Tick-Borne Disease Working Group
11:29 AM to 12:28 PM

>> John Aucott: Rich is going to lead us in a discussion of the roles and responsibilities of the working group and voting procedures.

>> Richard Wolitski: Well, sort of. Not quite voting procedures. What I'm ready to do is kind of run through a little bit of the roles and responsibilities to help clarify some of the questions people have been asking: who does what? And how does it work? And then, with the charter -- I mean, I know actually most of you know the charter inside and out already, but we'll go and highlight just a few things, and then go ahead and -- go ahead and show you some resources and places where you can find all the documentation about it, in case you haven't already found it.

So, I'm just going to start off with what I'm going to be talking about today. First, we'll start with roles and responsibilities for the chairs, the members, the staff in my office who are supporting the working group, and then our contractor, Communicate Health, who is providing support as well. And then, we'll talk a little bit about the charter.

So, one thing I did want to do is kind of, you know, say a little bit about our understanding about the role and the implications of being a special government employee. So, our understanding is that, in fact, some of the things I've seen in writing say that, you know, we're really bringing on the individual members to provide us with independent opinions and expertise and judgment. They're not functioning as an employee of the government in provision of their opinions and thoughts. They're really here to provide their expert opinion. They're here to challenge the issues that are raised in the discussion. They're here to make sure that the information that's reviewed and discussed is complete.

I mean, they are really fully able to participate as members, bringing to bear the full weight of their experience and their expertise. People are not -- have not been, and will not be asked to conform their opinions to any existing policy or procedure. That's not what -- that's not going to happen. People can have differences of opinion in the group. And as we kind of get into the process of talking about how the group functions in some more detail, we'll get into voting and how recommendations will be formed. Already within the group, there's been discussion, and it hasn't been put to a vote, but the general sense that I have, and I'll look to John and Kristen to see if they agree. It seems like, really, the group is going to want to acknowledge differences of opinion when they exist. So, the idea is not going to be that there'll be just one statement, and if half the people plus one agree with that, the perspective and opinion of the rest will be silenced. That's not how it's going to work.

So, I just want to kind of like, assure people to the extent that I can about that. And then, what we'll do after this meeting is on our website, we'll put up some information about the special government employee status, and how it affects the work in this group. So, we'll -- kind of when you have questions and other issues, we'll do our best to respond to them, and at least share with you the information base that we're working from.

So, let's kind of talk about who's on the group, and what the different people do. So, this is kind

of a quick summary of roles and responsibilities that I put together for the various parties who play a role. So, chair and vice chair. Critically important positions. The chair is the person who is, you know, primarily in charge. The vice chair serves as chair when the chair is not available. And together, they work as a team to manage the process and to make sure we have good meetings, productive meetings, stay on time, and do the work that needs to be done. So, they're engaged in developing the median agendas with the members, with the staff, convening and adjourning the meetings, conducting the meetings. They will always approve the minutes for any meetings that they convene.

And they're engaged in actively planning the work of the committee with the DFO, myself, and the alternate DFO, Jim Berger [phonetic sp]. And they work with us to make sure that the committee is on track. That the work the committee's doing is in alignment with the charter, that we're conforming to the applicable regulations, such as the FACA regulations, the -- and then, I blank on the name of what FACA stands for, but you know what I mean. Basically the rules that govern -- oh, Federal Advisory Committee Act, that's what it was, that govern how these committees function, and ensure the openness and the transparency are there.

And they'll also work with us in figuring out what the committee's going to need to help it do its work. So, that will have to do with things like resources related to literature searches to taking the public comment that comes in and summarizing them, providing it to the members organizing information. So, we're going to be able to provide, you know, a number of services to the working group that will help them work more efficiently. Because I think one thing that's important to keep in mind is that they're doing this for free. So, even though they're, you know, in a special government employee status, they're not making money off of doing this, and have -- we have to kind of keep the expectations for the members, the time that they spend, in reasonable bounds. We can't ask them to spend six months full time doing literature reviews and doing that sort of work. So, we have to build the systems that support them in making it possible.

So, we talk about the members -- and this is true for the chair and co-chairs as well. There's no secret special agreement with them about supporting any agenda, or anything like that. You know, members are here to provide independent subject matter advice and expertise. That is why they're here, because they have knowledge experience that we want to hear about and learn from, and incorporate into the work that we do as part of a federal response. They're going to give input and advice on the procedures and processes of how the working group itself functions. They're going to ensure that the right information is available to the group that do literature searches -- that they're done in the right way, and they're going to review those and say, hey, how come this article wasn't included? This is missing. This is important.

So, they're going to be actively participating in all parts of the work that we do. They'll be voting on the issues that are presented to the group and put forward into motion for a vote that will certainly include any and all recommendations that the working group would put forward. That would include review and approval of the draft report to move forward for review. And that will include participation in subcommittees. So, the discussions we've had now -- up until now is that we really would like all the members to participate in at least one subcommittee, and probably thinking with limits on time, probably one. And the chair and vice chair will then play a role in visiting each of the subcommittee meetings, and kind of monitoring them, and kind of seeing that

they're on track. So, they will not be serving as members of a given subcommittee, in part out of respect for their time, but also -- what happens when you're having a meeting and the chair comes in? People -- chair says something, their weight -- the words that they say can have a differential weight in the process. And so, we want to kind of keep them on the sidelines for this part of it so that when the issues come to the full working group, they can be kind of be objective, and not having been part of that process and part of the discussions in the working group -- in the subcommittees.

So, then, what do we do in the office of HIV/AIDS and infectious disease policy? So, I am charged with responsibilities as the designated federal officer, and Jim Burger, who's seated here at the corner, is the alternate DFO. And he exists as the alternate to kind of provide backup and support to me if I'm unable to perform my duties, but we also kind of work together on a regular basis with the rest of team, and kind of planning the activities that we do to support the working group.

