NWX-OS-OPHS-OEP-OER

Moderator: Syreeta Evans
May 31, 2016
2:27 pm CT

Coordinator: Welcome and thank you for standing by. At this time all participants are in listen-only mode until the question-and-answer, the public comments section.

The call is being recorded today. If you have any objections to that, you may disconnect at this time. Now I would like to turn the call over to your host, Dr. Susan Levine. Thank you. You may begin, ma'am.

Dr. Susan Levine: Okay, thank you. So I'm going to do a quick roll call and then we'll proceed. Adrian Casillas.

Dr. Adrian Casillas: I'm here.

Dr. Susan Levine: Okay. (Elissa Potch). Dane Cook.

Dane Cook: Here.

Dr. Susan Levine: Donna Pearson.

Donna Pearson: Here.

Dr. Susan Levine: (Gary Kaplan).

(Gary Kaplan): Here.

Dr. Susan Levine: Is that Gary? It didn't sound like, okay. Faith Newton.

Faith Newton: Here.

Dr. Susan Levine: Jose Montoya.

Dr. Jose Montoya: On the phone. Here.

Dr. Susan Levine: Lisa Corbin. Rebecca Collier. Mary Ann Fletcher. Of course myself, Susan Levine, and then I'm just going to - I'm sorry, I didn't take down everybody's names in terms of ex officio so if you would please identify yourself as I call out your institution. NIH.

Dr. Vicky Whittemore: Vicky Whittemore.

Dr. Susan Levine: Okay. CDC.

Woman: (Unintelligible).

Dr. Susan Levine: Okay, Social Security Administration.

Michelle Shaffer: Michelle Shaffer.

Dr. Susan Levine: Okay. CMS. CMS? AHRQ.

(Unintelligible): (Unintelligible) here.

Dr. Susan Levine: Okay. HRSA.

Erin Fowler: Erin Fowler here.

Dr. Susan Levine: Okay. FDA.

Dr. Janet Maynard: Janet Maynard here.

Dr. Susan Levine: Okay. And then lastly, liaison organizations. (Steve), you're here I know.

(Steve): I am.

Dr. Susan Levine: Carol Head?

Carol Head: Here.

Dr. Susan Levine: Okay, I think I got everybody. Should I proceed with some very brief opening remarks, (Nancy)?

(Nancy): Sure. Let me just …

Dr. Susan Levine: Oh, you have your webinar logistics. Go ahead.

Woman: Yes, let me just quickly say I think we're doing much better today as far as the logistics. I think we got some of the kinks out. I still want to apologize to everyone for not having the capacity to listen off of your computer. For the next webinar, we'll make sure we can do it that way. And also, the operator

made a slight - we will not open up these lines for public comment as we did yesterday.

The people who have signed up for public comment will be called. They have received their time period that they will be called and they will provide their public comment after the operator calls them and puts them in queue. It will work just like yesterday.

Other than that, please go ahead, Sue.

Dr. Susan Levine: Okay. I really don't have much to say because we have a nice line up this afternoon. We'll have the remaining agency updates and then we'll have public comment. And then Donna Pearson's working group will proceed with a very nice presentation, a report from the IOM P2P working group and then we'll have several recommendations to discuss as a committee. I'd like to get that done before the break at 3:15 because there's other things we wanted to get to. It's conceivable that they may spill in but not spill over the break but hopefully not for very long. And then after the break we have committee discussions to discuss future and I want people to be thinking about this if they can, even during the call (unintelligible) working groups. (Nancy) threw out at least one good idea and I know Faith has an idea for a future working group. And so please try to formulate those in your minds because I'll be asking for that. And then we will have a quick wrap up and then we'll adjourn.

So why don't we proceed now to the agency updates? I guess we can have NIH first, please.

Dr. Vicky Whittemore: Good afternoon, every, and thank you. This is Vicky Whittemore and I'm a program director at NINDS and the NIH liaison to (SESAK) and what I'm going to do today is tell you about some of the activities and things

we've been discussing and working on since last fall, when the working group - the trans NIH ME/CFS working group was sort of reconfigurated (sic) and if I could have the next slide please.

So we're very fortunate to have representatives on the working group from almost all of the NIH institutes and from several of the centers and offices. And I have to say it's just been a true pleasure working with all of these individuals, who are really very dedicated to making things happen here at NIH. And the next slide please.

So the way we …

Dr. Susan Levine: Excuse me. I'm sorry to interrupt. Is there a way to expand that so we can actually read it? It's so tiny. Are other people having the same problem.

Woman: Up in the corner there's an upper corner on the right side.

Dr. Susan Levine: I got it. Okay. Thank you.

Woman: It's the same thing we did yesterday.

Dr. Susan Levine: Now I remember, okay.

Woman: All right. But I think that's a good reminder. There is up in the right side there is the four little arrows going away from each other. Click on that.

Dr. Susan Levine: Thank you. Thanks so much. Sorry, I'm very technologically challenged. Go ahead.

Dr. Vicky Whittemore: I think that was the only slide. The previous one that has such small print. My apologies.

Dr. Susan Levine: No, that's fine. Go ahead.

Dr. Vicky Whittemore: The trans NIH working group has been meeting since last November and the way we've been thinking about things is to group them into short-term, intermediate and long-term goals. So what are things that we could do right away and things that needed to be done, what are some intermediate goals that we could plan for for the future, and long-term goals so even further beyond the next one or two fiscal years, which you'll see I'll come to are still pretty vague. And I think that's intentional because we fully expect that there will be a lot more activities as we move forward and want the plan to remain flexible so that we can be responsive to the needs of the research community.

So we have - and I will touch on some of the things that we have done to date. So we've completed a portfolio analysis which I will talk about briefly. We have developed an inventory of available biospecimens where there are linked scientific data that could be utilized and researched. We've begun to coordinate with the investigators involved in the NIH intramural study and I do have to point out here that the intramural study is a totally separate group of individuals from the people who are involved in the trans NIH ME/CFS working group. So it's investigators who work at the clinical center on the NIH campus and those individuals sometimes sit in on our trans NIH working group meetings but are not part of the working group per se.

We've started discussions and are thinking about collaborations in the future with the CDC multisite study. We issued a notice soliciting administrative supplements. And so what this means is that we put a notice out to the community - to the research community that anyone who has an existing NIH

grant can submit a request for additional funding to either expand the current studies they have, or if you're not an investigator studying ME/CFS but are developing an assay or have some interesting research that could be applied to ME/CFS, then that we'll also welcome. And we have I think received one to date. I know that I personally and some of the other program officers have talked to several individuals who are interested in submitting administrator supplements, both ME/CFS investigators and others from outside the field.

We're going to initiate a common data elements project and I'll touch on that more in a minute. We are developing a plan for communication with and engagement of ME/CFS stakeholders, so this involves webinars, invitations to discuss specific topics with us, so we're developing that plan. We are about to issue a request for information to solicit input on areas of research priorities and we're hoping to release a funding opportunity announcement and I'll come back to that as well.

So our intermediate goals you can see are really continuing all of these avenues, as well as working with the FDA and assessing clinical trial readiness and really moving things forward as much as we can. One of the things that is clear is we would like to increase the number of training grant applications submitted to NIH. It was surprising to us when we did the portfolio analysis that to date no post doc or fellow (K training), clinical training grants have ever been submitted to NIH for ME/CFS. And so that's a clear message that we need to really get out and boost the young investigator pool and really get them interested in doing research and submitting grants to NIH. And as I said, the long-term goals are right now pretty vague but really it's meant to be that because it's hard for us to think that far out in terms of what the community will actually need going forward. So if I could have my next slide please.

So as part of the portfolio analysis, we looked at total funding and this won't be a surprise to any of you - you see that huge dip in 2012 when NIH had a cut in its funding. But we're coming back and it's now almost I guess about 7.5 million in fiscal year 2015. And the entire portfolio analysis will be put onto the NIH website for ME/CFS in the near future. But I'm just showing you a couple of slides here. And the next slide please.

This shows you by NIH institute, so (NYAD), NINDS, etc. the amount of funding from each of these institutes. And you can see that across the board this is just 2011 to 2015, (NYAD) has certainly funded the largest amount of research on ME/CFS with NINDS following and then several other institutes that have anywhere from $1 to $2 million investment in ME/CFS research across the board. And in the next slide.

So the common data elements project is one of the things that we are launching this summer and we'll have a meeting of the stakeholders in conjunction with the meeting this fall in Fort Lauderdale. This is to develop content standards that will allow clinical investigators to collect the same data and report it in the same way such that studies done at different locations can be shared and using the same kinds of information. And so this will involve many of you who are on the phone today. We want to really involve the stakeholders, the clinicians, researchers, and patients and patient advocates in helping us with this process. So we're just getting this under way.

Beth Unger has agreed to help with this in a substantial way, so thank you, Beth, and we've had some initial discussions with the FDA folks, with Janet Maynard who is also very interested in working with us on this project. One of the things that we hope that this will do is really to facilitate data quality and data sharing and will give us standardized outcome measures that can be

utilized in clinical studies and then down the road in clinical trials as well. And in the next slide.

Like I said, we've begun to have discussions with Beth and the folks involved in the CDC multisite study. And this is really to capitalize on their expertise, because these are clinicians that have been involved in the study, have seen thousands, I'm sure, of patients with ME/CFS over the years and we're beginning to identify areas of collaboration where we can really work with them in terms of utilizing biospecimens and research studies, potentially utilizing the data base that they've created and again standardized measures across the board that would be key in terms of working on the common data elements project. And in the next slide.

Create new knowledge was one of the recommendations in the P2P report. And as I said, the intramural study is going to get under way hopefully I think this summer or fall at the latest and as many of you may know, they are going to work closely with the clinicians who are part of the CDC multisite study to help with the identification of patients. So that it's very clear that the patients that are being studied meet criteria and everyone agrees that these are patients that have ME/CFS. We are working very hard to stimulate new research and looking at ways in which we can do that and as I said, one of the ways we've done that so far which is an easy, quick way for us to get some additional funding out on the street is through the notice for the administrative supplements. And in the next slide.

We are about to issue a request for information so I would really hope that many of you would provide input to this research priorities. We will report out the summary of the responses we get for that RFI and that will help us also in terms of moving forward, in terms of any kind of targeted initiative we may think about putting in place in the future. Again, as I said we're developing a

plan for communication and engagement of ME/CFS stakeholder. And if it seems as if we're taking a long time to do that, I have to say that it's just a matter of process and making sure that we're doing things in the right way and engaging stakeholders in ways in which for example we don't put someone in conflict such that they would not be allowed to apply for grants. So we're being very careful there but it's coming soon, I can assure you. And in the next slide.

Again, timing is an issue here. I wish I could say more but I am actually presenting a concept for a funding opportunity announcement at NINDS Council next week and so I'm not allowed to speak about it prior to the concept being cleared, but our hope is that NINDS Council - excuse me - will recommend approving that concept that will then allow the trans NIH working group to move forward with issuing requests for applications. And I have to say, this has been an effort across the trans NIH working group working together and thinking about the best ways to provide some initial support for ME/CFS research and I also want to assure you that this is probably likely not the only RFA or RFAs that will be issued as we move forward.

One of the things that is complicated is when you are looking at funding initiative across institutes and although we're not working in our little silos within our institutes, we're truly working across NIH, it becomes really complicated when you think about how to do the actual funding part of this. But we're getting there and we're working through that as well. So I'm hoping that I will have some good news next week and then we can start to more openly talk about what we're planning in June and going forward. So I think that was my last slide. Thank you.

Dr. Susan Levine: Thank you. Thank you very much. Okay. Why don't we proceed with FDA followed by HRSA and then if any of the members or anyone else has questions we can do that afterwards. Janet, go ahead.

Dr. Janet Maynard: Yes, good afternoon. Can you hear me okay?

Dr. Susan Levine: Yes.

Dr. Janet Maynard: Great. So I am Janet Maynard and I'm a clinical team leader at FDA and I really appreciate the opportunity to provide an update on FDA's activities related to ME/CFS drug developments and for our last meeting. So FDA has been involved in a variety of activities focused on drug developments for ME/CFS and I provided some links which are hopefully helpful regarding some of these activities at the websites listed on this PowerPoint slide.

So I wanted to highlight some of our recent activities, and the first update is regarding a pharmacy compounding advisory committee meeting that was held on March 8, 2016 and the pharmacy compounding advisory committee meeting discussed six bulk drug substances nominated for inclusion on the Section 503A bulk drug substances list. And one of those substances was D-Ribose. D-Ribose was nominated for inclusion on the list of bulk drug substances for use of compounding, for use in the treatment of heart disease and ME/CFS. And during the advisory committee meeting FDA staff provided information about ME/CFS including the serious nature of the disease.

The majority of the committee members did not recommend inclusion of D-Ribose on the Section 503A bulk drug substance list but importantly D-Ribose is available as a supplement. In addition, and we thought it was important that

the committee recognize the significant medical need for patients with ME/CFS and the serious nature of the disease.

The second update is regarding an internal seminar on ME/CFS that was given by Dr. Lucinda Bateman. Dr. Bateman has expertise in ME/CFS. She discussed the terminology, the finding features, lack of biomarkers, overlap with other syndromes, and low rate of clinical diagnosis. In addition, she reviewed the Institute of Medicine or IOM's report on ME/CFS. The core criteria of ME/CFS were reviewed and the serious, chronic, and complex nature of (unintelligible). This seminar provided important information regarding ME/CFS to staff at FDA.

My third update is regarding an internal seminar held at FDA regarding the Patient Focus Drug Development of PFDD initiative. PFDD meetings allow a more systemic way of gathering patient perspective on their condition and treatment options. The PFDD meetings are forums to allow FDA to obtain patient perspectives on the impact of a disease or condition on daily life, patient views on treatment options, and decision factors taken into account when selecting a treatment.

A PFDD meeting on ME/CFS was held in April 2013. There were many outcomes from this workshop that have helped catalyzed drug development for ME/CFS including a draft guide for drug development for ME/CFS and the Voice of the Patient report. During the FDA seminar the PFDD meeting on ME/CFS was given as an example of how patient input helps facilitate stakeholder collaboration and drug development.

So in conclusion, FDA remains extremely supportive of efforts to help develop safe and effective treatments for ME/CFS. I really appreciate the opportunity to present today. Thank you.

Dr. Susan Levine: Thank you, Janet. Okay let's move on please to HRSA.

Erin Fowler: Hi everybody, this is Erin Fowler from HRSA. I just wanted to give you an update on what's been happening regarding ME/CFS in HRSA. So next slide please.

In HRSA we have the Bureau of Health Workforce which is BHW and the mission is theirs to improve the health of underserved and vulnerable populations by strengthening the health workforce and connecting skilled professionals to communities in need. And basically, that is done through institutional grant programs, scholarship and loan repayment programs, and support for service and retention. And I just wanted to talk about those two slides just to make sure that everybody is acquainted or reacquainted with HRSA's mission and vision and how it functions. Next slide please. You can go to the next slide.

