And I -- I put them a little bit on then possible is surveillance as a separate issue and diagnostics of other organisms as another possible. How are we doing, Rich?

>> Richard Wolitski: I'm working on getting them categories separate from all of this and move things up and hand them out.

>> John Aucott: Okay.

>> Female Speaker: Can you read them out? One, two, three, four, five, whatever?

>> John Aucott: Sure. This is just our -- these aren't the finals obviously.

>> Female Speaker: Right.

>> John Aucott: The first was, you know, vectors in ticks and prevention plus or minus surveillance and education. The second was testing and diagnostics linked with education. The third was pathogenesis and transmission linked to treatment and interventions. The fourth was access to services and affordable care. And then, a possibility of a second treatment -- or second diagnostic for other pathogens. But that's a little duplicative so I'm kind of putting that as an if we have enough room.

>> Richard Wolitski: I got lost a little bit John. So, you've got vectors, prevention plus or minus surveillance.

>> John Aucott: Yep.

>> Richard Wolitski: Testing and diagnostics.

>> John Aucott: With education.

>> Richard Wolitski: And education.

>> John Aucott: Yep.

>> Richard Wolitski: Okay. Pathogenesis and treatment.

>> John Aucott: Pathogenesis, transmission.

> Richard Wolitski: Transmission. Okay.

> John Aucott: Next one, access to services --

> Richard Wolitski: [affirmative]

> John Aucott: -- and affordable care. And then, a possibility for diagnostics for other pathogens.

> Richard Wolitski: Okay.

> Allen Richards: That last issue, I think the way diagnostics are going now, you're doing syndromic diagnostics, etc. So, you're looking at a bunch of agents that cause a particular type of disease. Respiratory or fever based or whatever. And with next generation sequencing and stuff, you're going to be looking for multiple agents. So, I would actually --

> Karen Vanderhoof-Forschner: Combine them?

> Allen Richards: -- don't think you need that second diagnostic section. But that you would -- in diagnostics actually go in that direction that would cover co-infections as well as other possible causes of the disease presentation.

> John Aucott: Karen?

> Karen Vanderhoof-Forschner: That was going to be to combine the diagnostics to one committee.

> John Aucott: Right.

> Karen Vanderhoof-Forschner: And that they can look at the -- I think that's a great idea. And I do not think that education should be lumped in with testing and diagnostics and education. It got read at the same time. But I don't think it's the same thing. Education is going to be informed by a lot of the initial research done by the subcommittees, so that would be a later activity when we know more and where the gaps are.

> Estella Jones: Although would that possibly fit under the access to services? Since it sounds like there may be gaps in physician training? And therefore, it could impede people getting access to service.

> John Aucott: Oh well, I like that. What do you think Pat?

> Patricia Smith: I think that's excellent, yeah. That will fit nicely.

> John Aucott: So, how many do we have up there, Rich?

> Richard Wolitski: Up here we've got one, two, three, four, five, and maybe six. And then,

the last one I didn't quite follow. We take education out of testing and diagnostics, right?

>> John Aucott: And put it with access to services. Access to care and services.

>> Richard Wolitski: Okay.

>> John Aucott: And then, erase the last line. The question mark diagnostics, erase.

>> Richard Wolitski: Okay.

>> John Aucott: So, that's five.

>> Scott Cooper: I would also add with access to care, services, and education -- which I agree -- I think for clinicians. Add to that, we've got as it's contained in the Act, support for patients. Whether it's the patient advocacy, which also would go along with education for patients themselves. So, I think that's important to have under that.

>> John Aucott: Excellent.

>> Karen Vanderhoof-Forschner: I think the vectors, prevention, and surveillance should be one group with similar goals. Similar activities. Number one and two would be combined to one subcommittee. Vectors, --

>> Richard Wolitski: Like that?

>> Female Speaker: Yeah.

>> Female Speaker: Good idea.

>> John Aucott: Yeah. We had actually said that. Thank you.

>> Richard Wolitski: Just a question for clarification. So, the differentiation between prevention and education is the education that goes with access to care is primarily for health care providers and other educational efforts to prevent acquisition would go under prevention here?

>> Estella Jones: Well, I think education could be both.

>> Richard Wolitski: Okay.