So, some of the roles that the DFO and the alternate DFO have include ensuring compliance with FACA regulations and any other laws or regulations that are applicable to the advisory committee process. We'll work with the chair and the vice chair, and it is a function of ours to approve the agendas for the meetings before they are released to the public. If the chair and vice chair are not present, we are the authority to call a meeting, to attend the meetings, and to adjourn the working group meetings in certain circumstances. I've never seen that happen before, but the law does allow for that role.

And FACA groups, like this working group, have to have a federal representative -- the DFO or alternate DFO present just to make sure that kind of the rules and processes and everything are being required -- are being followed. And then, we maintain records. And they will say we're anticipating maintaining a whole lot of records. The amount of public comment that we've received thus far has been large, and we've developed a -- basically a database that allows us to log every comment in when it's received, and to log in the responses that have been provided to people. And to really, then, keep track of what are the things that people are saying? What are the issues? And we kind of monitor that, and produce summaries of the topics that are being discussed. And we just got that system set up, and we'll be providing information back to the working group members that come in from the public comment as well.

So, that's kind of a little bit about roles and responsibilities for us. And then, finally, I want to mention we have a contract in place with, really, an organization that's been doing a great job for us thus far. And that's CommunicateHealth. And they're under contract with us to support the writing and communications' activities of the group. And they also help with some of the logistics. And so, if you imagine the idea of writing this -- what I imagine is going to be a pretty large report to Congress and secretary. That's going to take time, and it's going to take a lot of people contributing to it.

So, we will have support of writers who will go to the subcommittee meetings, who will come to these meetings here today. And they will work with the members to produce a report that reflects the ideas and the resolutions that the working group has developed. And in some cases, people may want to do some of their own writing. And that may be okay, but the challenge is

going to get a report that speaks in one voice, and to have it so that it really holds together; it's coherent. And so, they're going to bring their skills and abilities and expertise in doing this type of thing and helping with us.

So, some of the things they do -- this is with planning and staffing, public meetings, they'll attend the public meetings and take notes, and draft the summaries. They'll help to prepare draft meeting agendas and summaries for all of the subcommittee meetings, and they'll draft Congressional reports, summarizing the recommendations of the tick-borne disease working group. So -- and again, nothing happens without the approval of the working group members. And so, there's not going to be information released, recommendations that come out separate from what's been discussed in these public meetings, reviewed and improved by the working group members. So, those are kind of just the highlight of some of the roles and responsibilities. And I'll pause there, and see if any of the members had any questions that they wanted to ask about that. We talked about it a little bit before, and I think people had -- Pat, yes?

>> Patricia Smith: Yes, my only question -- and I think you just answered it, but under the chair and vice chair, it says: "approve minutes for meeting." You meant, I'm assuming, that the board will eventually approve them. Is that correct?

[talking simultaneously]

>> Richard Wolitski: They will come out to everybody to have the opportunity to review them --

>> Patricia Smith: Yes.

>> Richard Wolitski:: -- but I'm guessing that not everybody's going to have the time, each and every time, to do it, with super detailed response. And so, in this way, the chair and vice chair, they have to sign off on it. Other people have an opportunity to provide input into it because we want the meeting minutes to be accurate, and it's going to be easy to catch when they're not because all of this has been recorded, and so, people will have access to a full recording of meeting one and meeting two. And there also will be a transcript that will be produced as well. And so, the purpose of the minutes is really to kind of condense all of that down so people don't have to relive this again and again and again to find information. Okay? I think time for one last question, if there's one. No? Okay, great.

So, let's kind of move onto the charter. We talked a little bit about this in meeting one yesterday, and I'm just going to kind of reiterate some points because I know not everybody who is here today in the room or watching online was here yesterday. And then, I'm going to go to our website, and just going to show you where you can find all this information, and show you where we'll be providing additional information about the working group as it becomes available.

So, now, as everybody knows, the working group was established in 21st Century Cures Act. And they're charged with providing us with expertise, wisdom, knowledge, experience, and reviewing our activities as a working group, and as we bring in information about what the federal government's doing. They'll be reviewing those, and providing input and suggesting how that response can be improved. They will be -- in this group, one of the things, too, we're going

to look at is duplication of effort, overlap. And so, the group, when they kind of reviewed the inventory of activities that the various government agencies are doing, they'll be looking not only for gaps, where things are missing. They'll also be looking at duplication and saying, "Why are three different people doing the same thing? Can't we get them to work together and just do this once?" And proposing suggestions for improving our efficiency and our effectiveness and our impact on the lives of people who are affected by tick-borne disease.

And I'll also be looking as part of this, I'll be looking at research and I'll be looking at the research priorities and gaps in those as those. And also, the programmatic activities and gaps in those as well. So, we'll kind of have today, I believe, be talking a little bit more about the specifics of some of those issues, and kind of flesh that out a little bit more as a group. Talked yesterday as well about the Federal Advisory Committee Act and the Government Sunshine Act, which both together kind of put in place the legal framework for these types of committees, and really have it, bottom line, the requirement around transparency and openness. The meetings will all be held in public, and they'll be at least -- for the full working group, there'll be at least 15 days' notice in advance. Every meeting will have a public comment period, like we had this morning, and it's critical that the work of the group is presented to the public in a way that's understandable.