Okay. So after the last meeting since it was my first meeting on the Council as an ex officio I tried to dive a little bit deeper into what HRSA is doing regarding ME/CFS. And I worked with the Division of Medicine and Dentistry to find out what was going on in their grant program and what their grantee is related to this subject and they surveyed their grantees and one of them came back and talked about the National Center for Integrative and Primary Health Care. They are a grantee that was fully funded for three years in September and their product period ends in 2017. Next slide please.

And the purpose of the grant is to advance the incorporation of competency and evidence-based integrative health curricula and best practices into primary care education and practice. And also to develop a set of competencies and education materials relevant to health care practitioners. Next slide please.

So one of the things that I found out they were doing, I had talked with the project director and they were working on developing a handout for patient education materials specifically related to chronic fatigue. There is a draft that is out there that's currently not available right now. It's going to be a library of patient handouts online and print versions. It's a sixth grade literacy level in both English and Spanish, and it can get either from primary care practitioners or directly to patients though a patient portal on the website. There are no plans at this time to develop curriculum from this specific grantee but they do have a patient education materials that I didn't know about and I'm not sure if the group knew about. So I just wanted to let everybody know that. I'm working closely with other folks in the Bureau of Health Workforce to figure out what other grantees are doing related to this topic as well. Thank you very much.

Dr. Susan Levine: Thank you. Okay, let me open up the floor to our members to ask any questions of these agency presenters.

(Steve): Sue, this is (Steve) and I work as some of you know when I'm not the treasurer of (unintelligible) CFS I'm an attorney and one of the big questions we always run into was whether somebody was ME/CFS can work or not. And there really are a paucity of studies and I was thinking that it would be great if someone were interested in doing a study that would involve doing CPETs and neuropsych tests on a group of people with ME/CFS, a range of them and possibly even a tilt-table test to get some objective measures and show their efficacy in measuring ability to function. Thanks.

Dr. Susan Levine: Sure. That sounds like a good idea. If I might, let me ask Vicky and possibly Beth also a question regarding - we all know what common data elements means but because we haven't really settled yet on a common, I guess, for lack

of a better way of putting it case definition for this illness, despite (unintelligible) just coming out and so forth do we actually have common data elements? I guess what I'm trying to ask is how do you determine what those common data elements - can you give me a couple of sentences like nuts and bolts in terms of how one would arrive at a common data element? Beth has been working with this also, so …

Woman: So the process that NIH has or NINDF I should say, we have a contractor that helps with this and we set up several working groups that are organized around the various aspects of the disease. So for example neurological symptoms, we sort of aren't that far in laying this out yet but so one of the things would be within that to have cognitive measures and then you would agree that if you're using these five tests to measure cognitive measures, then these are the elements that would be reported out. So you go through that process for all aspects of the disease. And so you can be somewhat agnostic to a specific diagnostic criteria because in the end if you have say a group of 500 patients and you've measured all of these agreed-upon common data elements, and you decide that, well patients with this common one X symptom do not have ME/CFS, then you just can exclude those patients from any kind of further analysis. So it's a way to measure similar things without being wedded to a specific criteria.

Dr. Susan Levine: Right, no that makes a lot of sense, because I know that's obviously an issue. Sure. Thank you.

Dr. Beth Unger: And this is Beth, if I could sort of echo. I think that is really one of the key points is that we need to collect that data that will allow us to stratify these patients through a variety of different ways so that we are not putting different people together and particularly once we get biomarkers to correlate with some of the additional markers. So the field needs to evaluate how well

questionnaires work to measure various aspect of ME/CFS in terms of the questionnaires and then in general common data elements will evolve as we understand more about the illness and there will be a series of guidelines.

The main advantage in my mind is that everybody will agree to measure the same aspects in the same way. And usually investigators come up with a core of theories and then they have their own theory about what might be important in addition and they can add those on, and then convince everybody else that they're right and then everybody measures them. And again, the process is that those people who study the illness are the ones who get together and agree on what is the best common data element. So it's not imposed, it's sort of by consensus.

Dr. Susan Levine: No, that makes a lot of sense because I know we're still evolving what those elements might be and so forth but that explanation makes a lot of sense. And you know, it's going to take time but I think you know, because of the complexity of the illness but well we still have another half hour or so before we get to public comments so if anybody else in the panel on the group wants to ask questions of FDA or HRSA.

Carol Head: This is Carol Head, I have a couple of questions for Erin at HRSA. Thank you, Erin, for updating us on your work. It is a desperate need in the patient community to have effective and correct information available to patients and I am very glad you're working on that. I'd be interested in understanding whether you - how you are obtaining information from knowledgeable patient groups and/or researchers such that the documents that you all present really do reflect the current best thinking about treatment. That's my first question.

And then second, when would you expect that documents would be ready for review by the patient community and then when perhaps would they be ready to be disseminated more broadly to patients?

Erin Fowler: Thanks for your questions, Carol. The first question I think is really probably around quality assurance and there's not too much that HRSA does at a project officer level or even at the branch chief level to assess the content that's going on. I mean, the grantees are the ones that are working with the patient advocacy groups and different stakeholders. HRSA just kind of manages the process for the grantees that supply the information and that are building the curriculum and these data bases.

In the funding opportunity announcements there's definitely some criteria that needs to be there in their work plan or something - it's in their work plan to make sure that the grantee knows what they're supposed to be doing, but when it comes to the development of the materials it's doesn't come to HRSA for any kind of quality check. They have their own timelines when it comes to when the information will be available since they have until 2017. And then also they have nonfunded noncontinuation so this could go on for a couple of years but I do know that with the chronic fatigue specifically that handout they do have a draft and I can find out from the project director when it would be available and I'd be happy to send it out to the group for your situational awareness.

Woman: Erin, I think that would be great if you could send it out and perhaps you and I can speak offline. I would love to know more about the contractor and their plans and see how we might be able to contribute information if that's helpful.

Erin Fowler: Okay, sure.

Donna Pearson: This is Donna and I had a follow up question for Erin.

Dr. Susan Levine: Sure, go ahead.

Donna Pearson: In the response that was provided it said that the CIMPC had agreed to include a case including diagnostics and treatments in their curricula. And I don't know if I misunderstood what you just said, but I thought you said that there would not be anything added to the curriculum. So could you clarify that for me?

Erin Fowler: The grantee is not required to - for MCIPA does not require to have anything in their specific curriculum around chronic fatigue. They just happen to be doing a patient and education material flyer.

Donna Pearson: So the statement and response is inaccurate or am I misreading it?

Erin Fowler: I don't have the response in front of me. I'd have to look at it. Is the response from HRSA?

Donna Pearson: Yes.

Erin Fowler: And it's CIMPH?

Donna Pearson: Yes.

Erin Fowler: Okay. I have to look at it again.

Donna Pearson: The second part of that would be to clarify again it's a name issue, but you're saying chronic fatigue. Is not the same thing the disease we're all talking about today, so it would be good to know which thing they're really talking about.

Erin Fowler: Well, they are specifically talking about chronic fatigue. I know that there's some - there's been a lot of discussion about the name and I don't know if everybody out in the community especially the primary care providers and specifically the populations that we deal with in underserved communities have caught up to this specific name. So I know that there's some question about it. But I do know that when I looked at the flier they are still using the name chronic fatigue and I realize that it is different.

Donna Pearson: Apart from the name, what disease are they talking about?

Dr. Susan Levine: There are certain criteria that are necessary for the patient to be identified.

Donna Pearson: Is that what they're talking about?

Erin Fowler: From what I could understand from the flyer, yes. But I don't think it's that specific. I think it's fairly broad and these are not necessarily people that - I'm not sure which subject matter experts they're using but again, I'm happy to find out more information from the grantee.

Donna Pearson: That would be great. And while I can, I just want to ask Vicky a question and I had sent her some questions in advance. Thank you for incorporating many of the answers in your talk but I wanted to know if the trans NIH has capacity to follow the science that is happening around the globe. We know the (unintelligible) biomarker ripe for patenting in Australia. There's a study that shows progressive brain changes by longitudinal MRI. We're reading about the possibility of a rare gene variant as a result of the Norway Rituxan study. You know, we hear from Dr. (Montoya) about antivirals and I don't remember the name, may be (John Chee) or something about enteroviruses and low-dose Naltrexone and all these things and one (unintelligible) recommended a cross-

agency leader once we were hoping to get some kind of synergy going on with all this information. So I think Vicky you might be the person. Again I'm putting you on the hot seat, but is there some kind of coordination happening about all the research?

Dr. Vicky Whittemore: No, thank you Donna for that question. I apologize that I didn't address that. I meant to. So I think all of us who are on the ME/CFS working group are trying as hard as we can at present to keep up with what's happening. Having said that, though, I think there is room for us to do a better job. We have already - so Dr. (Kourachef) and I have had a conversation with our counterparts in Canada. They have recently funded I believe planning grants. They are considering putting - there are planning grants for an ME/CFS research consortium across Canada. I've been in touch with my counterparts in Europe as well who are considering a similar kind of consortium across Europe and I'll be attending the meeting in London I guess in a couple of weeks.

The Invest in ME Conference. It's a research conference in one day with the public and patient advocates. And so I have several meetings planned for that meeting. And what I'm hoping is that we can put together a global alliance for lack of a better term for now where we can really set up a way in which we can work across what research and what's happening across all of these countries. So we're trying, Donna, and I think that any help that we can get from the patient advocacy groups or any patients in alerting us when they hear of things that are going on is also very helpful.

Dr. Jose Montoya: Can I just say a comment and a question to Vicky. I think it's refreshing to see these reports today from the NIH, FDA and HRSA. The trans NIH ME/CFS working group is comprised by members from at least 15 disciplines. This is really terrific. This is the kind of multidisciplinary approach that is required

for a disease that has such diverse genotypes and highly variable kinetics. It is probably the best option to address the vacuum in basic sciences and clinical care in ME/CFS. I notice, Vicky, that the chair is the - from the Neurological Institute of Neurological Disorders and a question, can you share with us the rationale to having selected the chair of the neurological institute and is this something that will be permanent or it will be rotated? It's more a question than a criticism.

Dr. Vicky Whittemore: Thank you, Jose. So as you all know, the working group used to be run out of the office of research of women's health and there was a decision made when you know, about a year ago now I guess, when there was a lot of media attention, there were a lot of interests at NIH among those of use program directors who oversee grants and research on ME/CFS to really reinvigorate the working group and Dr. (Kourachef) actually stepped forward and volunteered to be the chair. (Francis Collins) asked him and he agreed to do that.

I think going forward it remains an open question whether that will be rotated or how that will transpire as we go forward. He's been absolutely terrific to work with and has good relationships with the other ICE institute directors across NIH and so that plus I think encouragement from Dr. (Collins) which is always helpful has really brought all of these institutes together to work together. But I think it's an open question, Jose, how that will work going forward.

Carol Head: This is Carol Head with a question. Erin, going back to you and HRSA and apologies for going back, but some of the comments you made in response to Donna Pearson's questions alarmed me and you and I will be in touch offline but I am especially concerned if the patient materials being prepared are for chronic fatigue, not even chronic fatigue syndrome, let alone ME/CFS.

Chronic fatigue is very widespread in our culture and is really irrelevant to the disease we are studying so perhaps I really think it's important that there is patient research and researcher input on this and perhaps we could speak directly with the contractor because if information is disseminated about chronic fatigue as though this is addressing the problem that we here on this call are all deeply concerned about that actually would move us backward. So do you have any thoughts about that?

Erin Fowler: Yes and I actually misspoke. I'm really sorry about that. It is chronic fatigue syndrome so that's the correct terminology that they're using on the flyer. Again, these are not contractors, these are grantees so they're people from academia and other medical institutions that have applied for grants. So these are not contractors.

The other thing, Donna, I just wanted to clear something up as well when you had mentioned the National Coordinating Center. It's one and the same in what I was talking about. I Am Prime is also the same - the CIMPC is the same thing. In the response - I looked up the response. It does say that they agree to include in MEC as case including diagnostic and treatment of the disease in the curricula. At this time though when I had spoken with them just two weeks ago they were only talking about developing the flyer and I don't think they were going to go in the direction of actually having and developing curricula like they thought that they were for this specific syndrome.

Dr. Susan Levine: Let me see if I understand this correctly then, Erin, with the University of Arizona grantee. Is there someone who, you know, chairs the grants you know, process. In other words, how do they decide who to fund the grant for or if it's a quality piece of work or quality proposal?

((Crosstalk))

Erin Fowler: There is a funding opportunity announcement that goes out and then …

Dr. Susan Levine: But who makes the final decision about the funding that proposal.

Erin Fowler: Yes. I was just going to get to that.

Dr. Susan Levine: Okay. Sorry.

Erin Fowler: So the funding opportunity announcement goes out and then there's an objective review and subject matter experts from across the community come in for three days and they review all the applications. And then they make the determination.

Dr. Susan Levine: I mean can you give us an example of who for instance? Is it someone we might all know? I guess we're concerned about the vetting process and the quality of you know, evaluation.

Erin Fowler: Well so this is a HRSA wide grant process so if folks want more of a specific presentation on the grant process I'm happy to do that.

Dr. Susan Levine: Or let us know if it's available somewhere on a website. So we have an idea of like, I don't think it's very clear to either me or the other members if I'm wrong that you know, what, who actually decides whether this is a worthwhile project that you're going to fund and whether it's truly ME/CFS and like Carol said doesn't disseminate information that will lead astray.

Erin Fowler: I'm sure that it's not ME/CFS, CMCFS because the grant proposal that went forward was not specifically ME/CFS, it's only going to be part of the library

of 200 handouts that they are going to have in this virtual library. So when the proposal went forward there was an objective review with different physicians from across the country that have probably experience in developing curriculum and specific diseases that primary care practitioners should know about and they determine which ones they want to put in their library. It's really all up to the grantee and then how they get funded is up to the subject matter experts in the panel.

Man: So is there nothing on ME/CFS that's guaranteed to be as part of this? This is (Steve).

Erin Fowler: There is. There's one educational material and it's a handout that talks about ME/CFS.

Dr. Susan Levine: Well I think the reason we're a little skeptical is that I for one am very involved with trying to promote medical education in this area. I know (Jason) and others have published surveys that show that very few medical schools including my Alma Mater even have ME/CFS in the curriculum and furthermore have objected to my bringing in board. I mean, I told the story on another webinar where the dean in my medical school just said - practically laughed over the phone like saying we're not going to teach this or, you know, it's not important. So that's why we're skeptical.

Erin Fowler: No, I understand and I'm happy to go back and get more information or even have a conversation with (Nancy) about maybe this group coming and speaking at the next meeting so that folks are a little bit more educated about what's going on around this.

Dr. Susan Levine: Well we just want to make sure that you know, the grantees are you know, fully vetted and that they are giving out material that's you know, true and competent and so forth.

Donna Pearson: This is Donna. Rather than learning about the process, I don't think we're concerned as much about the process. We're concerned about the content. We're concerned that the educational materials are accurate. And I'm hoping that after today's meeting Erin, you could double-check on this because it was written off as a positive development in training for clinicians and we were very excited to read this response from HRSA and I'm hoping that somehow we can still have that, as long as it is appropriate. And somewhere in there I read -- and I can't remember where -- but it was in a response from HRSA that you would be using the IACFS primer material on guideline.gov regarding treatment and such. Also a very positive response. So it's very disappointing to hear what we're hearing today. I hope you understand that and I'm hoping that you can perhaps help us in some way to get this rectified.