>> Estella Jones: And that support to patients, because yes you need the clinicians to have an understanding of what they may be presented with. But also, it seems like it could include the broader education piece, so that folks who are at risk for developing these tick-borne diseases would have that information to say "Oh, well maybe this is what is wrong with me" to engage in that level of conversation.

>> John Aucott: Patient education specifically.

>> Estella Jones: I think they both could fit in that category.

>> Lise Nigrovic: And some of these themes like education and research are very cross cutting. So, perhaps we don't want to bucket all of them, but rather make sure we hit on those topics for each of our subcommittees.

>> John Aucott: And I think we have to have the flexibility to do that. I think this is a little bit artificial that we're creating boxing. But absolutely. So, can we go through them, Rich? The first one's -- yep.

>> Richard Wolitski: Now, a combo of vectors, prevention, and still people said surveillance pretty strongly, so surveillance would go here as well.

>> John Aucott: Yep.

>> Richard Wolitski: So, there. And then, testing and diagnostics. And I think you also said clinical diagnosis as well?

>> John Aucott: Yeah. It would encompass clinical as part of --

>> Richard Wolitski: So, I'm including clinical?

>> John Aucott: Yeah, it needs to be encompassed as part of that.

>> Richard Wolitski: And pathogenesis, transmission, and treatment.

>> John Aucott: Correct.

>> Richard Wolitski: And access to care, which would include education for clinicians and patients.

>> John Aucott: And does that include support to?

>> Richard Wolitski: I think that includes the support part too.

>> John Aucott: Didn't we reef that too?

>> Richard Wolitski: [unintelligible]

>> John Aucott: Yeah. That's what I was thinking. Yeah. Support. So, we actually have four right now.

>> Karen Vanderhoof-Forschner: So, did we -- are we taking away the other tick-borne disease? Or are we just moving it up to --

>> John Aucott: So, one idea that had come up was because there are so many pathogens, should there be a special subcommittee that looks at co-infections per se as a standalone group. And one thought I had on that is also maybe that's also where transfusion associated tick-borne infections could live as well because the babesia and miyamotoi might be -- you know, so I can envision a subcommittee that looked at other non-Lyme tick-borne diseases and might have a sub focus of, you know, transfusion associated illnesses as well, which is an important theme with babesiosis, for instance.

>> Wendy Adams: I think they're so different from one another that you really need a separate place to put them. And I think you really have to highlight the differences from those between other tick-borne diseases and Lyme itself because they are being right now, in many cases, just grouped and lumped. Physicians look for Lyme, but they don't even -- they're not even recognizing how many other infections can be in the same tick. So, I think -- I think it needs a dedicated space. This is a tick-borne disease working group. And so, we need -- we need a separate category. I think it's a harder subcommittee to put together because it has to encompass so many things. But I think it's just as important.

>> John Aucott: And it does kind of get around -- which was the second issue I was putting off, Karen, which is, you know, how do we address all the different tick-borne infections. That's going to give them a home, because frankly, you know, why these things -- these subcommittees are going to be focusing on Lyme disease as the high priority pathogen. So, this kind of gives a home to the rarer, but, you know, [unintelligible] is an important topic. But rare.

>> Patricia Smith: I'd just like to ask a question. And I don't know the answer to this. And think you two gentlemen will have the answer. Since this is a six-year committee, does that -- how does that come into play. Like for example -- and this had been my thinking about this -- you know, we focus on Lyme, but we still bring in some of the other tick-borne into some of these areas, like diagnosis. But that -- okay, that's going to encompass our -- what I'll call the first-year report. All right, now what about down the line. After that? Couldn't there then be a broader focus involving other tick-borne diseases after some of this has been -- at least the process started and looked at in light of disease burden?

>> John Aucott: I mean, my understanding is that that's true. But Rich?

>> Richard Wolitski: The way that we understand the Act, and I'll say William can too shake yes or no, really there's a report that's due every two years. And it's really intended to kind of stay on top of the issues and to report, over time, on a core set of issues. Certainly, the report could go deeper in subsequent years and expand on things. But I would not want -- I mean, I think the intent is really that over the six-year period we're looking at recommendations and then down the road, were they adopted or not in the subsequent years. It's a continuous process of monitoring. And so, they shouldn't be completely different reports would be my only point.