So, one of our challenges and charges is to take some of what's going to be really complex scientific information and talk about it and present it in a way that regular, normal people can understand. You don't have to have a Ph.D. or M.D. to kind of read through all of it and make sense of it. Something happened here, and we lost a little bit of stuff here, but -- also, the laws require that we make records available to you so that there is not a secret set of documents or a secret set of reports that the committee members get and nobody knows about. And all of the sudden, they're making decisions and talking about things that seem like it's coming from left field and it doesn't make sense with what you've seen presented in public.

So, from these meetings, we will be posting -- and as I said already, recording of the broadcast, transcript, minutes, and then in addition, all the slides will be available to people. And in the future, if there are reports and documents and things that are being reviewed by the group, those also will be made available on the website. And that, quite frankly, is one of the challenges that we are working on dealing with right now, because they expect we're going to have hundreds of documents that the group will have reviewed here in the full group and then in subcommittees, as they're formed. And so, we're kind of looking at the best ways to make that available to you so that it's clear what we did and what we looked at.

And then, I got some stuff that didn't fit on this slide. And this is kind of the point around closed meetings. So, these laws and regulations allow for closed administrative meetings and subcommittee meetings, so they can really facilitate the process of discussion of -- in administrative meetings, issues that may be related to personnel or to discoveries, or things that might have an influence on markets, or affect patents, those kinds of things. And I don't expect those to happen very often, but they could. And then, subcommittee work just because they're bringing in such a broad group of people. There're going to be ideas and things that people are going to discuss, debate that will be, you know, just kind of spontaneous, in the moment.

And people are going to misspeak, say things incorrectly, and it kind of is something where we want to allow people to have that process, that time to talk with each other, debate with each other, and consider new ideas. And then, when they go through all that messy stuff, kind of talking about stuff, working about stuff, and they get to the point of having something that is a product, is a recommendation, that then goes to the full committee, the full working group, so that it can be discussed in public, and people can be asked questions about why are you saying this? Or why did you think this? What's the evidence? And those sorts of things. So, everything subcommittees do comes back to the full working group. There are no independent actions, resolutions, decisions that are anything but a draft in the subcommittee meetings. And when we get to the timeline later this afternoon, we'll kind of -- you'll see some of that, and how it kind of looks, in terms of time, for people.

So, again, just kind of going back to the charter and some of what it calls on the group to do. It really is, you know, all focused on this report. And so, that's one thing that, you know, some people have made suggestions, asked me questions about. Can the working group do this or that? And sometimes, they're -- you know, really like doing programs or doing research or doing activities that, you know, you really need to have full time paid staff available to do. And our charge doesn't allow us to do anything else than to assess what's being done, and to provide recommendations in this report.

And so, the report will look at the full range of tick-borne diseases. The group may choose to focus more effort initially on one area or another, just because there's a limited amount of time done. I want to look what advances have been made recently in the field that need to be incorporated more into practice. We're looking at the federal activities that are being conducted across the agencies of HHS, and in other departments. And they'll be looking at a full range of activities, and we'll kind of have that discussion of how broad does this go? Does it include policies? Guidance's? Educational materials? Programs? Is it programs of any size? And those are just the kind of things that are some decision points that will inform the inventory that will need to be sent to and completed by the various agencies to report back what their activities are.

And then, let's see. We'll be looking at gaps in the research, as we said before. And also, making suggestions for improving efficiency, getting rid of duplication of effort. And they will also -- comments made to the working group. Oh, also -- and part of this process, you know, the public comment that we get through the tick-borne disease mailbox, all of that becomes part of the public record as well, if people indicate that they want this to be included as part of the public record. And so, we'll be compiling all of that, providing it to the committee, and the public comment that's provided in writing to us in conjunction with any given meeting is also part of the record. And so, we will be posting those online as well.

One thing that we will going back to a few people about is that in some cases, it seems like information about other people, other patients, has been included in some of the records, and we just want to make sure that we don't violate anybody's privacy and confidentiality. And so, in some cases, we may have some follow up with people to ensure that individuals who are named had given their consent to be named, and that they really do want their identity to be used in this way. So, that was kind of all that I had prepared on -- going over the charter and the roles and responsibilities. And part of why it's a little light is I want to show you where you can find

everything. And hopefully, this will answer questions you have.

So, this is a page that shows all of the advisory committees that are overseen in the office of the assistant secretary for health. And so -- oh, you can't see that. I'm here talking to you like you can see stuff on the screen, and it's like, no. I can see it, but you can't. So -- okay. All right.

>> Male Speaker: Sorry about that.

>> Richard Wolitski: That's okay. I'm glad we noticed it before it went like, for 10 minutes, and sounding like an idiot. So, this kind of shows all of the different advisory groups that are overseen out of the office of the assistant secretary for health. And tick-borne disease is one of them, and I just -- oh, it's down here. There we go. So, this is still a work in progress, where it's continuing to add more information to the website as time goes on. But on the website, if you go to it, you'll find all of the background documentation in detail that provides the foundation for the working group. You'll find the 21st Century Cures Act, the charter, and you'll find information about how the committee functions, and the work that we do.

And this page here -- the how we work page, just sort of summarizes the requirements from the 21st Century Cures Act that kind of really speak to the balance and the diversity of opinion that we're required to have as part of this process. It shows you the members of the committee and the staff who are working on it. And for each meeting, it will have all of the information about upcoming meetings once the dates for those are set. When the agendas are developed, they'll be posted online. And it will say that, no, we don't plan on doing it like we did this time every single time. We were in a little bit of a rush, and we didn't get the agendas up as early as we would've liked to have, but they will be here for folks hopefully at least a few days in advance before the meetings.