Erin Fowler: I will find out more information from the project director, absolutely.

Donna Pearson: (Unintelligible) so much.

Dr. Susan Levine: I have one question for Janet and I didn't take down the whole website name, but you mentioned something about D-Ribose was nominated as a product that was looked at and then rejected by a lot of the CFS experts. Is there a place or a link where we can look at other medical therapeutic interventions that were suggested or can you explain that a little bit more, I guess.

Dr. Janet Maynard: Sure, I'm happy to explain that. So there was a pharmacy compounding advisory committee meeting that discussed different substances that were nominated for compounding. So it was not a meeting specifically about

ME/CFS but rather it was about different products to be compounded. And one of the products that was discussed was nominated for two indications. It was nominated both for heart disease and the way it was referred to in the nomination was actually chronic fatigue syndrome. So that's how it was discussed. So it wasn't a meeting just about ME/CFS, it was a meeting about compounding.

Dr. Susan Levine: I see.

Dr. Janet Maynard: And I'm pretty sure I sent out right before the meeting the links to the pharmacy and compounding advisory committee documents, because there are a lot of documents that are available just about the process and what was discussed. But I'm definitely happy to send out that link again.

Dr. Susan Levine: Let me clarify. You're talking about compounds as opposed to pharmaceuticals?

Dr. Janet Maynard: Correct, so it's about medications that are being compounded. So in order to obtain a compounded drug generally a patient would get a prescription from a physician. And you may be aware that there's been some changes in compounding oversight so now FDA is having these advisory committee meetings where we discuss different substances that have been nominated for compounding. So generally someone nominates those substance, something like D-Ribose and they also explain what they think it would be used for. So in this situation D-Ribose was nominated for heart disease and ME/CFS. So it's a little bit different than when a drug comes in to be approved for an indication. Rather this is in relation to the ability to compound the drug.

Dr. Susan Levine: Okay. Thank you.

Dr. Janet Maynard: So would it be helpful if I sent out on the (unintelligible) the web link that has more information specifically about that meeting?

Dr. Susan Levine: Sure. I think that would be helpful.

Dr. Janet Maynard: I can definitely do that.

Dr. Susan Levine: And again, the other thing I wanted to know about is there any attempt by the FDA to solicit proposals or applications for drugs that could be used for ME/CFS?

Dr. Janet Maynard: I'm not aware of any specific mechanism by which we can solicit for a proposal so it's a little bit different than maybe a grant situation where you could do more of a specific solicitation.

Dr. Susan Levine: I guess what I'm trying to get at is what your agency -- and again, this is not meant as a criticism -- but is your agency doing anything to sort of pursue or support ME/CFS in terms of what you're able, capable of doing as an agency in terms of drug development?

Dr. Janet Maynard: Right. So the way we really try to be most supportive of drug development for ME/CFS is to be very clear in our expectations of how a drug be approved for ME/CFS and that's why there's the draft guidance on drug development for ME/CFS which sort of lays out what we would have in terms of expectations for drug development. And we've tried really to be supportive of a variety of different mechanisms by which we think a pharmaceutical company could get a drug approved in terms of either targeting a very broad population or a narrow population and the guidance also lays out that really what we want is we want a drug that makes patients feel and function better.

I think we all recognize that CFS ME is clearly a very complex disease and there are a variety of different ways that medication maybe could help, either could help in terms of post-exertional malaise or maybe in terms of cognitive dysfunction. So we think that a drug could potentially be approved for any of the different symptoms. So we've been really open in working with stakeholders trying to think about which symptoms sort of make sense to target for that specific drug and help trying to think about how could we assess whether or not a drug is effective.

Dr. Susan Levine: Okay. All right. Thank you. Does anyone else have any questions for any of our agencies?

Carol Head: One more. This is Carol Head and I have a question for Vicky. Vicky, first I have to say thank you. The work that you and NIH have been doing is moving us forward more quickly than in the past and I am so grateful for your personal advocacy on behalf of this disease so I'm a little hesitant to ask this question but I feel I must. And it goes to one of the tough issues and I acknowledge that this is tough, and it's back to you know, both P2P and the state of the knowledge recommended finding agreement on a single case definition. And yet we know that there continues to be discussion and lack of agreement about that. I do agree with you that it's possible and advisable to reach common data elements without the need for a common case definition. But can you comment on just your sense of when and how the NIH would help drive toward a common single case definition for this disease?

Dr. Vicky Whittemore: Thank you, Carol. That is a tough question but we've talked about it in the working group and the way we're thinking about it now is that the IOM report provided the diagnostic criteria and what we would need to do for research is to operationalize that diagnostic criteria into research tools. So for instance if post-exertional malaise is one of the criteria for diagnosis of

ME/CFS then -- and this really ties into our common data elements -- if that's true then what tests will the experts agree or test or tests are needed to diagnose someone with post-exertional malaise and what are the outcome measures that would then become our common data elements.

So I think our thinking is that that's the best approach for moving things forward and I think what Beth touched on when she commented earlier is going to be critically important as we move forward to really be able to identify individuals and subgroup them because we may in fact find that ME/CFS is really many different diseases being called the same thing. Or a spectrum of symptoms that all fall within what we're now calling ME/CFS. So I think our response at this current time would be that we would work on that by doing the common data elements, really doing good vigorous clinical studies that will help us to identify you know, causes, pathophysiology and truly what are some of these subtypes that we may be able to identify down the road. So I'm not sure if that clearly answered your question but I think that's how we're thinking about it at the current time.

Carol Head: Thank you Vicky. I recognize the complexity and difficulty of it and I appreciate your insights about - and acknowledgement that NIH is still you know, cognizant that this is an issue and contemplating it. So thank you.

Man: Susan, one comment. That makes me think of how important it is to do some kind of evaluation involving the CPET which is the best measure of post-exertional fatigue, which is part of post-exertional malaise. And also the neuropsych testing which will get at the whole cognitive problems that people with chronic fatigue have. And one of the confusions is that people who do neuropsych testing often are not aware of what the pattern of chronic fatigue syndrome fog problems are in the testing. I know there are a couple studies, but they're not finalized and more work could be done.

Dr. Susan Levine: Frequently for me is an issue as a clinician is not only that, but you know, the cost and the availability of a CPET in my area. I mean, people have to go to Ithaca to see (Betsy Keller) and there aren't many clones of her around the country I'm sure there's a lack of that. Plus the patients risk thinking themselves more ill if they do the full CPET as everybody knows. And then the neurocognitive testing is also very expensive and it's very hard, like you say to find someone who knows out to evaluate the outcomes and put it into the whole perspective with ME/CFS but hopefully we can find some shorter tools, simpler tools to give us a good you know, response that's valid without the cost and without the lengthy, you know, putting the patient out so to speak.

Woman: Right, right.

Man: Biomarkers there's not much else we can do right now.

Woman: One of the things we've thought about is sort of an interesting study design where instead of scheduling someone for example if you're doing a longitudinal study scheduling them to come in the first Monday of every month, you have certain measures that you ask them to record or some you know, somehow report in when they're having a crash or when they're feeling well so that it's not - you're actually catching the true nature of the disease.

Dr. Susan Levine: Yes, that makes a lot of sense.

Man: Vicky, on your slide number 3 for the short-term goals, 16, 17, there is the release funding opportunity announcement. What is the most specific information you can share with us in terms of you know, the dates and

obviously you may not have an idea about the amounts, but do you have more specific information you can share with us?

Dr. Vicky Whittemore: So this is an NIH thing that we're not allowed to discuss anything related to initiatives before they're released because it's seen to be unfair. So if I told you, you would have an unfair advantage of people who are not listening to this and didn't hear me talk about it. So our timeline is the NINDS council meets on May 26th and that they will make a decision at that point whether or not they approve our concept for the funding announcements we want to put out and then it will probably take us, I'm not sure another month or so to get approval across all the institutes who are participating. Every institute has their own process for approving these kinds of things but I'm hoping that we can have the funding announcements out in the street in June, July at the latest, which would mean we'd probably have applications come in in the fall and funding next spring. So that's kind of the timeline that we're looking at.

Man: Thank you.

Dr. Susan Levine: Thank you. I want to remind everybody that we have five more minutes - four more minutes and do people want to take a two-minute water break before we start promptly at 1:15 for public comment.

Man: Can we take a five-minute break?

Dr. Susan Levine: We'll be around later in case you want to ask more questions and there's time.

Woman: Well we can't take a five-minute break. This is the one time of the meeting we have to start on time because we already have people in the queue.

Dr. Susan Levine: Okay, perfect, we call. Well it's 1:11 I just wanted to make people aware in case.

Woman: We just need to start at 1:15.

Dr. Susan Levine: Okay.

Woman: Which is three minutes from now.

Dr. Susan Levine: Okay. All right. I guess any further comment by anybody or? Can we start earlier or? What do you suggest, (Nancy)? We just wait …

Woman: We can't start earlier.

Dr. Susan Levine: Okay.

Woman: We have to get help from the operator.

((Crosstalk))

Dr. Susan Levine: I want to thank all the ex officios. I think everybody did a great job and we hope to hear back from HRSA on a few loose ends but you know, everybody did a wonderful job and a good discussion.

(Steve): This is (Steve). I've been on the (CIFSAK) for many years now and I'm really heartened by the degree of movement that we're finally getting after all these years and I hope it continues logarithmically. Thanks.

Woman: Thank you for that comment.

Dr. Susan Levine: I guess (Nancy) you have the names or I have them also.

Woman: Remember I gave them to you? That's why I suggested you print out.

Donna Pearson: Since we have a couple minutes to kill, this is Donna, I wonder if I had asked Vicky this question and we didn't get to it, if there was a way for collaboration with all of the centers so that we were kind of all on the same page - CDC, HRSA, AHRQ and NIH regarding the concept of the disease, how we should educate, what research we're doing et cetera. I don't know if anyone can answer that question.

Dr. Beth Unger: This is Beth and I agree with you and that's part of what we hope to be doing with our project for collaboration. The steering committee I talked more about the technical development work groups. The steering committee includes representatives from all of the ex officios agencies in HHS. So my hope is that through this process of communication we will all gradually get on the same page. I don't know that we'll be there like jump instantly but I think talking and communicating will be the way to achieve that.

Woman: And it has some of the professional organizations for the providers, which is…

Dr. Beth Unger: That's the technical development working group that's going to provide materials but then the steering committee wants to evaluate how they want to use them and the goal is that once we all see - we won't be reinventing the wheel, we'll be sort of working from a set of kind of approved contents.

Woman: So we need to go ahead and thank you, Beth and thank you Donna. We need to go ahead. Is (Marcella) there? Are we going to have the operators now?

Coordinator: Yes I am here ma'am. Did you want your 1:15 parties all open at once or individually?

Woman: They're going to individually give remarks.

Coordinator: All right. Thank you. And who would you like to go with first?

Woman: So just a moment. So Sue, did you find your list?

Dr. Susan Levine: I'm still looking for it. I apologize.

Woman: Okay so the first person (Marcella), is Eileen Holderman.

Coordinator: All right. One moment. I'll check with my assistant so see if they're on line yet. Ms. Holderman has joined.

Eileen Holderman: Thank you. Can you hear me?

Dr. Susan Levine: Yes. Go right ahead.

Eileen Holderman: Good afternoon to the advisory committee members and to all stakeholders listening. My name is Eileen Holderman, I'm an advocate for ME GWI and other neuroimmune diseases. Recently I served as consultant to ME Advocacy, an organization advocating on behalf of nearly one million American men, women and children suffering from myalgic encephalomyelitis. Specifically I collaborated on their blogpost titled NIH Sidesteps Critical Problems with the ME/CFS Study, which is a detailed analysis of the numerous problems with the study design and protocol and which offers solutions to these problems.

The organization has given their consent to me to talk about the blogpost. The blogpost outlines many problems such as multiple and ever changing criteria some of which are deeply flawed, biased and/or inexperienced investigators and advisors such as (Walid, Gill, Falagan) and others. Additional problems with the study design such as a small cohort size excluding patients who are most severely affected such as a homebound and bedbound, the use of Lyme disease comparison groups which will cloud results, the exclusion of the two-day CPET testing for (pennae), the refusal to release the specific budget for the study, the exclusion of ME experts when designing the study, and finally the failure to set up a transparent two-way communication process between NIH and the ME community, researchers, clinicians, advocates, patients and caregivers at every step of the way. Obviously with just three minutes allowed for follow up comment I can't address all the problems mentioned but invite all of you to visit the website ME Advocacy.org and click on the blogpost for a detailed analysis that proposes solutions.

Therefore with the remaining time I have I will focus on the critical issue of the study's criteria. It is of utmost importance that the strictest criteria that ECC or ICC created by our ME experts not the CDC or government agencies be used in studying ME in order to ensure that investigators are looking at a homogeneous patient cohort. The NIH intramural ME/CFS study has changed criteria six times.

First NIH announced they would use the (Reese) criteria which has been rejected by mainstream scientists and denounced by (CISAK). Then after backlash from advocates NIH announced the study would utilize the TTC IOM (Facuta and Reeves). After more protest NIH announced they would use multiple consensus criteria including Canadian criteria. Then Dr. (Knapp) stated that NIH would use (Facuta) and CCC. After the NIH telebriefing a new website for the study showed one specific criteria to be used, the CCC.

Finally, Dr. (Korashef) in his letter to ME Advocacy stated that the CCC and IOM would be used for selecting patients I the NIH study.

For over 30 years U.S. government agencies had created erroneous definitions and names for this specific neuroimmune disease myalgic encephalomyelitis causing devastating harm to patients and other nations like the UK who created the flawed Oxford definition used in the case trial have done the same. Our community needs NIH to step up and officially state that the (Reeds) criteria in questionnaires will not be used in the NIH intramural study, resolve the outstanding problems with the study design and protocol and establish a transparent two-way communication and participating process with all ME experts. Thank you very much.

Dr. Susan Levine: Thank you Eileen.

Woman: The next speaker is Billie Moore.

Dr. Susan Levine: Go ahead Billie.

Coordinator: One moment.

Billie Moore: Hello?

Coordinator: Ms. Moore, your line is open.

Billie Moore: Thank you very much. I am Billie Moore advocacy chair of the New Jersey ME/CFS Association speaking for the organization. This year we are seeing progress from the HHS in getting help to patients through various HHIS initiatives as a result of the IOM and the P2P reports. It is very encouraging that the NIH and CDC have made explicit efforts to involve expert clinicians,

researchers and patient advocates in these initiatives. We do appreciate this new focus on the disease, long overdue but very welcome. From here on I am going to refer to the disease as ME in keeping with the IOM's recognition that "CFS should no longer be used as the name of this illness."