>> Karen Vanderhoof-Forschner: I differ a little bit on the thinking on this. I think that if we're going to focus on the people that are here and suffering that my taking just Lyme disease and running through these excellent subcommittees that it would serve everyone well if what's

running through the subcommittees is not only the vector -- the one vector that's right up with the co-infections that go through that same tick, because people are going to present not just with berlybedorfi [phonetic sp] infection, but other AC axial infections. And so, we don't know for a fact how they compound each other or confuse each other. And that's one of the things that pathogenesis and transmission is. When Dr. Horowitz sees a patient. He probably doesn't say, "Well this year I'm going to look at Lyme disease. If you don't get better, I'm going to test you for something else next year. It's that whole constellation that that one patient is coming in and the focus appears to be on the ticks that transmit Lyme disease. And then, the next step would be the next disease burden, which would be Rocky Mountain Spotted Fever and some of the other things. But, for now let's -- I think we should think of this as a way to answer, in those committees, Lyme disease and the coinfections from the same tick.

>> John Aucott: What do people think? Yeah, it's --

>> Vanila Singh: I just have a quick question. Sorry.

>> John Aucott: No.

>> Vanila Singh: For Rich. Is it statute when it says Lyme disease and other tick-borne?

>> Richard Wolitski: It's tick-borne diseases. So, it includes all of them.

>> Vanila Singh: Right.

>> Richard Wolitski: Including Lyme.

>> Vanila Singh: Right. That's the statute. That's what Congress said. I'm not -- I don't know who much leeway there is. I'm not advocating for one thing or the other. I'm just wondering out loud. Is that -- does that have to be followed? Like, as they laid out? Since you've just tossed it around.

>> Richard Wolitski: In the discussion that I just heard, I didn't hear anybody proposing that all of the other tick-borne diseases would be ignored completely. So, I think it's a question of scope and emphasis. And so, will all of them be addressed equally? And we go through the same level of rigor and do separate literature reviews for each of them and do separate analysis of prevention, separate analysis of treatment and all of that? Or do you kind of put more emphasis in some places and note what there is to note that's significantly different or some issues that need to be addressed with regard to other non-Lyme tick borne disease? So, it's arranged that the committee can define for itself what it wants to do. But I don't think it has to do everything at the same level of intensity or thoroughness.

>> John Aucott: We're actually hearing how testing is actually moving in that direction. So, I think, you know, by separate subcommittees, there are some that are going to fit naturally easily with that. And then, others like pathogenesis less easily. So, I think we have to kind of grapple with that with each subcommittee. But that's kind of why I wanted to entertain a subcommittee on co-infections, to kind of get at that issue of co-infections as a single issue.

> Wendy Adams: I think we could also use that committee as the ramp for the following two-year segments, right? To get that level of knowledge about those 15 different tick-borne diseases in one place. And then, use that as kind of the spring board for setting up the federal response to those tick-borne diseases.

> Estella Jones: Well, and from a process perspective, if you had the other tick-borne infections as a subcommittee it wouldn't seem to exclude their ability to interact with those other cross cutting subcommittees, because I don't anticipate any of these subcommittees are going to work in a vacuum.

> Richard Horowitz: Yeah. It's quite important, I think, to have a separate one for the co-infections. It plays a huge role in the patients. At least the ones that I've seen. And so, I think it's a big chunk to take and I think it should probably be put separately. And I think it will get more focus if it gets its own subcommittee. Okay.

> Female Speaker: And also it would clearly address the statute to include the other tick-borne infections.

> John Aucott: Yes. So, how are we doing, Rich?

> Female Speaker: And there are gaps in knowledge too that might --

> Richard Wolitski: I've got five.

> John Aucott: [affirmative] We've got five? All right. So, I think it's time to open up -- because again, we've got to move to get these -- I'm with you -- we've got to get through to the is. So, we've got five that I think we're pretty good on. We could agree on those and we could have a motion. Or we can continue discuss whether there's any further groups needed. Pat?