And they will be -- this is where you find, also, the information about what happened at each meeting. And this will continue to stay online for -- until the work of the group is done, and then, sometime after that. And any reports that come out of the group activities will be posted here as well. And we'll have a notices section that when there are things that come up that affect the working group -- so, if there is a call for subcommittee members, for example, this would be the place where you would find it. And right now, we just have the two formal federal register notices, but we're also kind of investigating and seeing whether we can provide some more informal updates about the process of the group so that people don't go two months, three months, wondering like, what's going on with them? That we can kind of give you some information about status of the activities.

So, that's the website. It has also a place where you can contact us, and this is where you get the tick-borne disease mailbox email address. And that's really the place to send everything. If you send it to me, as somebody here in the audience today kind of said, "I sent you an email weeks ago and you didn't respond." And I missed it because it got buried under a lot of other things that came in that particular day. And sometimes, unfortunately, that happens for me. So, if you want to make sure that you get it answered, you send it to tick-borne disease mailbox, and it will absolutely get addressed there.

So, that's all I had for today. I don't know if there are any questions or comments anybody else wanted to add, but -- are we good? Okay, all right. Let's go into our next thing.

>> Kristen Honey: Thank you very much, Rich. So, for our next part of the agenda, we wanted to talk through -- let me just make sure I'm on the right thing. Basically, the vision and the North Star, and the mission and kind of values that will unite us all. We may not always agree on facts, but we can at least agree on principles and how we will operate as a working group.

So, for this next 20 minutes -- or 15 minutes, I guess, we were hoping to come away with a vision for the working group. The working group members have some example mission statements from other parts of HHS and the government to sort of help us brainstorm. And then, after that, I was hoping we could talk quickly about a mission, and maybe have a subgroup of people who, after we -- who had volunteered to flesh out a mission, and we could vote on that formally the next time we all get together. And then, lastly, the core values. So, I guess my motion is that we discuss a vision, maybe come to a mission statement or vision statement today. We find a group of people who are willing to work on the mission, and then we discuss our values.

>>Male Speaker:
The post is a motion?

Kristen Honey:
Yes.

>> John Aucott: [unintelligible] second that. All in favor of Kristen's proposal, say aye.

Audience Members:
Aye.

>> John Aucott: Opposed? All right.

>> Kristen Honey: Excellent. So, for a proposed vision statement -- and when we say vision statement, we are talking about an aspirational description of what an organization or what this working group would like to achieve or accomplish in the mid-term or long term future. It is intended to serve as a clear guide for choosing current and future courses of action. I think of it as the ideal future state of our North Star. And the one that I came up with -- and this is obviously for discussion, and just a starting point, is a nation free of tick-borne disease and where evidence-based patient-centered outcomes return everyone to full wellness.

>> Richard Wolitski: So, I'm going to try to capture that, Kristen. A nation free --

>> Kristen Honey: Yep. A nation free of tick-borne of disease and where evidence-based patient-centered outcomes return everyone to full wellness. Originally, I had 100 percent wellness because I'm a numbers geek, but then I put it to full, so --

>> Richard Wolitski: So -- one more time. Sorry.

>> Kristen Honey: Where --

>> Richard Wolitski: A nation free --

>> Kristen Honey: -- evidence-based --

>> Richard Wolitski: Okay. Where evidence-based --

>> Kristen Honey: -- patient-centered --

>> Richard Wolitski: [affirmative]

>> Kristen Honey: And if you want to put patients before evidence-based, that's cool.

>> Richard Wolitski: So, patient-centered -- so, I'll fill in the -- I spell these out properly as soon as we get it down. So, a nation free of tick-borne disease and where evidence-based patient-centered --

>> Kristen Honey: Outcomes --

>> Richard Wolitski: Outcomes.

>> Kristen Honey: -- return everyone to full wellness.

>> Richard Wolitski: Okay. And I'm going to bring this up and make it bigger, so people can see it more clearly in the room. And then -- okay. So, now, thank you. Sorry for the distraction -- as I got this down.

>> John Aucott: So, let's open it to discussion among the working group. It's our first chance to have some discussions. Wendy?

>> Wendy Adams: Yeah. So, I think we have to -- I like the direction. I think we really have to acknowledge the problem with evidence-based as a rit-large [phonetic sp] in lime disease just because of the lack of funding and the difficulty of doing, you know, placebo controlled, randomized clinical trials. So, I just want to put that out there, and how we phrase that. What -- I guess, strength we use to enforce that, and whether or not we can reference data without making it incumbent upon perfect data for everything, which -- in which to achieve that goal. So, I just want to put that in context of the particular situation on Lyme disease.

>> Kristen Honey: So, maybe instead of evidence-based, swap it out for data-driven?

>>Female Speaker: What about scientifically supported?

>> Richard Wolitski: I would also add a nation free of tick-borne and chronic disease because we as a country are battling, at this point, rising healthcare costs and because lime is the great

imitator where 5 percent of the U.S. population has chronic fatigue and fibromyalgia. And there's Alzheimer's disease every 67 seconds in this country where spirochetes have been found in biofilms in the brain. I think chronic disease will also help our country with the rising healthcare costs, and it broadens it out just a bit.

> Karen Vanderhoof-Forschner: I also have great concern of the cost to patients for finding medical care, and I think somewhere in there, there should be reference to either delivery -- the goal being delivery by their family health practitioner, or by low-cost treatments, or a low-cost evaluations. There's got to be something where we want to get to a point where patients can afford this, and don't have to take a mortgage out on their house.

> Scott Cooper: If we can consider, also, changing outcomes to care, I think it's a little bit more personal of a word.

> Female Speaker: I think it is on. I think --

> Kristen Honey: You want to do some substitutions, and see what the new sentence says based on those comments?

> Richard Wolitski: So, which of them do you want to incorporate? So, we got two proposals for replacing science-based with either data-driven or scientifically supported.