Myalgic encephalomyelitis is the preferred name of the community because it is the historical name and because of the neurological effects of the disease. The CFS label carries decades of negative baggage which has been described repeatedly. All HHS department should stop using CFS as the name of the disease. Even worse is referring to it as chronic fatigue. It is not chronic fatigue. ME/SEID MEC might be acceptable as a name but only if it includes the (CISAK) IOM work group additions to the IOM criteria as shown in the recommendations 8, 10, 15 and the box 1 proposed diagnostic criteria Page 12 of the workgroup August report which is on the (CISAK) website. Adding these modifiers will distinguish the IOM criteria from (Facuda) in addition to making diagnoses by not expert medical personnel more accurate than using the IOM diagnostic criteria alone. However, before the HHS adopts new criteria, patients and experts must be consulted.

Naturally, much more needs to be done for patients with this dreadful life-robbing and frequently life-ending disease. Major money needs to be directed to studies and to all aspects of ME, 250 million in NIH grants a year would barely make up for the loss of 30 years of appropriate level research funding of ME, what was called CFS. A minimum of 100 million should be allotted every year by the NIH. RFA should be funded to the maximal amount possible starting as soon as possible. Equally critical is the need for approved treatments from the FDA. There has been no (unintelligible) from the FDA towards this end since its 2013 drug development workshop and the Voice of the Patient report.

The drug guidance document was not detailed enough to provide useful information to drug companies. Continuing passivity from the FDA regarding treatment is unconscionable. The time has come for the FDA to gather in the companies that make drugs that are being used off label for ME to help those firms find a path to test these drugs for approval for ME. The one drug that is in the pipeline should be given additional approval now. Give hundreds of thousands of other patients nationwide the opportunity to get their lives back as so many of the study patients for this drug have done. Centers for excellence affiliated with university medical centers are critically needed for patients. We support all the recommendations of the COE workgroup that were mentioned yesterday. It is a need of the highest importance.

Finally, I want to urge the HHS to find the funds for (CISAK) to give ME two full days of in person seminars with visual webcast. This audio only webinar structure is insensitive to the needs and limitations of the millions suffering from this terrible disease. It is a totally unacceptable way to run the (CISAK) meeting and becomes another example of how little respect and dollars this patient population receives from the HHS. Thank you.

Dr. Susan Levine: Thank you.

Woman: The next person speaking is (Metina Nicholson).

Coordinator: One moment please. Ms. (Nicholson)'s line is open.

Dr. Susan Levine: Go ahead. Go ahead (Metina).

Coordinator: (Metina) do you have your mute button on? She is connected to the call and her line is open. One moment. I'll put her up privately and see if I can get her to respond.

Dr. Susan Levine: Okay.

Coordinator: Ma'am try that again. Now we can hear you. Go ahead, ma'am.

(Metina Nicholson): Okay. Hello. I did tell (Mary Finig), Billie and Eileen ME is not CFS. I find that name is - doesn't describe our disease, especially for severe ME. I feel it's a slap in our face. I support anybody who has CFS but needs to be studied separately. Secondly I think we also forget about the people with severe ME. As you heard yesterday of a father they take care of their patients 24/7. Same with (unintelligible) and many others. That is critical that we get immediately the care they need and the support for their patients.

Secondly in regard to the CDC and their education, no education by anybody at our government to go out until we know the definitions, the name and we're all consistent in our messages. I worked in pharma for 20 years. I was the top of my game. I did award winning medical education and no one has asked me to ever be on any committee. You cherry pick your people to do what they want. I appreciate everyone at the same time trying hard but you have no idea of our struggle. I struggle and I'm moderate to almost near severe. I don't have help. I have to care for my mother and my father and half the time I'm in bed, half the time I don't even know what I'm doing. I got back from Dr. (Levine)'s meeting, I collapsed on the train. Some stranger helped me.

Life is not fun and you have no idea what people suffer. I mean our doctors are awesome. The center of (unintelligible) presentation was awesome. You can find $50 million. You found it for the cancer (unintelligible) which I am totally behind. You found it for HIV. You need to find it. We've been struggling 30 years and pretty soon I'll be struggling on my own. And as FYI, I was in (unintelligible) before an expert and I spent six months all by myself

because my doctors that I went to had no clue. And no again education goes out until our experts and patients approve it. We can work in collaboration. We are here to help solutions. Please use us. We need to get these severe ME patients help ASAP and we have those solutions.

And secondly I want to make sure that anything we do is open to all people. Stop cherry picking the people that you think that you want to hear. I will talk, right now I'm mad because I feel for these people, (Brittney) and (Tom) and (Denise) and those children, (Ken) and all the people struggling for 30 years and I'm waiting for (Amplogen), (Rituxan) there's a lot of (unintelligible). D-Ribose was a joke, a slap in the face. We can get D-Ribose now. It doesn't work for me but it does work for everybody. We need to prioritize. Please use us. We are very smart. We have doctors. We're sick not stupid. We have doctors, we have (unintelligible) pharma, medical education. I went to (unintelligible) I developed (unintelligible) presentations. I might be slow but I can help with others who are faster. But I'm here to help and I won't be in this (unintelligible) I'll roll up my sleeves just like everyone else.

We all want to help. So I hope you please will take that into consideration. Understand ME is not CFS nor do we want to ignore CFS patients. So I hope we can get together and start working together and no more blinking. We just need solutions. Thank you very much and I'm sorry for my tone. I do appreciate everyone but I wish we would do it right. Thank you and have a nice day.

Dr. Susan Levine: Thanks (Metina).

Woman: The next speaker is Charmian Proskauer.

Coordinator: You may give your comments. Your line is open.

Charmian Proskauer: Thank you for the opportunity to speak. My name is Charmian Proskauer. I am current president of the Massachusetts (unintelligible) ME and Fibromyalgia Association. I am speaking today in support of the creation of centers of excellence. We hope that in addition to more research on ME/CFS these will provide clinical care for patients and training of medical professionals. Access to care is a huge issue for most ME/CFS patients. The service that is most requested of our association and we get four or five requests a week from all over New England, is to help patients find a doctor who knows anything about ME/CFS and can treat them. This is for both primary doctors and specialists. Although we do our best to identify providers who can help patients, we know of only 40 doctors in the entire state of Massachusetts that we can recommend highly for their knowledge of ME/CFS and their respectful treatment of patients. When we add the requirement that the doctor is actually taking new patients and accepts Mass health insurance Medicaid, the number falls below 20. Of these only six are primary care providers and two are pediatricians.

Six primary care providers and two pediatricians to serve the needs of a state with a population of nearly seven million and an estimated 28,000 ME/CFS patients not including children. And that is just in Massachusetts, not including the surrounding New England states. With regard to children our association has been working for the last several year to educate school nurses about ME/CFS. About one-third of the 400 school nurses at a recent conference had students in their school that they suspected might have ME/CFS and required educational accommodations. In order for the students to get the needed accommodations, a letter from a doctor confirming the diagnosis and describing the disability is needed.

Many school nurses we speak to say they or the child's family cannot find a doctor who can make a diagnosis of ME/CFS so the child does not get the help they need. Many families are then subject to or threatened with legal action from the school due to the child's extended absences. While the medical education initiative being led by the CDC is laudable and we are actively participating in it, educating every doctor is a very slow process. Patients including children need access to care now. Establishing centers of excellence which include clinical care would provide places patients could go for at least an evaluation and general treatment management advice to give to their own health care provider. We strongly support the creation of a center of excellence in New England. New England has ten medical schools and one osteopathic school and is a center for medical research. Despite Massachusetts being considered a medical mecca, it is a desert as far as ME/CFS is concerned. Patients need access to knowledgeable care and they cannot wait many more years. Thank you.

Dr. Susan Levine: Thank you.

Woman: The next speaker is Terri Wilder.

Coordinator: We're joining Ms. Wilder now. Ms. Wilder you may make your comments at this time. You have an open line.

Terri Wilder: Thank you. Good afternoon. My name is Terri Wilder and I'm a person living with ME. I should tell you that I was only diagnosed about ten weeks ago so it's a little strange for me to introduce myself to you this way as I typically introduce myself this way. Good afternoon, I'm Terri Wilder and I'm an AIDS activist and I'm a member of Act Up New York. Yes, that Act Up. The AIDS coalition unleashed power, the infamous activist organization that shut down

the FDA, demanded that the CDC change the definition of AIDS and include women specific illnesses and stormed the NIH.

If you worked in government for any length of time I am fairly certain you have heard of Act Up. While I've only been diagnosed with ME for ten weeks I can tell you that it didn't take me very long to figure out that what we are doing here is we are repeating history. I have told multiple people that I'm having déjà vu. You see I've been working in HIV since 1989 and one of the reasons that Act Up was founded was because health officials, government researchers, medical bureaucrats, medical providers, and pharmaceutical company executives believe that they were the AIDS experts when in fact the experts were the people living with AIDS. A person with AIDS point of view were made invisible and their real world knowledge about the changes that needed to be made to end the crisis was ignored. I need to be honest with you and tell you that people told me that nothing would happen today if I gave public comment. Nothing would change and that the government would continue neglecting people like me with ME as they have for the past 30 years by just throwing us some crumbs. So for the past ten weeks I've had two things on my mind.

How long am I going to be able to hold onto my job so I don't lose my health insurance, and how could government institutions like the NIH, CDC, HRSA and FDA repeat history by doing nothing for the millions of people who have this disease. If I end up really sick in the next few months or years it will not be because the disease or its complications made me sick. If I'm getting sicker from anything I will be getting sick from the sexism and psychogenic views that are so deeply entrenched in this disease. I will be getting sick from the CDC for pushing unexplained fatigue definitions and putting incorrect information on their website about ME.

I will be getting sick from the neglect and disdain that has driven away researchers and pharmaceutical companies that can discover a treatment for my disease and I will be getting sick from government committees that won't allow people like me who have this disease to sit at the table and (unintelligible) inform policies and programs that might actually save my life. We have a model for allowing people at the table. People just refuse to use it. I know because my friends with HIV get to sit at the table. So how many people are dead either directly or indirectly from this disease who might be alive today if research had been done to develop more drugs for ME?

Would they be here today if the government took this disease more seriously and established ME centers of excellence around the country? Would they be here if the government invested funding to the tune of $250 million vs. $5 to $7 million? Would they be here if the government invested funding to the tune of $250 million versus $5 to $7 million? Would they be here if the designated federal official for this advisory committee actually have something on her bio on the WomensHealth.gov website that actually gave me a clue that she actually had some commitment to ME. The name of this disease cannot be found anywhere in her bio.

So how many lives? Someday this will be over, remember that. And when that day comes there will be people alive on this earth who will hear the story that once there was a terrible disease in this country and that a brave group of people stood up and fought and in some cases gave their lives so that other people might live and be free.

I'm having déjà vu and I don't want history to repeat itself, so if you work in Health and Human Services, the CDC, the NIH, the FDA, or any other government agency, write down my name. My name is Terri Wilder and I don't want my tombstone to say, "I died of government neglect."

Dr. Susan Levine: Thanks Terri.

Woman: And our final person for public comment is Robert Miller.

Coordinator: One moment please. Mr. (Miller), your line is now open, you may go ahead with your comments.

Robert Miller: Yes, thank you. Thank you Chair, Dr. (Lee), and members of the committee for the chance to speak today. I'm Robert Miller, a patient and advocate about three decades now. I'm calling from Incline Village, Nevada, about 40 minutes from my home in Reno. Currently I'm getting a four and a half hour infusion of a very potent antiviral as my immune system continues to fail me.

I need to continue on it for the next six months to attempt to rid my body of several viruses. Once I'm through this treatment I can return to Ampligen treatments which help to boost my immune system and stabilize my symptoms.

I state this for all who say there are no treatments for my disease as that's a false statement. There are treatments. They're not cures but they're treatments. ME/CFS experts such as my doctor, Dr. (Daniel Peterson), can sub-type and treat patients according to each patient's needs.

Using extensive lab work and other testing these clinicians can help us. As I stated, these are not cures, but without such treatments like Ampligen I am, as was described yesterday by (Mark Camenden) regarding his son, bedbound and doing a life sentence of pain and solitude.

I commend and I thank Dr. (Collins) whose willingness to begin studying ME/CFS and for charging Dr. (Courships) with this task but there must be funding to support the work. The supplemental grants that are being talked about are a good start. NIH should fund, along with FDA, a clinical trial of Ampligen. It's safe and effective for a group or subgroups of patients.

We know that if NIH funds the right studies it'll generate private investment so that NIH does not need to solely carry the funding burden. That's why it's so important for ME/CFS to have an FDA approved treatment like Ampligen, the AZT for ME/CFS patients.

Pharma will only invest money researching ME/CFS if they see money can be made. Pharma invests billions of dollars in treatments for cancer, multiple sclerosis, HIV, arthritis, and more because FDA has approved profitable medications for those diseases. Not so for ME/CFS. Ampligen's treatment by FDA is a cautionary tale. Ampligen is one study away from approval but we need NIH funding to get it there.

Doing an Ampligen study would allow NIH to learn much regarding patient immunology and neurology and more. NINDS is funding a trial of Rituximab for myasthenia gravis. They can add an arm of ME/CFS patients to that study. It's false to state that NIH does not fund clinical trials. NINDS, NIAID and NIAMS funds dozens of specialized clinical trials. For our disease it's the smartest (unintelligible) NIH can employ.

Please recommend to the Secretary of Health that NIH aggressively fund clinical trials in Ampligen, Rituximab and other therapies urgently. This committee has tried for years but you've largely been ignored. I pray that those days are over and that we see a new day. I thank you all. Thank you very much.

Dr. Susan Levine: Thanks (Bob). Think that's the last of our public comments.

Woman: That is the last.

Dr. Susan Levine: Okay. Donna are you ready to proceed with your presentation or do you need a couple minutes. You can let me know.

Dr. Vicky Whittemore: While Donna's thinking about that, this is Vicky. I forgot to mention something earlier and I'd like to mention it now. (Unintelligible) our note taker and minutes producer, and she has requested that when members of the committee speak, they identify themselves by name. She has a list of all the names but doesn't recognize all the voices. So if you could give your name before you speak that would be great and try not to speak over each other.

Donna Pearson: Well can we get that first light on, this is Donna. Thanks. I had planned to lead this entire session but I'm not at my best right now so I've asked Carol to get us at least through the first recommendation. I just want to say (Denise Lopez Mahano), hit it on the head yesterday when she said that patients have to lead tightly circumscribed lives.

I'm personally able to function beyond the level of many patients, thanks to pacing and avoidance of triggers and a protocol of medications, including an immune modulator and an antiviral and a number of other things that disease experts know can help but that we don't share through our HHS educational materials.

I was recently reminded just how horrifying this disease can be when a combination of things caused a relapse worse than I've had in a long time. I'm now on my way back, I hope to my best illness baseline, but I just want to say

lying in bed in pain, barely able to move, unable to sleep, unable to interact with my family because the sound of their voice is so bothersome, extreme nausea, violent vertigo, fever, G.I., it's indescribable.

And I was reminded of my dark thoughts, of years back when I figured there was no hope of improvement and I'm so lucky that I really do seem to be on the way back. I'm mentioning this to you because the experience really reminded me of the immense suffering caused by the disease, and I have so much empathy for the seriously ill who have experienced that level of misery every single day. I don't know how they do it.