> Patricia Smith: I want a clarification because co-infections can mean a lot of things. Again, co-infections can mean, you know, from ixodes scapularis, just the co-infections from there. Or are we talking about other tick-borne diseases? Which -- and so, I think that has to say either co-infections and other tick-borne diseases other than Lyme or something, because co-infection, you know, you're not going to get a co-infection with Lyme disease with certain tick-borne diseases.

> John Aucott: Sure.

> Patricia Smith: They are not going to --

> John Aucott: I assumed we were being inclusive to any North American tick-borne pathogens, basically.

> Patricia Smith: Okay. Well, then maybe should that be phrased in such a way? Because it's -- --

>> Estella Jones: Or you could say "other tick-borne infections, including co-infections" or something like that.

>> John Aucott: I like that.

>> Patricia Smith: Yeah. That's perfect.

>> Dennis Dixon: Yeah. I like that. I was struggling with co-infections when it might be a single infection if it's non-borrelial.

>> John Aucott: Right, right, right. So, we've got a good <unintelligible> for now. It's hard for me to look that way and this way.

>> Richard Wolitski: Just to make note of the note I added here. So, assuming in this framework you said earlier that research would be considered in each of the groups. And so, I'm just mapping back to what's required. And that gets met by a cross cutting theme of research that all the groups address, is that the thinking?

>> John Aucott: I believe so. Yeah.

>> Vanila Singh: I mean, I will just put out there. I think education should be across all the groups too, because it is involved prevention, diagnosis, you know, understanding pathogenesis and treatment. I don't think it's limited to access. So --

>> John Aucott: Makes sense.

>> Richard Wolitski: Let's see.

>> John Aucott: Education and research are cross cutting. Research is cross-cutting.

>> Richard Wolitski: So, take out education for clinician and patients here. And that becomes a cross-cutting theme that gets considered in all the areas. Is that what people want?

>> Female Speaker: Agreed. Yeah.

>> Richard Wolitski: Okay. Thank you. I'm doing it. There it goes to leave.

>> Patricia Smith: Then do we have to broaden that to include the public then. Just the --

>> John Aucott: Education?

>> Patricia Smith: Because you're not in the -- you don't have the --

>> Vanila Singh: You could use dissemination of information in the report. Rich, I don't know, again, that might a statutory issue anyway.

>> Richard Wolitski: So, one might imagine if you're doing education in the same way as a cross counting theme. Then there needs to be something about -- for prevention. Who needs to be educated about prevention? And is it being done. Who needs to be educated about surveillance and how this data collected and what did it mean. How does that need to be done? It needs to be educated about treatment. Second would be, kind of applied to all of these, there would be different audiences, potentially and different messages. Different goals for the educational content. But that could be one way that people could handle it.

>> Vanila Singh: So, provider, patient, public?

>> John Aucott: Yeah, provide, patient, public. Yeah. Right. All right. Another subcommittee or are we missing any obvious holes? Are there gaps in our subcommittees?

>> Karen Vanderhoof-Forschner: I have a comment. It doesn't fit in and does not quiet to this. And it's not another subcommittee. But I just want people here to know that as you start researching and working on this, remember people of other colors. One of the things that happened at the Lyme Foundation is we went down to a conference, a medical conference, and there was this sense that none of the doctors had seen an African American with Lyme disease. And they were saying, "They're immune. You've got to study their system." They were not immune. We wound up getting a doctor who heard it. Give us pictures of patients and the rash wasn't red. And the mistake was, doctors are looking for red color. And it looks like a black and blue. So, keep in your mind --

>> John Aucott: Yeah.

>> Karen Vanderhoof-Forschner: -- the effects on the whole population of -- when you do this research.

>> John Aucott: That's a great point. I mean, Kristin and I talked about special populations. So, let's throw that out there now. People of color, minorities, women, and children? You know, so we thought about a special populations subcommittee as well. I mean, Lise, you feel like children need their -- are they special [laughs]?

>> Lise Nigrovic: They're very special.

>> John Aucott: Yeah.

>> Lise Nigrovic: It could be considered also with cross-cutting themes because it's not --

>> Patricia Smith: I think it is.

>> Lise Nigrovic: -- specific. But I appreciate the comment.

>> Wendy Adams: And certainly access to care. And access to care, like that -- that's one of our subcommittees. So, actually access to care seems like a great place to broadly encompass access to care for everybody.