> Kristen Honey: Personally, I like data-driven. It's a little broader. And scientific method, you know, there are debates about good science, bad science, quality science, replicable science, data-driven. The data is the data. That's --

> Dennis Dixon: I like that, too.

> John Aucott: You like the data-driven, yeah?

> Dennis Dixon: I'm tempted to take us into the mud and the weeds, now. The aspirational goal of free of tick-borne diseases sounds wonderful. It's in the broad realm of infectious diseases. I think we would be struggling with the reality of a nation free of infectious diseases, or a world free of hunger. If there were a way to get at a degree rather than absolute for something like this --

> Kristen Honey: Yeah, I think with the vision statement, you want to go for the kind of blue sky, North Star, recognizing that it may not even be attainable, but that's the vision.

> Richard Wolitski: And Kristen, I wonder if might be helpful to go and just kind of quickly review the several examples that the members had -- other people hadn't had a chance to hear those. Because I think it helps you --

> Kristen Honey: Sure.

> Richard Wolitski: -- understand this. But really not the thing that the group's going to do

itself, but --

> Kristen Honey: Yeah, the mission --

> Richard Wolitski: -- what it hopes will happen.

> Kristen Honey: -- the mission statement helps us ground it more into like, how we operate and what we're going to do -- the more near term. But for this long term vision statement, examples include the HHS Disparities Act: A nation free of disparities and health in healthcare. Very achievable, small-scope. The President's Council on Fitness, Sports, and Nutrition: All Americans lead healthy, active lives. So, you really want it to be where we're going, that future state. An ideal utopia. So, no infectious diseases.

> John Aucott: I mean, I kind of -- you know, you're getting at -- and it's sort of the HIV strategy: United States will become a place where new HIV infections are rare. You know, maybe it's -- you know, that's closer to what you're getting at, yeah.

> Richard Wolitski: So, switch back to our document in progress. So, we've done this part. Let's get rid of it. So, chronic. So, that would go here. And it's tick-borne and chronic diseases? So, committee's going to -- and kind of take on the -- make a contribution towards improvements in other chronic diseases. Is --

> Kristen Honey: It'd be tick-borne and related chronic diseases.

> Richard Wolitski: [affirmative] Okay. And then, my staff is laughing at me because why did I get up here to type? Because I'm the worst typist in the world. So -- okay.

> Kristen Honey: And this might seem silly, but looking at it now, I kind of want to flip data-driven and patient-centered, so we put the patient first.

> Male Speaker: So, where do you see data-driven, then, going? So, where patient-centered --

> Kristen Honey: Just do patient comma centered -- or patient slash -- dash centered --

> Male Speaker: Yep. Okay.

> Kristen Honey: -- data-driven.

> Richard Wolitski: Yes, we need a hyphen here. And probably --

> Pat Smith: I sort of like what Karen mentioned about getting in there something about doing this on a scale that's not going to bankrupt people, which is what's happening now. So, some small phrase that would indicate that we tried to do this in a manner that will be physically -- economically viable. That would --

> Richard Wolitski: And so, one thing that I think may help the group get closer to that is if we

had the -- what other suggestion replacing outcomes with care. Do people want to do that? If we do that, then it gives us something to hang the cost off of. Okay. And you said, that is affordable? Or what would you want to say?

>> Kristen Honey: Affordable care. Patient-centered, data-driven affordable care?

>> Richard Wolitski: Okay.

>> Female Speaker: Or you could say economically viable. Physically viable.

>> Patricia Smith: If we do it that way, then I think we need to say for the patients --

[talking simultaneously]

>> Female Speaker: Yes, for the patients --

>> Patricia Smith: -- so we're not assuming that it means --

>> Female Speaker: Right, exactly --

>> Female Speaker: -- the government [inaudible] --

>> Female Speaker: -- that they can cut costs, right?

>> Richard Wolitski: Right. So, two different alternatives. One place to put it is kind of in this string of modifiers. So, it can be patient-centered, data-driven, and then -- what were we saying? Economically affordable? Is that the proposal? Okay. And then you get care -- that returns everyone to full wellness. Or you could say patient-centered, data-driven care that is economically viable or that's affordable by everyone --

>> Female Speaker: Or feasible. Economically feasible --

>> Richard Wolitski: That would be another alternative. So, it's kind of up to you --

>> Female Speaker: -- viable [inaudible].

>> Richard Wolitski: -- I'm mostly just typing and helping facilitate the process.

>> Female Speaker: Feasible.

>> Richard Wolitski: Economically feasible? Okay. And where do you want it? As a modifier, or as a -- kind of a result?

>> Female Speaker: I can see shortening it a bit, where it's a nation free of tick-borne and related chronic disease -- sorry, a nation free of tick-borne and related chronic disease where patient-centered, data-driven, economically feasible care returns everyone to full wellness. So, you can

get rid of that last and.

>> Richard Wolitski: [affirmative] That would be -- I think this is it, yeah?

>> Female Speaker: Does disease have to be diseases?

>> Male Speaker: We can do that, yes. Because it should be --

>> Patricia Smith: I still have a problem with -- I don't mind economically feasible, but again, when I hear that, that means economically feasible to the nation --

>> Female Speaker: So, perhaps, for patients?

>> Patricia Smith: For patients, yes.

>> Female Speaker: Let's say economically feasible care for patients, or --

>> Male Speaker: Could you skirt the issue and say "broadly available" instead?

>> Female Speaker: That's possible, too.

>> Patricia Smith: I think you have to put in there economically feasible for patients because otherwise, we're really not making the concept that we want there, articulated very well.

>> Male Speaker: So --

>> Kristen Honey: So, maybe instead of having patients twice, we could do the first one, call it human-centered.