So while it's true that the death rates may be lower than it is for cancer, AIDS, or Ebola, I really hope that we will all work hard to do everything possible to find every dollar we can for research and do everything possible to produce the best possible educational and awareness materials to help these people. They so deserve the opposite of the stigma they get. They really deserve recognition for their fortitude and their bravery and they deserve our compassion and respect.

So I'll get off my soapbox now. The background document distributed last week included information that is pertinent today's discussion so hopefully it's been thoroughly reviewed by all. Carol is going to take it from here and hopefully, like I said, get us through at least the very first recommendation. I'd like to participate actively in discussion after that if I can. Thank you very much Carol.

Carol Head: Well this is Carol and I thank you Donna. Donna we have enormous respect for the work that you have done to bring these three recommendations to fruition despite all the difficulties in your life. We love you and we respect

you and I am honored to step in now and channel your voice here in these next moments.

So let me describe how the presentation is structured. There are three recommendations that are put forward here and they all are, in one way or another, address the recommendations that our (CFSAC) had made last August that were responded to by the agencies in some instances and in some of those issues were not responded to.

So this is sort of Round 2 on many of the recommendations for which we felt the response did not yet take us where we needed to be and so we are persistent and so we keep at it. And in some instances there are new elements here.

So the structure really is three recommendations. For each of the three there are several pages often as to the background: how we got there, what the thinking of the group was, and then I will read the actual recommendation.

And the way this has been planned by Donna and the team was that for each of the three there would be discussions and a vote rather than waiting until the very end for a vote. But of course that's the prerogative of the Chair.

So with that, next slide please. So first, there a couple slides here of overall introduction to this discussion and I think the intent of Donna and our team was to acknowledge what has been done so far. And really there has been more activism within the agencies of (CFSAC) I think in the last year than previously and that is certainly a good thing.

As we know the NINDS has stepped up to provide initial leadership and continuous staffing of a revitalized chance NIH working group. The group

includes a number of Institute directors and, ideally, will benefit from the resources of multiple institutes and centers.

A number of existing studies being funded by the NIH were itemized in the responses provided by the NIH. We were especially pleased to learn that intramural scientists will be studying patients using the world class resources of the clinical center. The three-phase study is expected to help gain better insights into the biology of the disease and eventually inform the development of therapies which will benefit patients.

Finally from this initial study of individuals with post-infectious ME/CFS, which is considered a subset at this time, are expected to lead to expanded studies of other subsets in collaboration with public and private institutions.

A special thank you, again, goes out to our ex officio, Dr. Whittemore, for facilitating the updated NIH response as it was posted online and provided the other good news: the trans-NIH group is working on a comprehensive research strategy which acknowledges the need for biomarker research and will include RFA's. It is hard not to hear a cheer go up, Vicky, when you made statements about that about a half hour ago.

This group is continuing to explore options for community engagement as mentioned during the NIH call of March 8, during which Dr. (Collins) stated, you know, these are words that many of us repeat to ourselves as we go to sleep at night so, "I want to assure you that from the perspective of the NIH Director that this Institution is very committed to this area of research and please take our commitment with great, great seriousness."

Next slide please. I would also note as has been noted by some other speakers that there is also recognition that the intramural study, like any study, has

flaws and our organization, like others, continue to work and discuss with NIH some of our concerns about the intramural study.

So here we go, the CDC is continuing to collect data that will address some of the gaps identified. The CDC regularly meets and collaborates with the experts involved in the multi-phase study and the direction of the study, moving forward, is determined based on findings with (unintelligible) expert.

Most recently the study was expanded to include pediatrics and some housebound patients. A special thank you goes to Dr. Unger for making herself available to answer questions and provide further information as requested.

As we discussed already today, options are being developed regarding development of common data elements and possibly a data coordinating center. NIH response is also referenced (unintelligible) between grant (unintelligible) and encourage investigators to submit grant applications focused on new approaches to the disease.

Regarding the clinical treatment trial, the NIH advised investigators to discuss ideas with program staff prior to the peer review process to help ensure the applications meet all the requirements. We hope these responses mean that the NIH is truly interested in proactively facilitating successful (unintelligible) research and clinical treatment trials. Time will tell. Next slide please.

Regarding the (CFSAC)'s recommendation to significantly increase research funding the response that we've received from the federal agencies does not address or acknowledge the injustice, an enormous disparity between funding that is commensurate with the burden of the disease, which would be

demonstrably roughly $200 million annually versus funding that is reflected in the NIH budget.

We do hope that the trans NIH working group has spoken on that issue and we also hope they quickly realize their goals of stimulating new research and interesting investigators from other research areas. We've already seen one such attempt via the April setup announcement about the availability other administrator supplements.

And, importantly, the solicitation was reported to be just the first (unintelligible) outreach to the scientific communities under new plans to revitalize this area of interest. And we have heard of additional interesting solid new developments from Vicky Whittemore today.

On the topic of medical education I think we've expressed some concerns there and will continue to follow up with (AHRQ) about their agreement with the Arizona Center for Integrative Medicine and Primary Care for ME/CFS, or as we've now learned, for CFS. Next slide please.

And this is my last. There are two more slides sort of introductions that really give the context for why we are responding in this manner with three new recommendations to the many recommendations that were made last August.

Additionally the CDC has created a technical development work group comprised of disease experts, professional associations and patient advocates, and organizations in order to get advice and (unintelligible) regarding new educational materials to be developed.

This is an opportunity that gives advocates a chance to interact and exchange ideas with representatives from important medical associations. And numerous representatives of the CDC as well.

Discussions have started and we truly hope that the carefully crafted recommendations regarding educational materials will be used. With the CDC continuing their multi-site study and the NIH beginning to invest in research, we're hopefully witnessing a turning point that we had anticipated when we met last year.

Next slide please. Given the updated responses provided by the NIH and the limited time frame available for discussion, our working group decided to focus primarily on three areas highlighted on this slide.

First, although HHS agreed that updating this proposed diagnostic criteria is important, the time timeline will "depend on the availability of new evidence." We feel that this approach is much too open-ended, especially given the amount of time it takes for change to occur at the Federal level.

Second, second recommendation. We again want to stress the importance of the (CFSAC) recommendations regarding views of the new criteria in the clinic and we also like to recommend ongoing collaboration with experts and stakeholders for final review of educational materials.

And third, as there was no response at all to our recommendations to "acknowledge the distinct disease identified by the IOM" and "change the narrative," we believe further discussion is appropriate regarding the critical needs for clear distinction between this disease and medically unexplained fatigue.

Next slide please. All right, now this is the first slide that is outlining the working group's long and thoughtful discussion of Recommendation 1. Shall I break here for questions or shall I continue?

Dr. Susan Levine: I would continue.

Carol Head: Okay, thanks Sue. All right, our first recommendation is simply asking for commitment and a timeline for review of the IOM criteria. The IOM was clear that their document should be considered a base of understanding to be improved over time but should be formally reviewed as soon as firm evidence would allow for improvement in diagnosis and care.

They went one step further though, stating that a formal review should occur in no more than five years even if the research is unclear regarding the possibility of modification. We know that funding will be needed and we only need to look back at the recent chain of events to see how long this type of process can take.

The IOM criteria can be traced back to a (CFSAC) recommendation from the Fall of 2012 and the contract was signed almost a year later and the IOM had 18 months to do their work. And when the report was released in early 2015 our workgroup was asked to review and make recommendations for the meeting later in the year.

So it's a three and a half year period as you can see. We now have the TDW, the CDC's TDW involved, which is a positive step but requires even more time. Bottom line it's been four years since launching the effort and we're still in process of creating new educational materials.

So, the goal of this recommendation is to request that the appropriate agencies get together now to proactively discuss, plan, and budget with a needed review within the recommended time frame.

Progress regarding this disease has been hampered by the Fukuda definition for more than two decades despite the fact that the criteria was designed to be an overly broad and temporary research definition. We believe that a serious commitment regarding the important timeline recommended in the Institute of Medicine Report is warranted.

Next slide please. So this is the exact wording of Recommendation 1. Initiate the process for review of the IOM diagnostic criteria so as to occur no later than May 2019. (CFSAC) recommends that HHS initiate the Federal processes required as soon as feasible.

Methodological and local disciplinary workgroups can be convened in a timely fashion and in no (unintelligible) later than May 2019, a mere three years from now, to examine and update the IOM diagnostic criteria.

Further, (CFSAC) recommends that said workgroup be required to consider and incorporate new evidence to update and refine the criteria for sensitivity and specificity during different stages of disease and different levels of severity.

I'm almost finished here. I do want to read one paragraph of rationale for this. Essentially this is saying, "Let's get a jump start on it." If we want to actually have results of an evaluation by May 2019, knowing how long the process takes, we should be starting soon anticipating the length of that process.

So here's the final paragraph of the rationale for Recommendation Number 1. The IOM recommended that a multi-disciplinary group be convened to reexamine the proposed criteria when a firm evidence supports modification or within five years, whichever comes first.

At this time it is fully expected that updates will be appropriate, sooner rather than later. Indeed, recognized disease expert and IOM committee member Dr. (Nancy Klimas) stated to this community that a one year delay in the contract date of the IOM's review could have had an impact on the proposed criteria on newer evidence.

Given the time consuming Federal procedures of funding requirements inherent in such an endeavor the process should be initiated as soon as feasible. Additionally to ensure that robust evidence is available and the timeline can be met, (CFSAC) urges the NIH to issue RFA's which aggressively pursue the studies needed to validate potential biomarkers that have already been identified.

As the IOM cutoff date for literature review was May 2014, two years ago, a review that occurs no later than May 2019 is warranted. So Sue that completes the commentary about Recommendation 1 and we welcome discussion.

Dr. Susan Levine: Okay. Okay, let's open the floor to comment. Please identify yourself before you speak.

(Steve): This is (Steve) and what struck me about my process in the Chronic Fatigue Syndrome Advisory Committee is the absence of the definition for many, many years and then the multiple definitions. So I would think that the sooner we start this process the better off the community will be, both the advocates and the professionals researching this.

Dr. Susan Levine: Yes, I agree. Does anybody have any conflict with any of the wording of this first recommendation? I like it, I think it sounds very good. And I think Carol and Donna have presented a very persuasive argument.

Dr. Gary Kaplan: This is Gary. Can you hear me?

Woman: Hi Gary. Yes.

Dr. Gary Kaplan: Yes, I'm wondering if what we'd actually like is a standing committee that meets yearly to reevaluate this data. So create a standing committee that's always going to meet once a year to reevaluate this stuff rather than have it thrown together at the last minute and done every three years.

Get a standing committee that's constantly reviewing the data. It should start accelerating and the data coming in should start accelerating as research funds get freed up. So rather than give them three years before needing to put together a committee, get a committee that's constantly looking at the data once a year and commenting on it. Thought?

(Steve): I like that idea. This is (Steve).

Donna Pearson: Well this is Donna and we would need to talk about the fact that producing new educational materials and changing websites is time consuming and I think our ex officios might speak to that whether or not it would be realistic to attempt to change it every single year.

Dr. Gary Kaplan: I don't know that you need to change it every single year but if you have a standing committee whose purpose is to look at it every single year, evaluate the research and put it into action. I mean three years is a long time.

Dr. Susan Levine: I think in a way what Gary might be saying is that to have, kind of, to make people accountable so that we don't wait until three years is up, I guess that's what you (unintelligible)...

Dr. Gary Kaplan: Yes.

Dr. Susan Levine: ...where you have some way of ensuring that we do some work on this every year and somebody compiles the new biomarker findings or whatever else.

(Nancy): This is (Nancy). Just thinking, their process for doing this I don't believe was specified with great detail. I will tell you that the IOM study cost a million dollars and that's a lot of money, especially to come out of our office and so I don't know if, you know, having a standing IOM committee is difficult and so you may want to think about recommendations on how you want to do this, whether it be every three years or every year or whatever.

Dr. Adrian Casillas: Yes (Nancy), this is Adrian, I have to step out for just a few minutes, okay?

(Nancy): Okay. So...

Dr. Adrian Casillas: I'll stay on the line but I'll notify you when I get back on. Shouldn't be more than 20, 30 minutes.

(Nancy): I think we've got six still voting members so we still have quorum.

Dr. Adrian Casillas: Oh perfect, okay. Thank you.

(Nancy): (Unintelligible) Adrian.

Dr. Adrian Casillas: Bye.

(Steve): Yes (Nancy), this is (Steve). I didn't take Gary's recommendation as only being an IOM group, it could be some other group that looks at it because there're many groups that could take it on and be formed to do it.

(Nancy): Right, that's why I just said maybe to be a little bit more specific or leave it, you know, open ended or however. I'm just saying it doesn't say in there.

Dr. Gary Kaplan: Yes, I did not mean for it to be an IOM group. I would just like a standing committee created somewhere in the system, be it NIH, be it an offshoot of this committee, be it something, that once you're looking at this for CDC, once you're looking at this stuff and saying, "Okay, here's the latest update in terms of what's going on."

Three years is a millennial in what's going on in research these days. And the other piece of it is having a standing committee, these are people who know that each year they're going to need to be looking at this data and they'll have to organize themselves and they'll have to comment on it. It is about accountability.

Dr. Susan Levine: Well what did you guys envision, Donna and Carol, as you were writing this recommendation? Did you have any other thoughts about how specifically or - I mean how did you arrive also at the May 2019 number?

Donna Pearson: Well as you know we asked that there be a review in two years. Just ask for one review in two years and that was basically denied. So it never occurred to us that we would ever be able to have an annual review. My suggestion would be as long as we can really quickly whip up completely different

recommendation I hate to spend 30 minutes on this and then not get to the really important next thing.

So I guess I would ask Gary, if Gary are you thinking of adding a sentence in there or are you thinking of completely revising the recommendation entirely. I think everyone would prefer a review sooner than later but we also have to make sure that the review is respected by the HHS.

And as you know we had the CCC in 2003 which wasn't IOM and therefore it wasn't evidence based I supposed and therefore has not been accepted by our government. So I don't know if a workgroup would get that respect either. I don't know if the term respect is right but I hope you know what I'm trying to say.

Dr. Gary Kaplan: I understand completely what you're saying and I agree. So what you do is set up the workgroup for success, but I don't know the specifics of the processes within HHS. I would have to have a conversation with (Nancy) who can give me either some people to go talk to or possibly with Beth Unger and try and get an understanding as to how that process gets set up, what has been done for other diseases, so that there's an ongoing review process as opposed to an episodic and the information is being processed in a much faster rate than it would be otherwise.

So I need to understand what kind of mechanisms would be available within HHS to accomplish that and I certainly don't think I would like to not see another IOM funding process. I think that is not a particularly good use of our money. So can something be done within HHS or can HHS (unintelligible) committee of NIH?

Dr. Susan Levine: In the interest of time because we want to get on to the other recommendations, what you said at the beginning Donna maybe you guys could work on inserting a sentence that suggests that it is reviewed on a periodic basis within that three year timeframe, perhaps?

Carol Head: This is Carol. Let me make an alternative suggestion, perhaps too and I also just want to respond to a question why May 2019. I believe this is correct that that would essentially be the five-year period that the IOM had recommended and we wanted to make sure that we went no longer than that.