>> John Aucott: Okay. So, maybe we could add that -- Rich, access to care for everybody with those populations included.

>> Richard Wolitski: Yeah. I'm going to make this note that special population issues be considered in all of the groups; that's what I heard people say.

>> John Aucott: The other thing that we'd -- I like to throughout there is, you know, drug and vaccine development. Is that an area that we want to have a subcommittee on?

>> Lise Nigrovic: Right. I would think of the vaccine development would be hit upon in prevention and the drug development under treatment. But perhaps, it needs more specific information.

>> John Aucott: It ends --

>> Karen Vanderhoof-Forschner: I'm not wild about it. I think --

>> John Aucott: Which one?

>> Karen Vanderhoof-Forschner: I think the idea of using this committee and some of the reports to evaluate other companies' products, to bring onto the market --

>> John Aucott: That's definitely not our role at all. So, I would --

>> Karen Vanderhoof-Forschner: Exactly. So, I'm thinking vaccine trials, that should be part of our recommendation one way or the other. I don't think we should be evaluating -- do you want to say something? I just don't think this committee is the right place. The FDA can do their thing. And the CDC can do theirs. But I don't think this --

>> John Aucott: Remember, we're supposed to identify gaps and, you know, agnostically identify gaps that are gaps. Or that are areas of controversy. And that may be an area of controversy. It sounds like it is.

>> Dennis Dixon: <unintelligible> noncontroversial. Just explain what we're doing and research in those topic areas. Basic translational, clinical, so it gets at drug and vaccine research.

>> Vanila Singh: I agree with you, Dennis, on that. I think it's an area to research, improve drug development for other options. Improved innovation, optimal, better side effects. I mean, we want cutting edge to be also focused for this, you know, these patients. You know, not to advocate for bad things. We want to advocate for research as it would be in any given disease state.

>> Dennis Dixon: So, we can talk to you about what's the new stuff on the horizon that's in our research portfolios. And it sort of depersonalizes it and doesn't attach you to a particular product.

>> Scott Cooper: Yeah. And I think you have to keep in mind too, this is -- the statutory language is pretty clear. And it kind of comes high up in this Act. It's an update or summary of what's going on out there. So, I think if we report it that way -- there's no opinion associated with it. Or endorsement. I think we keep, you know, to the statutory language.

>> Karen Vanderhoof-Forschner: Will we get in trouble if it turns out some of the recommendations are contrary to clinical trials going on for other products? I mean, if you look at pathogenesis, and it turn out -- this isn't what I'm -- I'm not trying to focus on the vaccine. But if it turns out a vaccine or a new kind of drug doesn't work because the pathogenesis doesn't match up, is there going to be any pressure on this committee to sort of look the other way? I mean, there's -- we'll give our opinions of what we believe should be done, right?

>> Lise Nigrovic: I would imagine it would be generic like a vaccine -- research into vaccine development is needed, or something like that. Without any specific caveats or specific recommendations as a gap analysis.

>> Karen Vanderhoof-Forschner: Here take it.

>> Ben Beard: So, Lyme disease aside, vaccines are a critical tool in public health for preventable diseases. And I think -- I realize the history with vaccines and Lyme disease is highly controversial. But, you know, at the risk of saying something unpopular, I think that a safe and effective vaccine that's been adequately evaluated is hugely, hugely needed in a disease with, you know, over 300,000 new cases a year and a target population that's at risk in those same places every year.

And I just think -- and I'm not making an argument for the current vaccine or the trials that are underway, but you know, three agencies represented in HHS, at least, FDAC and NIH, are all very much invested in vaccines as a public health need. And just because it's controversial, I don't think we should avoid it. And I think what we need is a national referendum of discussion with vaccines so that people with both views can get their concerns out. And to get the needs and define that and make that clear. And I think this is a great opportunity and a horrible opportunity missed if we don't address that.

>> John Aucott: And -- just a second. And I think it's important to remember we're called to address controversial issues. I mean, that's actually why we're here. One of our charges is to address gaps/controversial issues. And I think we've been doing a pretty good job about it. You know, in addressing things that other panel members might think are controversial. So, just because it's controversial or has a bad history doesn't mean that it's not part of what we're supposed to evaluate at least.