>> Lise Nigrovic: Although broadly available does imply --

>> Female Speaker: Okay, okay.

>> Lise Nigrovic: And you can have a treatment and you can't afford it, it's not available. So, it could -- I think it could be addressed in that way, too.

>> Female Speaker: The broadly available, I think, implies that it's affordable. It's -- so, I like that.

>> Richard Wolitski: So, is that kind of a -- I'm going to type it, and then we'll see.

>> Kristen Honey: Would it be -- broadly available, or broadly accessible?

>> Female Speaker: Might be a better --

>> Richard Wolitski: Yeah, accessible. Okay. So, then, we would swap out this whole thing for

that? Okay. And --

>> Karen Vanderhoof-Forschner: Should part of that statement include something about physicians having the ability to diagnose and treat patients without being harassed? I can't think of a more --

>> Female Speaker: Fear of reprisal.

>> Female Speaker: -- politically correct.

>> Richard Wolitski: I kind of want to encourage -- I'm butting in. So, think of the vision statement as the big goal, and there's any number of things that are going to have to happen to get that goal. Diagnostics would have to be improved. Physician, you know, ability. Training has to be improved. Patient awareness. And so, when I've seen this gone wrong before is when people start building on all the things, and it turns into the mission statement or something else. Not a vision where you've got, "Oh, of course. Everybody agrees this is the thing we want to do. This is what needs to be accomplished."

>> Kristen Honey: And I think the broadly accessible kind of gets at that a bit because if it was care accessible in all 50 states, then ideally, doctors in 50 states would have the freedom to prescribe as they see fit. And I do think there's a tradeoff between how long we get and how memorable our vision will be. So, short is sweet.

>> Male Speaker: And this gives it the "what" rather than the "how."

>> Male Speaker: [affirmative] It's the goal. The ultimate goal.

>> John Aucott: Are we happy with it? Last comments before I entertain the motion? Wendy?

>> Wendy Adams: Hold on. I'm just reading it, but --

>> Female Speaker: I think we need --

>> Wendy Adams: It doesn't -- there's something that doesn't foot -- the "that" --

>> Male Speaker: Yeah, take out the "that."

>> Wendy Adams: Yeah, if you read it, it's not the right --

>> Male Speaker: Okay, yeah. Sorry. Yeah, yeah. I was told to take it out before, and then I put it back in because it looked like it needed it, and it doesn't, so --

>> John Aucott: Any other comments or corrections? Vanila?

>> Vanila Singh: Just -- I'm just throwing this out there. Data-driven. Is that -- are we -- you know, or evidence-based. Evidence-based limits us because there's usually not enough resources

to do the proper trials, which we're going to advocate for. Data-driven. Is that just limited -- I don't know. I mean, I feel like there may be some compassion capacity there that we want to include.

>> Female Speaker: Say that again? That last part?

>> Vanila Singh: Maybe more -- some compassion? You know, I feel like data-driven's very stark, cold.

>> Kristen Honey: You don't think the patient-centered kind of helps balance it?

>> Vanila Singh: It does. I think that patient-centered has to be -- it's, by definition, should be there. I'm just throwing last minute last thoughts.

>> Male Speaker: It could be compassionate patient-centered, data-driven.

>> Karen Vanderhoof-Forschner: I'm back here to can we add in affordable after broadly accessible and affordable care?

>> Richard Wolitski: Where. What if we put it in front of --

>> Karen Vanderhoof-Forschner: Last -- third line, yeah --

>> Richard Wolitski: Yeah, what if --

>> Karen Vanderhoof-Forschner: Right after broadly accessible and affordable --

>> Richard Wolitski: And I think if we put it in -- you could put it in front of broadly accessible, and that'd leave the and, potentially.

>> Karen Vanderhoof-Forschner: Yes.

>> Richard Wolitski: Okay. Affordable, broadly accessible care. [inaudible]

>> Estella Jones: I would also like to propose replacing the word returns with restore.

>> Kristen Honey: Oh, good.

>> Richard Wolitski: Okay. People like that?

>> Female Speaker: Yeah.

>> Male Speaker: Okay.

>> Lise Nigrovic: One other question, just about the first statement -- a nation free of tick-borne and related chronic diseases. Does that imply that all tick-borne infections are chronic, or does

that separate those two out? I think there's issues around acute and non-chronic tick-borne infections as well that shouldn't be --

>> Male Speaker: It could just -- so, do you want to say a nation free of tick-borne diseases and related chronic --

>> Male Speaker: Allen, what was your suggestion?

>> Allen Richards: I would just say, tick-borne, acute, and chronic diseases.

>> Female Speaker: Yeah. [inaudible] I think recognizing --

>> Male Speaker: Yeah. Balance it to tick-borne.

>> Kristen Honey: I guess I was thinking of it like, the tick-borne disease, where acute -- would include acute and chronic. But then, for some, there may be complications where long term -- you know, so clinical infections could lead to, you know, a suite of other things.

>> Lise Nigrovic: It was phrased -- was tick-borne and related chronic, so it made that tick-borne also seemed like it was chronic to me in my reading, but --

>> Kristen Honey: I see, I see.

>> Richard Wolitski: So, I should look to our vice chair, who's leading this discussion, for resolution.

>> Kristen Honey: If -- what if we say a nation free of tick-borne diseases and related chronic diseases? So, it just sort of has tick-borne diseases as stand-alone. And that, in my mind, would clarify that it's acute and chronic for the tick-borne diseases.

>> Richard Wolitski: And do you want diseases plural for tick-borne, or do you want "free of tick-borne disease?" S or no S?

>> Kristen Honey: What is the name of our working group?

>> Richard Wolitski: It doesn't have the -- it's not plural.