But let me propose that we pass this recommendation unless, you know, other discussion reveals problems with it and then we take the next couple months to present a new recommendation at the in-person meeting for the (CFSAC) later this year because, I mean, I certainly agree with Gary wholeheartedly that having an annual review is an important element of moving forward (unintelligible) in this disease.

(Steve): Yes, I would like to mention that (Lilly Chew) sent me an email and it's her thought that research isn't going fast enough. There may not be enough data yet to inform changes. We obviously need funding and we don't want to make changes too quickly because research needs replication and some studies with astounding finding disproved later on. That's the history of the disease and I think she makes a good point which I wanted to share.

Carol Head: You know I hear -- this is Carol again -- and I hear that that again we would note that the IOM's review ended. Two years have already passed since the IOM's report research cutoff. So even if we convene folks to start talking, you know, 6 to 12 months from now they will be capturing and discussing three years' worth of research.

Dane Cook: Hi this is Dane, I'll also add that the CDC multi-site study will also have additional data to be able to review for that purpose.

Dr. Susan Levine: Okay, so the point is do we want to have this recommendation stand with the current wording or do people want to insert another phrase or just leave it as it is?

Dane Cook: I would say that this recommendation should stand alone.

Dr. Susan Levine: I think it's a good one. And then...

Dr. Gary Kaplan: I would agree with that as well as with the idea of updating the recommendation for more frequent review, a yearly review that we could potentially present at the next meeting. So this is in terms (unintelligible) least put it in place and move on from there.

Dr. Susan Levine: The only concern I have and (Nancy) correct me, I guess we wanted to wrap up this working group and move on to other ones so I'm not sure how...

(Nancy): Yes, yes, we do need to wrap up this working group. The whole intent behind the working groups was for them to be self-limited so that at the end of this meeting the job of the work group for both the IOM P2P and the centers of excellence, their job will be finished.

(Steve): Well why don't we have somebody make a motion that we want the voting members to accept this recommendation and move it along. Somebody seconds it, the voting members can vote and we can move on. This is (Steve).

Donna Pearson: So moved. Donna Pearson.

Dr. Gary Kaplan: Second. Gary Kaplan.

Dr. Susan Levine: Yes, me too. Sue Levine. Okay. All right so with that let's move on to the next recommendation.

Man: No, you've got to vote.

Woman: You have to vote, you have to say, "All in favor say aye."

Dr. Susan Levine: Okay, all in favor, say Aye. And say your name please.

Faith Newton: Faith is Aye.

Dr. Gary Kaplan: Gary Kaplan, Aye.

Dr. Jose Montoya: Jose Montoya, Aye.

Dane Cook: Dane Cook, Aye.

Donna Pearson: Donna Pearson, Aye.

Dr. Susan Levine: Susan Levine, Aye. Is Faith on the line?

Man: Yes, she said Aye.

Faith Newton: Yes, I just - I was like the first one.

Dr. Susan Levine: Sorry Faith.

Faith Newton: That's okay.

Dr. Susan Levine: And Adrian is still off. Do we have a quorum?

Woman: I think - well when six people say Aye you do.

Dr. Susan Levine: Okay.

Donna Pearson: Carol if you're willing, I think you did such a good job, if you would be willing to continue?

Carol Head: Sure, yes, if that's helpful. All right, well great. Recommendation 1 is passed unanimously and on to the next slide which is a - this begins the discussion of Recommendation 2. The goal of the next recommendation is to better clarify what we meant when we recommended that the disease be distinguished from Chronic Fatigue criteria. There was no response provided to this recommendation at all.

And based on discussions with Dr. (Lee) we suspect the intent of the recommendations may have been unclear. So this slide reflects information on the CDC website regarding the Fukuda definition for Chronic Fatigue Syndrome. As you can see a diagnosis of CFS can be made for unexplained chronic fatigue cases that are not due to ongoing exertion or other medical conditions associated with fatigue.

So any active medical conditions that may explain the presence of chronic fatigue should be excluded. Next slide too which should be Slide 10. So is this disease a medical condition that explains the presence of chronic fatigue? Yes, there is finally agreement in the U.S. and we are talking about a distinct disease, one that is a diagnosis to be made.

Additionally, thanks to the IOM and the P2P and the NIH RQ reports it's officially been recognized that the Fukuda definition identifies these raw populations of individuals with chronic fatigue and also that intervention trials using Oxford and Fukuda may not be applicable to patients with this disease.

Next slide please. So what do we do about patients to meet Fukuda but do not meet the IOM diagnostic criteria. The IOM had this to say about the issue. Quote "Patients who do not meet the criteria for ME/CFS/SEID should continue to be diagnosed by other criteria as their symptoms and evaluations dictate. Those patients should also receive appropriate care."

The IOM clearly recognized two or more sets of patients here. Those that have the disease they studied and those with other fatiguing conditions that meet Fukuda or other criteria.

Next slide please. This is Slide 12. This graphic is an attempt to be more specific about what we've (unintelligible) talked about the need to clearly distinguish this disease from medically unexplained fatigue. Today a diagnosis of CFS includes patients with a wide variety of unexplained chronic fatigue conditions and this also includes patients that have the distinct disease we currently call ME/CFS/SEID.

However since that distinct disease is now recognized as an active medical condition associated with fatigue as a "diagnosis to be made," it now meets the parameters for exclusion from a diagnosis of Fukuda CFS and should therefore be separated in every way: by name, by definition, by educational materials, by ICD codes, and so on.

What we're seeing now is new information like that on the websites called uptodate.com, on a site called healthwise.org, and on the American College of

Physicians, which combines the IOM criteria for diagnosis with pace study styles (unintelligible) and in some cases attributing poor prognosis to belief that the illness is not physical.

It's likely that CFS will continue to be a go-to diagnosis for patients with unidentified fatiguing conditions in the U.S. and we all agree that those patients deserve proper care. However, patients who meet the IOM diagnostic criteria should not be identified, studied, diagnosed, and treated in the same manner as those who've had unexplained fatigue.

As recognized in all recent federal reports, failure to address this ongoing confusion results in horror to patients and in inappropriate care. Regarding the name - someone may want to consider muting their phone. Regarding the name, we know that the IOM says that this disease should no longer be referred to as CFS and we know that their suggestion of SEID was specifically designed to help distinguish the disease from unexplained chronic fatigue.

As we were told that the CDC plans to assess the name issue as part of the TDW process we remain focused on the concept of distinguishing the disease itself from CFS, regardless of what it is ultimately called. Also the CDC's response provided no clarification regarding an ICD code for the disease studied by the IOM.

In the United States today the leading term for the code being used is "Chronic fatigue, unspecified." It's often the only term that shows up when you type in code R53.82 on an ICD lookup page such as the one provided by the Centers for Medicine (sic) and Medicaid Services.

Continued use of this code by medical providers and insurance companies will only perpetuate the confusion and systems that track disease will count

patients with unspecified chronic fatigue, i.e., Fukuda fatigue and those that meet the IOM criteria as all having the same condition.

We do hope that an urgent push for biomarker research makes all the difference in clearly identifying patients with the disease studied by the IOM. However, in the meantime it's important that HHS do everything possible to clearly distinguish the disease from broad CFS criteria, like Fukuda, that do not require PEM or other core symptoms.

Next slide please. So here we now are at the specific Recommendations, Number 2, which I will read. Sufferers of the distinct disease acknowledged by the IOM, currently referred to as ME or ME/CFS or SEID, from the broader set of conditions defined by Fukuda and Oxford.

This staff recommends that new clinical guidelines, new CDC web pages, a new name, and a new ICD code, be established for the distinct disease identified and acknowledged by the Institute of Medicine, and that they be separate and clearly distinguished from the clinical guidelines, CDC web pages, name, and ICD code used for the remaining patients diagnosed with Chronic Fatigue Syndrome as defined by Fukuda.

Statements and Treatments. Treatment recommendations based on the Oxford definition should not be included in clinical guidelines for this disease. Until such time as a new ICD code is established (CFSAC) again recommends that the G93.3 ICD code be used for this disease.

I have just one more paragraph here to read, thank you Donna. The rationale for this recommendation. The Institute of Medicine has made it clear that ME/CFS/SEID is a diagnosis to be made and that the hallmark of the disease

is a systemic intolerance to exertion of any kind, resulting in body-wide exacerbation of symptoms and energy production impairment.

This hallmark impairment has profound implications for our diagnostic and treatment and management of clinical care practices. However, in the U.S. today the same clinical guidelines, medical education, disease name, and ICD code are being used for patients that meet the IOM and for those who do not.

Continuing to mix these two patient groups together perpetuates the confusion about the disease and causes harm to both groups of patients. Additionally, as indicated in (CFSAC)'s comments to the P2P workshop panel, we recommend that, "Studies using the Oxford definition not be used to inform treatment recommendations" for this disease.

And, as stated by the IOM, "The Fukuda definition identifies a larger, more heterogeneous group of patients compared with the other criteria. The committee recognizes that some patients diagnosed by other criteria such as the Fukuda definition will not fulfill all the criteria proposed here but it emphasizes that all patients should receive appropriate care," from the IOM report.

So that is the full presentation from the subcommittee on this recommendation and we all welcome discussion.

Dr. Susan Levine: Thank you Carol.

(Steve): I would recommend somebody move the recommendation and second it before there's a discussion. This is (Steve).

Dr. Susan Levine: That we do what? Just...

(Steve): Somebody move to accept it and that somebody second it so we know we're discussing something that is on the table. It just sets it up.

Dr. Susan Levine: Sure, I agree with that. Dr. Levine, Sue Levine.

(Steve): So some voting member needs to move it and some voting member needs to second it.

Donna Pearson: So this is Donna Pearson and I make a motion that adopt this recommendation for submission to the Secretary.

Dane Cook: Dane Cook, I second.

Dr. Susan Levine: Anybody else? I guess we don't.

(Steve): And now you need to discuss it.

Dr. Susan Levine: Okay.

Donna Pearson: Is there any discussion regarding anything that anyone feels should be changed about this recommendation?

(Steve): I know the International Association of Chronic Fatigue Syndrome is very in favor of fixing the ICD-10 code issues.

Dr. Beth Unger: This is Beth Unger, just commenting on the - again to remind you the process of changing ICD codes isn't just that somebody decides it, it's a process and the best way is to have a proposal through the committee and, I forgot - that I mentioned yesterday. It's part of (NCHS), they have a specific committee that

approves these recommendations and that committee is looking for data and consensus on why a new name is needed and how our new code will be used and how to differentiate it from the other codes. Just so you know what the bar is in these kind of recommendations.

Donna Pearson: So Beth is that something that needs to be handled by outside of the government or is that something that one of the agencies with the HHS can be involved in? You know I know Carol said she was going to look into it or IACFS or ME or whatever.

Dr. Beth Unger: Yes, generally it comes from clinicians that are involved in the illness and not from the agency themselves.

Woman: There is an advisory committee just like this one and they meet regularly and I know about five years ago there was a lot of effort put forward by some of the ME/CFS advocacy communities about getting that previous one changed and they would go to the meetings and present information. And the agencies just can't go to somebody, to this person at (NCHS) and say, "Change it." They have this long process that's run out of this advisory committee at (NCHS).

Donna Pearson: So we now have the support of P2P and IOM. Thank you very much for all your efforts to do that, so maybe we can make the case now.

Woman: Right, I think that's the next step and it's much more that this advisory committee over at (NCHS) likes to hear from people, both advocates and the clinicians and the users of the ICD codes, that's another important one are the users like the AMA and whoever it is that uses those - who creates all those cover sheets for when you go to a doctor's visit, they use the ICD codes and so that's who presents to this advisory committee. And we can get you the name

of that advisory committee. Beth can find that out and give it to you and you can look on the Federal register and find out when their meetings are.

Dr. Beth Unger: It's in my report from yesterday, I just have short-term - don't remember, I could pull up my slides but I mentioned the name specifically in that.

Dr. Susan Levine: So I think it would be helpful to perhaps tack on half a sentence at the end of this recommendation to show that we're going to make an effort to do that.

Woman: The HHS doesn't make the effort. That's what I'm saying.

Dr. Susan Levine: Okay.

Woman: To go through these steps.

Dr. Susan Levine: The individuals, the clinicians.

Woman: Well it's the clinicians and the people who present before the advisory committee who then advise NCHS who are responsible for - and they do 10,000 of these things, I mean it's a huge effort to come up with new ICD codes. I'm sure the next round they will have an ICD code on Zika, for example, which they didn't have before.

(Steve): But couldn't our advisory committee recommend to their advisory committee to do something positive in this area?

Woman: That's not how it works. I mean you can make that recommendation but they need to hear from, as Beth said, they need to hear the data and what the support and things like that. One recommendation isn't enough. They need reason to do it.

So I think my advice is to learn about the process that's needed and to find out what the advocacy and the clinical community can do to support it because the way I have been hearing about this for the last five years is that that's where the push comes from. It does not come from the Federal government.

Donna Pearson: So in the meantime, that's one small piece of the overall concept that we're trying to get across here which is to separate out patients with the disease from chronic fatigue patients who also deserve care and deserve research and deserve everything else as well.

And if the little ICD code piece needs to be handled separately that doesn't mean that we shouldn't recommend that, in my opinion. And our recommendation, because it's a part of identifying a separate disease.

Dr. Susan Levine: I second that. Yes, I agree with you.

Donna Pearson: So if there's...

Dr. Susan Levine: I think we like it the way it stands, I mean...

Donna Pearson: Well you can call the vote and we could move on if...

Dr. Susan Levine: Sure...

Dr. Jose Montoya: Before the vote. Jose Montoya. I'm having issue or trouble understanding the G93.3 ICD code because that refers to postviral fatigue syndrome and certainly I have seen patients who have not had a clear cut viral infection following the symptoms of Chronic Fatigue Syndrome. Most of my patients, but this is because of referral bias, come to me with that history of postviral

CFS or ME but there are many patients who do not have that and so I'm having trouble, you know, supporting the recommendation to give this a specific code that isn't specific for postviral fatigue syndrome.

Dr. Susan Levine: I think that's probably technically true but the alternative that's available now, I understand from the ICD-10 coding, is G53.82 (sic) which is just Chronic Fatigue.

Dr. Gary Kaplan: Unspecified. But I think -- this is Gary -- I completely agree with Jose. There's a subset of my patients unquestionably have postviral but there's another set that, you know, unknown etiology so I don't want to get locked into 93.3.

Donna Pearson: But that code is also referred to as benign myalgic encephalomyelitis and it lines up essentially with the WHO code for the disease that we're talking about. Regardless of the name again. So I think postviral fatigue is only a part of what gets lumped into code G93.3 but it's certainly a better option than this general chronic fatigue code which is something that is under signs and symptoms instead of under neurologic disease as the G codes are, is my understanding.

Dr. Susan Levine: Well maybe we could - how do people think about - because there's some disagreement here about removing that last sentence and just saying that we're still investigating?

Donna Pearson: Well the interesting thing is both Jose and Gary were not at the last meeting when the (CFSAC) in fact did recommend this code for use temporarily. We've already actually recommended...

Dr. Susan Levine: Yes, well I don't actually have a problem with it, I'm just saying to bring us closer to an agreement and keep the recommendation which is an important one. But...