>> Karen Vanderhoof-Forschner: I just don't want to mistake you that I'm anti-vaccine. I'm up to date, my daughter's up to date --

>> John Aucott: [laughs]

>> Karen Vanderhoof-Forschner: And I got the quad this year. So, I haven't missed one. So, it's not -- that is not the issue here.

>> Wendy Adams: Yeah. And I think the concern is just that resources get placed from one thing to another. And in a word of very limited resourced, priorities need to be created and that -- you know, bringing vaccines in as part of that conversation is important, because there is a trade-off. They're expensive, they take a long time to develop. And they don't help patients now. So, I think in that context, they are important to include. Realizing that you have all the voices at the table, so you can address all those different issues.

>> John Aucott: Pat?

>> Patricia Smith: Yes, I mean, certainly -- particularly, the Lyme vaccine is a controversial area. But that doesn't mean, again, that it should be excluded. It is something that we need to look at. We need to see what's out there. But in -- we have, I believe, a responsibility, you know, in doing that, also to look at what we consider to be problems that might be associated with that, because that is our responsibility to point that out. You know, whatever those problems we think are -- or what we have found them to be, whether it be with, you know, the types of vaccines that are being offered based on history, whatever. But I think that it's -- that we -- it's imperative for us to be able to provide that type of information. Again, it's not up to us to make the decision. Not as a body, anyway. We all may be doing that in different ways.

>> John Aucott: Right. So, what do people feel about adding that?

[inaudible]

>> John Aucott: You've put it under prevention?

>> Male Speaker: Yeah.

>> Male Speaker: Absolutely.

>> Ben Beard: So, yeah, I mean, it is prevention. But you could -- and it would be to have a category for vaccines and immunotherapy because there's minocromil immunotherapy and other things like that that are a little but parallel to vaccines, but different. Alternatively, if it's lumped in together with vectors, prevention, and surveillance, then we just have to keep in mind that's a very, very, very broad -- it's got entomologist, epidemiologists, communications experts, immunologists, you know, it's a huge variety of people on a subcommittee, which we can do, but we should just keep that in mind.

>> John Aucott: Right. Immunotherapy might be another controversial thing, but again, something that is, you know, fixed with the scope of what may be addressed. So, what do people think about vaccines and immunotherapy as a group?

>> Dennis Dixon: I think it fits under research, because we don't have them available for use right now. So, they're not products. They're in the discovery phase. So, we could describe

what's happening. If we're supposed to be looking at what the government is doing.

>> John Aucott: Yep.

>> Dennis Dixon: We can describe what we're doing in the research sector in all of those things. If we don't have anything on monoclonals, it's not going to be there.

>> John Aucott: [affirmative]

>> Dennis Dixon: And why have a committee on monoclonals if you don't have anything? We have just the survey. So, our step one is to look at what we're doing so that we can determine what's not being done.

>> John Aucott: [affirmative]

>> Dennis Dixon: I think you could slice the melon in various different ways and still have a melon you could put back together. So, I wouldn't be too troubled on where it is for convenience. I think most of it's going to be at the NIH research bench. And we could just build it under the broad categories of research that's' being done in this topic area, and we could put it in buckets that you could take out and put in another truck if you want to put the bucket in a different truck. But you've at least got that categorized.

>> Vanila Singh: Right. We're taking inventory basically right now. And we can look at it as near terms and long term as well.

>> John Aucott: So, we would include immunotherapy vaccines and new drug development?

>> Dennis Dixon: It would include what it is. [laughs] What we've got is what it is.

[laughter]

>> Female Speaker: Are you still --

>> Male Speaker: I like labels thought.

>> Female Speaker: No pre-exposure immunotherapy or post-exposure? Or is that --

>> John Aucott: Well, that's part of it. There's pre-and post-exposure to immunotherapies. And there's new drug development. I mean, those are all kind of in what you do. It probably basic research. Yeah.

>> Estella Jones: Well, and under the current format then those things would be not in the same group. I' not advocating for them to be in the same group or not. But they would be in the group or not. But they would fall within where they would be -- switches are what you're referring to, I think.

>> Richard Wolitski: Yes, that's true.

[end of transcript]