>> Kristen Honey: All right, then. Singular.

>> Dennis Dixon: I'm still struggling with related. Does that mean that there are not carried by ticks, but they're related how? In symptoms, or etiology?

>> Kristen Honey: Like, say someone got an autoimmune condition because of a tick-borne -- unless the infection's cleared, but there's still some related issues. That would be a long term chronic. So, I think we've heard people talk about chronic fatigue, fibromyalgia -- all these things that may no longer be a tick-borne disease, but still issues.

>> Dennis Dixon: I think that's how [unintelligible] got the topic by circumscribing and under tick-borne, acute and chronic. Because then it's clear that you're not talking about non-tick-borne chronic.

>> Vanila Singh: Are there also related diseases, co-morbid diseases that actually affect the outcomes or the -- you know, progress or process of the tick-borne disease? I guess that's one of the things I've heard through the working group, and prior to it.

>> Male Speaker: Ben?

>> Charles Benjamin Beard: Well, so related to [unintelligible], it can have several meanings. There could be related, you know, pathophysiologically. You know, I think what you're really driving at is associated, not related. That might be a little bit better term. Because that way if you're talking about PTLDS or autoimmune disorders or whatever that are associated with a tick-borne illness, then --

>> John Aucott: I think that's a good point. And is -- do diseases versus illnesses -- does that make a difference to people, if we call them disease or illness?

>> Female Speaker: Yes, I think disease is better.

>> Karen Vanderhoof-Forschner: I prefer disorder for those things that are not diseases, but disorders. Tick paralysis.

>> Patricia Smith: I prefer disease. I'm sorry, but -- because I think that disease -- everyone -- it's kind of universally accepted, disease, as opposed even to an illness to a lot of people, I think, and people that we talk to out in the patient -- I mean, I think people like the word disease. But I'm not -- you know, I'm not wedded to that.

>> Wendy Adams: I think disease is important because it kind of elevates -- if you start going down disorders, then you start hearing about, you know, things that are a little more amorphous and where the etiology is a little less defined, and that's a slippery slope.

>> Richard Wolitski: Are we close? Yeah?

>> Female Speaker: We need an "and" before affordable and broadly.

>> Estella Jones: Restores? Did you get restores instead of return?

>> Richard Wolitski: Oh, I didn't. I blanked out, so --

>> Estella Jones: So, I actually recommend restores patients to full wellness instead of everyone --

>> Richard Wolitski: Let people look at that while I make this other change.

>> Charles Benjamin Beard: So, one last comment on that from me is -- I mean, I'm certainly completely supportive of restoring patients to full wellness, but depending on how you read that, it kind of misses the point of prevention. We have 350,000 new cases of Lyme disease every year, and you could say by ensures -- you know, rather than, you know, restores or returns. That's just varying sort of reactive to me. And I -- granted, it's hugely important, but is there a way to make that also perspective? Because these are new cases every year they're adding to this condition.

>> Richard Wolitski: Just to add an observation from -- for HIV and for hepatitis. They both focus on new infections, and then talk about the health and well-being of people who have already contracted them. So, you could say associated chronic -- a nation free of tick-borne disease and associated chronic diseases where new infections are rare, or with no new infections, whatever you kind of want as your vision -- that would be one way of bridging it.

>> Female Speaker: I like where new infections are rare, and patient wellness is fully restored through compassionate, patient-centered, data-driven, blah, blah, blah.

>> Richard Wolitski: And patients -- okay. This tracking thing is driving me nuts. Where new infections are rare, and patients are restored to full wellness through? Or by?

>> Female Speaker: Sure.

>> Richard Wolitski: Which one?

>> Female Speaker: Patients restored to full wellness through or by -- either way. You can just get it up there, and then we can see.

>> Richard Wolitski: By -- and take this part and bring it back up.

>> Female Speaker: Full wellness with?

>> Female Speaker: With?

>> Female Speaker: Yeah, maybe with.

>> Richard Wolitski: With instead of by?

>> Female Speaker: Yeah.

>> Richard Wolitski: Okay.

[inaudible commentary]

>> Richard Wolitski: And this is supposed to be and. So, I think it's a question of do you want this -- the and -- do you view these as sort of a series of modifiers, or is the and differentiating --

>> Female Speaker: I kind of need it --

>> Richard Wolitski: -- the moderators from each other and --

>> Male Speaker: We're moving from simple to more complex.

>> Female Speaker: Yes.

>> Female Speaker: Yeah.

>>Female Speaker: You can delete some of the words at the end. I would --

>> Male Speaker: Because they're already --

[talking simultaneously]

>> Female Speaker: -- accessible.

>> Male Speaker: Yeah. Thank you.

>> Female Speaker: Given --

>> Male Speaker: Yeah, to me, I think it's getting a little bit unwieldy. And I would suggest -- as much as I like compassionate and I like the affordable in there, but patient-centered, I think, implies compassionate care. And broadly accessible also implies affordable. You know, broadly accessible. If it's expensive, it's not broadly accessible. So, that -- I'd recommend that, maybe just to bring it down a little bit, get rid of some of the words.

>> Male Speaker: I think since this is aspirational, those connotations are inherent in the definitions.

>> Kristen Honey: So, that would turn it -- if you would get rid of affordable and broadly accessible care, and then we can delete compassionate.

>> Lise Nigrovic: Are you saying broadly accessible implies affordable, so not get rid of broadly accessible?

>> Female Speaker: [affirmative]

>> Male Speaker: Okay.

>> Wendy Adams: It does, but I'm going to go back to the patient. I mean, I think the affordability, you've heard, is just a huge issue. And so, I do -- broadly accessible might mean something to medical providers, but it doesn't necessarily mean the same thing to patients. So, I would argue to keep that part in because I think it bears explaining, that we mean that as well as

broadly accessible, which might just mean being able to get good diagnostic care in a major academic facility.