Donna Pearson: I'm saying it might not have passed if they had been there, we don't know.

Dr. Susan Levine: Right, right.

Donna Pearson: But we did end up submitting that recommendation to the Secretary, just as an FYI.

Dr. Susan Levine: Well, why don't we go ahead and take a vote on this and, I guess we'll see. I'm in favor, Sue Levine, Yea (sic).

Donna Pearson: I'm in favor, Donna Pearson.

Dr. Susan Levine: Dane.

Dane Cook: I'm hesitant. You called the vote so fast I didn't think that the discussion was complete. I...

Dr. Susan Levine: By all means, continue (unintelligible).

Dane Cook: I appreciate Gary and Jose's concerns so, you know, I'm weighing out the options here and I'm trying to get confirmation of the ME language that's a part of that code.

Dr. Jose Montoya: But why, if that recommendation was submitted already, why is it being submitted again?

Donna Pearson: Yes, we could eliminate that sentence if it is of concern to you. It's just that we recommended a new code and there's going to be a time period involved before a new code happens. But maybe if we can our acts together we can get the code done before the deadline and (unintelligible) moot issue.

Dr. Gary Kaplan: So Donna, this is Gary. There's plenty of flaws in the ICD-10 that drive us all insane and the question is do we want to codify a clear error or lack in that code on a part of this committee saying that, you know, essentially what you're saying is that all ME/CFS is postviral. Not true. And so I don't want to give our imprimatur to a bad code to begin with.

We're stuck with workarounds as it is. Chronic Fatigue, undetermined origin, but since ultimately the purpose of the ICD-10 is to get as specific as possible so that we can clarify the incidence of diseases and subsets of diseases, all we're doing is reinforcing a bad diagnosis that they foisted on us. It's a problem they created, I'll grant you, but I don't want to be part of supporting that so I prefer to have that sentence removed. That make sense?

Donna Pearson: I think so. I don't know if my entire work group would agree but unfortunately they're not here to chime in. I don't have a problem with removing it because I think the recommendation actually stands at this point and HHS has decided what they've decided about it. So I think it's fine to remove that sentence is what I'm trying to say.

Dane Cook: I agree Donna. This is Dane.

Dr. Susan Levine: Anyone else?

(Steve): You need to have a motion and a vote to remove it.

Dr. Susan Levine: Okay. I propose a motion to remove the last sentence of second recommendation.

(Steve): Somebody needs to second it.

Man: Second.

Woman: So can you say that again?

Dr. Susan Levine: I propose to remove the last sentence of Recommendation #2.

Woman: That begins with "statements and treatment?"

Dr. Susan Levine: That begins with "until such time that a new ICD code is established."

Woman: You can take, get rid of, just keep it back on the share until they're done because...

(Steve): What happened.

Woman: There may be more word smithing, right?

(Steve): What happened? It just disappeared. What happened.

Dr. Susan Levine: It got smaller on my screen.

Woman: That's the Word part that we can actually edit. We can't edit this.

(Steve): That's fine.

Woman: So this is space and you just (unintelligible) it? I'll make this second?

Dr. Susan Levine: Thank you.

((Crosstalk))

Dr. Susan Levine: Okay, here we go. Does anybody - before we vote, does anybody want to make any other changes or we're happy with it the way it is now? Or any other proposals?

Donna Pearson: I just want to reassure the patients who are in favor of this that we actually did submit this recommendation so it's not that we're now changing...

Dr. Susan Levine: I believe you. I believe you.

Donna Pearson: Yes, we're just taking this out of this new one.

Dr. Susan Levine: Yes.

Dr. Gary Kaplan: Yes, I think this moves us closers to a better definition of what we're treating as you've written it and so removing that last sentence I think actually makes this a stronger statement.

Dr. Susan Levine: Okay...

(Steve): Could add something like the ICD-10 codes need to be improved to better handle ME/CFS. I can't make the motion, I'm not voting.

Dr. Susan Levine: Well it begs the question that there might be more than one ICD-10 code then for ME/CFS, depending on its origin, or its supposed etiology, or what the clinician believes is etiology at the time they see the patient.

Man: Sure.

Dr. Susan Levine: So we may indeed have more than one ICD-10 as, you know...

Dr. Gary Kaplan: How many codes are there for a fractured tibia? I'm serious, I mean...

Dr. Susan Levine: Well you're right. It's going to help the government determine prevalence, you know, we'll look back at insurance records and, you know, have an idea of pretty much of the prevalence of the illness, hopefully it will help at least in that way. And the more precise we are the more detail we'll learn about the, you know, potential subgroups is one way of learning about it.

Dr. Jose Montoya: And we have to be careful because we don't know it yet and I really go back to a comment that Vicky Whittemore made earlier that we don't know yet if this is one disease with many faces or this is, you know, several diseases with similar symptoms. You know, one example is you have HIV as a single etiologic agent of AIDS but AIDS has so many presentations. But on the other hand you have pneumonia that has similar symptoms but you have a lot of etiologic agents behind. So we don't know really where CFS/ME was (unintelligible) so we have to be careful that we don't lock in into something until we don't have enough data on the pathogenesis of the disease.

Dr. Susan Levine: Agreed. Right. So once again are people ready. I don't want to vote prematurely, I made that mistake last time but does anybody have any other comments on the wording here? Now that we've removed the last sentence?

Dr. Gary Kaplan: I think it's a stronger statement now.

Faith Newton: Yes, I'm fine with it. This is Faith. Especially with everybody's reasoning it makes sense.

Dr. Susan Levine: Okay, shall we vote then? All in favor say Aye please.

Woman: Aye.

Dr. Gary Kaplan: Gary Kaplan, Aye.

Dane Cook: Dane Cook, Aye.

Dr. Jose Montoya: Jose Montoya, Aye.

Faith Newton: Faith Newton, Aye.

Dr. Susan Levine: Sue Levine, Aye.

Donna Pearson: Donna Pearson, Aye.

Woman: That was unanimous and there was enough for quorum.

Donna Pearson: Well Carol are you up for it?

Carol Head: Sure Donna, if you like. All right two unanimous approvals. Onward to Number 3, the last proposal from this group. So Slide 4.

Our final recommendation is related to medical education about the new diagnostic criteria. This slide shows some of the objections made following

release of the IOM criteria last year, information that was garnered from hundreds of hours reviewing studies, articles, blogs, interviews, and so on in order to identify obstacles to acceptance that the IOM criteria by the broader community.

When the subcommittee started our work, the IOM criteria was possibly on the way to being publicly "rejected" by a majority of the community. As mentioned last year during our first working group meeting, a number of members wanted to continue to push for adoption of the CCC.

On to next Slide (unintelligible) However as reflected in this slide - is this right, Donna?

Donna Pearson: Yes.

Carol Head: Okay. As reflected in this slide from last August we recognize the value in the IOM report and felt that it would better serve the community if we could identify the concerns of experts and stakeholders, devise a strategy to address those issues if possible, and present actionable recommendations in the hopes of moving forward.

Next slide. A big part of the recommended plan was to use the diagnostic criteria from the IOM itself to better educate and inform the medical community. We recommended that a disease overview be added and that symptom descriptions taken from the IOM Report be included. We also recommended listing frequently reported symptoms that support diagnosis below the core criteria and ask that a brief guidance document be created to supplement the criteria.

Recently we discovered that the CDC's TWD starting point for discussion has been the simple version of the IOM criteria and the algorithm which we specifically did not recommend. However, Dr. (Unger) has made it clear to us that the CDC's goal is to create resources that are appreciated and welcomed by the broader community while also being appropriate for medical providers.

Since our recommendations were carefully designed to address concerns that were raised and they seemingly been well received in the community, we'd like to stress their importance. So we are requesting that (CFSAC) August 2015 recommendations related to the proposed criteria be restated along with the recommendation to change the narrative for which there was no HHS response at all.

Additionally, because it's clear that the name, definition, and treatment issues will continue to be a challenge in terms of medical education, we feel that solid educational materials that best describe the disease and truly reflect the patient experience, can only be created with substantial involvement of disease efforts in the patient advocate community.

Next slide. All right. So here is the recommendation Number 3, itself, and then I have a rationale that will follow it. So, collaborate with disease experts and stakeholders regarding all educational materials prior to release. (CFSAC) recommends systematic collaboration with a workgroup or panel of recognized disease experts and stakeholders for review of all items of medical education produced by HHS agencies, institutes, and centers prior to release.

Additionally, (CFSAC) again recommends that the best way to move forward regarding the proposed diagnostic criteria was reflected in recommendations that were submitted to the Secretary in August 2015, specifically, Number 8, Recommendation Number 8 from August, use information from the IOM

report to detail and clarify the criteria. Recommendation Number 10, provide disease guidance with the criteria. And Recommendation Number 15, change the narrative.

So we (unintelligible) a rationale. Recognize disease experts have a wealth of knowledge and experience regarding disease history, clinical presentation, diagnostic testing, treatment options, and clinical trials and, as such, are valuable resources regarding this disease.

The new educational materials are being developed, advance review by a workgroup comprised of knowledgeable disease experts and stakeholders can provide an opportunity to increase effectiveness and positive impact regarding the goal of reeducating medical providers regarding this disease.

Such a workgroup could suggest wording or other changes to clarify messaging, anticipate questions and confusion, identify potential areas of stakeholder concern or controversy, and identify resources that may be of value.

Regarding CDC website content, brochures, video clips, infographics, and other new materials to be developed, information that accurately reflects the disease and the patient experience is vital.

For a patient community that has been stigmatized and underserved for decades, the availability of Federally produced educational materials that can be accessed by the medical community and/or be provided by patients to uninformed medical providers, caregivers, employers, schools, and others would be an invaluable resource in helping to improve the quality of patients' lives.

So that is the completion of the presentation from the (unintelligible) committee.

Dr. Susan Levine: Thank you Carol. Okay why don't we begin discussion on this recommendation.

Dr. Adrian Casillas: Yes. Hi, this is Adrian. I'm back in on the call, okay?

Dr. Susan Levine: Thanks Adrian.

Dr. Gary Kaplan: Is there a mechanism set up for other diseases that have these kind of working groups collaborating with stakeholders for review of all educational material? Does anybody know that? (Nancy) do you know that or Beth?

Woman: Is Erin on the call?

Erin Fowler: Erin.

Woman: Yes, Erin, because I know you all at HRSA make educational materials. Can you answer (unintelligible) the experience of HRSA what happens there?

Erin Fowler: From what I have heard the experience at HRSA is very limited when it comes to educational materials. There have been some (IAA)'s and (MOU)'s with other organizations that gave HRSA funding to help out with this but the majority of it is through grantees and the proposals that are sent to HRSA and granted funding.

So they're mostly through academic institutions and hospitals. So the educational material is not necessarily developed specifically by HRSA, it's developed by the grantees.

Woman: Do you know, Erin, if this would - you know about the Bright Futures project?

Erin Fowler: No.

Woman: Okay the Bright Futures comes out of (MCHB) but it's the one that develops the guidelines for primary practitioners, for pediatricians around what should be done and should not be done for children. You know about that process?

Erin Fowler: I know that there are definitely one off where this is happening in HRSA but it's just not a standard practice. That's all. So I think it's misleading to say that HRSA is a developer of educational materials because it's simply done through grantees. And I know that specifically in (VHW) there isn't a whole lot happening regarding (VHW) developing educational materials.

Woman: I know that this Bright Futures is done through a cooperative agreement so money is awarded to American Academy of Pediatrics...

Erin Fowler: Yes.

Woman: ...through a cooperative agreement but HRSA can collaborate but it is still a cooperative agreement.

Erin Fowler: Understood.

Woman: And maybe Beth you can speak to what's going on specifically with the TDW.

Dr. Beth Unger: Yes, but I think the question - and it's for the technical development workgroup we are seeking input and the process that we will be using is that people will see it as it's being developed but then once it gets to a certain stage

it goes through the process of being approved by the agency and inevitably there will be changes made, but in keeping with everything that we've learned by the input group.

But there is no process for a final approval by anybody other than the Federal government for these materials. So the input comes at the beginning of the process when we hear everybody's words and thoughts and we gather the data. Now it only makes sense that we get as much consensus as possible because we want to be able to move forward and do other things besides the web page.

And I don't know about other illnesses, how much patient input there is or what the process for gaining patient input, but increasingly not just CFS but all illnesses: cancer and (unintelligible) and everything realizes that medicine can't be imposed on - or health care can't be just imposed on the consumer, the patients. That it should be a dialog and the voice of the patient does need to be heard and understood.

And so I think that this process that we're starting should ensure that both the voice of the patient is heard as well as the voice of the clinician, because if clinicians see something that they don't recognize as being useful to them, because it's put in the language that the patient's like, it's not going to get us to the final outcome which is physicians that understand this illness and will respond appropriately.

So it will involve probably some compromise between the words that patients will use and the words that physicians use. And both groups have to understand each other - or I don't mean both, there's probably multiple groups and multiple points of view. And I think it's through the conversation that we will indeed change the narrative and I agree that we do change the narrative so that this illness is better understood by primary care physicians.

Woman: And let me just say about this, I don't know that I see it up there but the idea that this should be approved before it's released by CDC or whomever. That would require a whole new advisory committee under the Federal Advisory Committee Act and I don't that's going to happen.

As you know, Chronic Fatigue Syndrome has this one and it doesn't have, sort of, the breadth that the advocacy community is asking for, I think, for approval of these documents so what we can do is get input early on, but we can't ask for approval without establishing a whole new infrastructure which will not happen I assure you.

(Steve): What about getting reviewed by this committee of educational material before they're released and before they're finalized?

Woman: I mean that's a possibility, I don't know if it would fit because we only have 11 voting members and they come from all different kinds of areas of expertise or advocacy so I don't know...

(Steve): And that's an advantage though.

Woman: Well, but...

Dr. Susan Levine: Well it could even be another proposed working group for the future.

((Crosstalk))

Woman: I think it would have to be when CDC is through with their process.

Dr. Susan Levine: Okay.

Woman: Right, I mean but I don't want to say that that wouldn't be possible because that would be. I don't know if that's something that would work and we could certainly discuss that further.

Woman: (Unintelligible) from AHRQ. I also want to check at this point to say that (ARC) also has a physician's guide and a patient's guide based on the systematic review that's in the log. But we're holding off on it until we can coordinate with the CDC so that we have consistent messaging.

And (ARC) doesn't do that by itself, it works through its contractor at the (unintelligible) Center, housed at Baylor College of Medicine and they engage focus groups of physicians and patients and seek input into their messaging when they develop their translation product.

Donna Pearson: So this is Donna and I just wanted to be clear that we didn't say that we would get the finals - we meaning this panel, would get the final say. The recommendation is for systematic collaboration and not with an advisory committee because we knew what that would involve.

So we use the term panel or workgroup because we understand you can form workgroups without going through the whole (unintelligible) thing and having to make every decision in public. But the point of this, I think, was that there are small things that experts and stakeholders could recommend that could make a huge difference in terms of the way the disease is perceived.