>> Richard Horowitz: Yeah, I agree with Wendy because it could be broadly accessible where the drug is out there, but it's unattainable by patients because they can't afford it.

>> Female Speaker: I agree with Wendy, too.

>> Female Speaker: So, would adding affordable care at the end or accessible care do it? Or then, we still have the challenge --

>> Female Speaker: Affordable care.

>> Female Speaker: Affordable? Okay. And affordable care after data-driven, I guess.

>> Richard Wolitski: Yeah. And let's see -- where's my cursor?

>> Female Speaker: Or add them both.

>> Richard Wolitski: I can't spell it right, but [unintelligible] what you're thinking --

>> Karen Vanderhoof-Forschner: Could the person that suggested new infections are rare explain to me what that's telling me? Which new infections are rare? Is Lyme rare? Or new infections of Lyme rare?

>> Male Speaker: Tick-borne infections?

>> Karen Vanderhoof-Forschner: What's rare?

>> Richard Wolitski: So, it was kind pointing out an HIV strategy. That's what it talks about in infections rare -- and outcomes where people living with HIV are blah, blah, blah. So, it's what was -- it's a way other plans have addressed both stopping new infections?

>> John Aucott: It could be tick-borne infections.

>> Richard Wolitski: So you could put tick-borne in there.

>> Karen Vanderhoof-Forschner: I just wanted to -- you don't need to add words. I just want to know.

>> Male Speaker: Yeah.

>> Karen Vanderhoof-Forschner: To me, it doesn't mean much of a specific -- it doesn't mean anything specific. It's just additional verbiage. Lyme is not rare, and the co-infections don't seem to be rare, but in my opinion --

>> Richard Wolitski: If that's where you want to go, then you want to go where it's rare --

>> Female Speaker: If prevention is working so well --

>> Karen Vanderhoof-Forschner: Oh, okay.

>> Female Speaker: -- if prevention is working so well --

>> Female Speaker: That's the answer I was looking for.

>> Richard Wolitski: Does it make sense now? Or would you change it in some way?

>> Female Speaker: We start with a nation-free, and then we say new infections rare, so it's a little bit of a --

>> Kristen Honey: Yeah, except people travel internationally, so --

>> Patricia Smith: I'm sorry, but I still think we need the word accessible in there because something can be affordable, but that doesn't mean it's accessible across the country, which is, you know, a grave problem that our patients have been having for many years.

>> Kristen Honey: So, patient-driven, data -- patient-centered, data-driven, accessible and affordable care?

>> Patricia Smith: Yeah, I don't know that it needs to say broadly accessible, but I think accessible implies that --

>> Kristen Honey: Okay.

>> Patricia Smith: -- you know.

>> Kristen Honey: So, do folks feel like we're getting close, and maybe we could, like, table this and go over email to finalize it? But we put this as like, our tentative North Star? And then, we'll --

>> John Aucott: Good idea.

>> Patricia Smith: I move to table.

>> Female Speaker: Excellent.

>> John Aucott: All in favor of tabling, say aye.

>> Audience Members: Aye.

>> John Aucott: Opposed?

>> Kristen Honey: And given the amount of time left, I think we should table the mission, which is a little more in the weeds in what is this group going to do, what's our North Star, for after lunch. And very quickly, put up some values that we have so that people, over lunch, can be thinking about this. And the way we're thinking of these values are sort of principles that will guide us all. So, no matter what the data say or where the science takes us, we will always come back to these values. A few of them that are out there from U.S. Air Force -- people first, mission always. That's a great one because you're putting your humans first -- people first, and then mission allows for adaptability in the local context and stuff. There's -- let's see. We have -- which one do we have up there? We have all of them. Okay, so we have a few different sets of values up there. National Foundation of Integrative Medicine: open to everything, vested in nothing. Only seeking truths.

I doubt we could do this in federal government, but in God we trust, but everyone else must bring the data. We will follow the data regardless of where it leads. We advocate evidence-based over eminence-based medicine. We will share what we learned with the world as a service. Starbucks: "Everyone who gets our coffee in the morning, there are six values that unite that cup of coffee. Provide a great work environment and treat each other with respect and dignity. Embrace diversity as an essential component in the way we do business. Apply the highest standards of excellence to the purchasing, roasting, and fresh delivery of our coffee or cup, or whatever that is. Develop enthusiastically satisfied customers all of the time. Contribute positively to our communities and our environment. Recognize that profitability is essential to our future success"

And then part of the White House, we have this group called the United States Digital Service, which is kind of like the entrepreneurs and the tech innovators within the White House. Their set of core values is "Hire and empower great people. Find the truth, tell the truth. Optimize for results, not optics. Go where the work is. Design for users, not for them" So, that could be like, work with patients, not just remove from them. And then, create momentum. And the Office of HIV/AIDS and Infectious Disease Policy that is helping us co-host today's meeting: "Respect. Excellence. Accountability. Collaboration. Honesty, and Integrity."

And I have to say, I really like the HIV/AIDS Infectious Disease Policy Office has very clean words, and then a little bit more expanded on that. So, I think with that, we should take a break for lunch, and have everyone think about it. And when we come back, we could do the same thing of having a subgroup of people work on it over email. We can finalize it later. Or if people come back with five or six values that unite us all, maybe we'll put them -- you know, finalize them today. But with that, I will make a motion that we will break for lunch, and reconvene at -- was it 1:10 p.m.?

>> Male Speaker: U.S. Department of Health and Human Services, produced at taxpayer expense.

[end of transcript]