And, of course, we have to take into account how medical professionals need to learn and understand. But as, I think it was (Mary), who said during her - I lost my word, give me a minute - her public comment. I think she brought up the science clips issue. There was a science clip that had some wording in it

that we, all of us patients, knew clearly would be offensive and it was old information and there might be a better option for the science clip then that one thing.

It would be a simple thing to change something minor like that that would make a big difference. Or asking Dr. (Lapp) to talk about (PEM) a little bit more in his presentation. Again, huge difference it would make in how the disease is perceived. So that's, I think, where we're going with this recommendation. We might not be clear about how we're saying it but that's what we're asking.

Dr. Jose Montoya: And I think that - Jose Montoya - that we need to separate the vision, the ultimate vision, the intention that - because I completely agree with you, Donna, and (unintelligible) the spirit of the recommendation that there is so much information out there that physicians who are really knowledgeable about this disease and who have been facing all the issues that are so complex inherent with the disease have that - and many of these things were to a certain extent that need to be somehow compile in some kind of like body of recommendations of document.

But we need to make sure that that spirit, that vision, that intention prevails and separated from how it would be implemented. I guess what I should mean for the record that is there a great document that was put together by the International Association for CFS/ME in 2012. It was headed by Fred Friedberg and is called The Primer for Clinical Practitioners.

I think that that one great attempt in trying to summarize that clinical wisdom that is out there in the minds and the brains of clinicians who have brave for decades to really face this issue from, you know, the face of the disease that needs to be somehow compiled and made available for physicians.

Man: Jose, my...

(Steve): I think it's available through (ARC), isn't it? The primer.

Donna Pearson: It's on guideline.gov and...

(Steve): Or guideline.gov. Yes.

Donna Pearson: And my understanding from Beth Unger and now she's on the hot seat but my understanding is that the CDC looks for peer reviewed information in terms of treatment recommendations and that is the primary reason that the recommendations in the Primer are not getting put on the CDC. Maybe Beth could talk a little bit more about that because that might be something that (Steve)'s group could do something about. Are you willing Beth?

Dr. Beth Unger: Yes, I mean, that is the reason. I think we are in (unintelligible) of getting a process for having treatment guidelines reviewed and the quality of evidence rated. There's a whole process for that and that requires a systematic, you know, a combination of what AHRQ has started, the systematic review of the literature, recognizing the limitation of the literature, then you have to move to clinical expert's opinion.

And that doesn't mean it's not valuable but it puts it out there and actually allows anybody going to it to know where the recommendation comes from. Does it come from clinical trials, does it come from, you know...

Man: Observational settings.

Dr. Beth Unger: Yes, it creates the quality of evidence. And there's a whole process for doing that and that's really what we need to establish and that'll take all of us working together to move to that.

Dr. Gary Kaplan: So this is Gary. So I completely agree with the sentiment of what you want to see accomplished here. My concern is about there's not a mechanism to make it happen and it would necessitate creating another level of bureaucracy that would potentially significantly delay information getting out.

So that's my concern with that. I completely agree with the sentiment. We've got to improve the quality of the information getting out there, we've got to get some consistency in the information getting out there. I'm just not clear that this is going to get us where we want to go with this proposal.

Donna Pearson: So Vicky can you tell us - I thought that there was going to be - you're working on - this is a separate issue but my understanding is you were trying to figure out how to collaborate on the intramural study.

Or maybe it wasn't you that was doing that but NIH, and you were hitting roadblocks for the same reason. You couldn't do an advisory committee but you were looking into workgroups or other things. Do you know of anything that might be applicable to what we're trying to do here? Based on what you've learned so far.

Dr. Vicky Whittemore: Yes, any time you put a committee together that you call Advisory, you have to create a whole (SACA) committee. I've been trying to think about how we could do something, so what NIH typically does, you know, we don't typically - and NINDS anyway, doesn't typically develop medical education but we develop educational materials for the public.

And what's done there typically is it's written by folks in our communication office and then reviewed by whoever the disease expert is in the institute and then sent to several experts in the field for review. I don't know. I'd have to explore, Donna, a way in which we could establish a collaborative group across agencies and including patient advocates.

Dr. Beth Unger: Yes, sorry, this is Beth. I guess I'm just trying to understand what is wanted different from what we're doing, or trying to get started with the technical development working from the steering committee. Steering committee includes representatives of the Federal agencies so that they have input into comments.

Now we're a little slow getting started and we don't have a product but that is the process - the reason that we put this together was to have a way to get input from all of the stakeholders which is the patients and the advocates, their family, the physicians, the educators, so that comments like, you know, "this is the wrong picture" can be included when the materials are developed and I, you know, I don't know what's missing from that picture.

Donna Pearson: I think nothing is missing from that picture Beth. I love that picture. I think we're talking about making videos, I believe, for medical education of some type. Or you've made them in the past and I've heard former CFSAC members express concerns that they were not properly representative and, as you know, pictures that have not been properly representative, so it's not just that what you're doing - the TDW is very specific and we're talking about - you know, we're hearing right now from Erin that - well, you know (unintelligible) different educational materials

((Crosstalk))

Dane Cook: So this is Dane and I just want to piggyback on Donna's comment. This was really, I think, just a broader representation. And I had the same question because I think our whole group recognized the steps that CDC had taken to have a, you know, a vetting of the information that they were producing.

This was meant to be wider towards making sure that there is a process, and I agree with Gary there is not a mechanism in here to make it happen. But a process of review of materials more broadly across HHS agencies before they're released. And if those already occur it would be nice if we knew what they were.

Dr. Susan Levine: So are we - this is Sue here. I understand what you're all trying to say and certainly the spirit of it with some of the challenges that were presented here. Do we want to modify this recommendation or...

((Crosstalk))

Dr. Susan Levine: I mean I like the way it is.

Donna Pearson: Could we eliminate the words 'workgroup' and 'panel' so that, I mean, is that the problem? Because as Vicky said, phone calls, I guess, are made, or information is sent out however they do it with these other issues. I mean is that the problem I guess is my question?

We need ex officios to help on that one.

(Steve): I'm sure the International Association of Chronic Fatigue Syndrome will be glad to participate. I'm going out on a limb here. This is (Steve).

Dr. Susan Levine: So should we name your (unintelligible) liaison then? Should we put you in...

(Steve): I don't think that's necessary but I'm sure our organization would be interested in being involved.

Dr. Susan Levine: Because you named specifically HHS agencies, that's why I said, you know, and other organizations.

(Steve): Well we would be the recognized disease experts and stakeholders, I think.

Donna Pearson: I hope you understand that the goal here is to do the best possible job with medical education which I think everybody wants and I guess the question is how do we do that if this is not the method is there a suggestion of how we can do that?

Dr. Susan Levine: I mean I think it is a good method I just think it sounds like the mechanism to put it into place hasn't happened yet or may be too challenging right now.

Donna Pearson: If we submit the recommendation is it something that will then be considered by HSS agencies. I mean they don't usually take our recommendations, you know. We recommended to adopt the CCC and then they went and hired the IOM, you know, so they interpret what we're trying to get at and then they do what they can. So if the message conveys what we're trying to get at, perhaps we should submit it.

Dr. Gary Kaplan: This is Gary. Again, the issue is about maintaining the sentiment, the spirit of what you're trying to accomplish and I completely agree with that. My concern is about creating another level of bureaucracy and so if we simply eliminated the words "collaboration with recognized disease experts and stakeholders, review of all item of medical education" and eliminate the panel

and working group. Eliminate the words, a work group or panel, and simply elaborate this.

Dr. Susan Levine: Of, include, 'of' in there.

Man: Collaboration with recognized, yes get rid of the word, 'of', also.

Man: 'Of' needs to go too.

Man: Right. Yes, recognized as the expert tech, although review of all items of medical (unintelligible). Yes, does that preserve at least, acknowledging the fact that there is no federal mechanism available to create the work groups or panels. At least acknowledge saying, look you need to be including these people in your discussions.

Dr. Susan Levine: You need to be accountable right, or do have way to, yes. I think that makes sense.

Man: Donna, you guys labored over this long and hard, are you okay with that? is that, does that create a problem for you guys?

Donna Pearson: I think it's fine, we're saying systematic, we're hoping that our agencies will think out of the box for us. This is the situation is a mess as we all agree. I think we need to do everything we can to try to figure out how to get the best medical education out there.

Carol Head: This is Carol, yes I too am fine with that. I mean it is important to continue at it. It's not as though we're in a benign situation with regard to the public's understanding of disease and medical practitioners. We are in a negative position and so, you know, we must keep the pressure on to make those

changes and I think if we're moving those five words next, work for everyone then we should do that.

Dr. Susan Levine: Do we want to change the wording anymore or are we happy with the way it is, or? We've got about seven, well five minutes to really vote on this. Do we want to change anything?

Dr. Gary Kaplan: This is Gary I would move to accept it with the modifications as proposed with the removal of, 'a working group of' or 'panel of'.

Dane Cook: I second.

Dr. Susan Levine: I third.

Faith Newton: Okay, so any discussion and then we need to vote, is there any more discussion. That's, by the way this is Faith.

Man: Well you should call the vote Sue.

Dr. Susan Levine: Excuse me, yes. Well let's vote folks. Susan Levine, I vote aye.

Faith Newton: Faith Newton, yes.

Dane Cook: Dane Cook, yes.

Dr. Gary Kaplan: Gary Kaplan, yes.

Dr. Adrian Casillas: Adrian Casillas, yes.

Dr. Jose Montoya: Jose Montoya, yes.

Donna Pearson: Donna Pearson, yes.

Dr. Susan Levine: Okay well why don't we take a short break now. Then we'll return at approximately at 3:30.

(John): Could you put the last slide on, I just want to acknowledge the working group members.

Dr. Susan Levine: That's a very good idea.

Woman: I also, go ahead (John), I'm sorry.

(John): I was going to say, Carol maybe could, just do the last slide.

Carol Head: Sure, and you love, yes, so yes, here it is. Really huge thanks to the (Systac) members who, including Mary Ann who was not able to be here today, although that caused her grief that she couldn't. (Alexandra) thank you for your many contributions and certainly the really the invaluable discussion and knowledge brought to us by (Mary Dimlick), (Claudia Goudel), (Dylan Moore) and Charmian Proskauer. We would not have had as strong a product without their input, so many thanks to you all.

Dr. Susan Levine: Yes, I wish to acknowledge the contributions of (Mary Dimlick), (Claudia), (Billy) and Charmian. I'm sorry it hasn't been brought up and I'm sorry that they were not given an opportunity to speak, I guess we wanted to make sure we got everything done, but thank you all very, very much for this wonderful work product. So why don't we take a short break and return at 3:30.

Man: Great.

Woman: Great.

Dr. Susan Levine: Thank you all, we'll see you back at 3:30.

Woman: (Marsala), are you there? (Marsala) are you on the line?

Dr. Susan Levine: Hello.

Man: Hello.

Dr. Susan Levine: Hello hi, are we back on the call.

Man: Yes, I guess that's, I haven't heard anybody but you.

Dr. Susan Levine: Oh okay.

Donna Pearson: Donna.

Dr. Susan Levine: Hi, Donna.

Faith Newton: Faith is here too.

Carol Head: Carol.

Man: (Unintelligible).

Dr. Susan Levine: (Nancy) are you there?

(Nancy): Yes, I'm here.

Dr. Susan Levine: Okay. All right. Well I guess in the next couple of minutes we'll begin discussions about future subset working groups. We've talked about a couple of ideas already, I know Faith is interested in beginning a pediatric group and maybe I will let you have the floor first Faith. Then other people can chime in. I'd also like to hear from some of the ex officio's to - actually (Suchi) and…

Faith Newton: Sue before you do that can you see who all is here so we know we have a quorum?

Dr. Susan Levine: Sure. Let me take a quick roll. Adrian your here right?

Dr. Adrian Casillas: Yes.

Dr. Susan Levine: Dane?

Dane Cook: Here

Dr. Susan Levine: Donna?

Donna Pearson: Yes.

Dr. Susan Levine: (Carrie), Faith I know you're here. Jose?

Dr. Jose Montoya: Yes, here.

Dr. Susan Levine: Okay.

Faith Newton: Was Gary here?

Dr. Susan Levine: I think I heard his voice, no? Gary? Oh, okay. I guess he'll be on the line any minute now.

Faith Newton: Maybe we should just wait another minute or two.

Coordinator: This is the operator. We do have some of the committee joining back in now. We're getting their lines opened.

Faith Newton: (Nancy) while we're doing that can we type the charge for my recommendation up on the Whiteboard?

(Nancy): We're unimpressed with the Whiteboard. I think we'll have Syreeta do it on, in Word. Can you create a new Word document Syreeta? It's the Whiteboard technology allows for no mistakes.

Faith Newton: Lovely.

(Nancy): Yes, Syreeta is a much better typer than I am.

Faith Newton: All right, so pediatrics, education, working group. At least we can get it typed in and that will give everybody a couple minutes to still get on. The first charge that I wrote Syreeta is, evaluate the need and feasibility for cooperative efforts by HHS and DOE - for those of you who don't know that would be the Department of Education - to promote, I'm sorry to improve physician's awareness of their role in assisting pediatrics CFS, or actually in assisting pediatric any CSF patients. Pediatrics, yes. It should be in assisting pediatrics any CSF patients. Thank you. Any CSF patients and their families to acquire appropriate special services…

((Crosstalk))

Dr. Susan Levine: I think there is a c in acquire. Sorry.

Faith Newton: …to the schools. Actually instead if to it should be through the schools.

((Crosstalk))

Dr. Susan Levine: How about through the school system.

Faith Newton: Sorry and their families to acquire, right, through the schools, through the schools.

Dr. Susan Levine: Check on the appropriate spelling, right. Okay.

Faith Newton: Physicians is probably physicians awareness, yes. Second charge.

Syreeta Evans: Just a minute.

Faith Newton: I'm watching.

Dr. Susan Levine: Gary are you on?

Dr. Gary Kaplan: I am.

Dr. Susan Levine: Okay.

Faith Newton: Charge number two. Evaluate the need and feasibility for a cooperative effort by HHS and DOE for cooperative effort by HHS and DOE to develop, no I'm sorry. To promote a greater understanding by school nurses of the Stinson of pediatrics CFS, I mean CSF, and the accommodations or modifications.

Syreeta Evans: For or, or?

Faith Newton: Or.

Dr. Susan Levine: Or.

Faith Newton: Most likely to support, most likely to support these children in being academically successful.

Dr. Gary Kaplan: This is Gary, can I recommend changing most likely to necessary.

Faith Newton: That's fine.

Syreeta Evans: Repeat that again Gary.

Dr. Gary Kaplan: Just take the words most likely, so modifications most likely but, modifications necessary.

Faith Newton: Give her a second to correct the spelling too. What is, what I was looking for is that there is a huge cry from our patients, our children. That it probably, and I haven't done the research so I can't site it, but I hear from parents all the time that the biggest stress in their life is that, how is their child going to get through school. How is their child going to make it through middle school, how are they going to make it through high school, and what supports are out there.

They have no idea and that's a huge stress on many of our families. They just simply don't know the process and what to do. Is there, is there something, is there a way we can work together with HHS and DOE and what would that

involve to help our families get the services that they need. So that they are successful in school.

The second one specifically by focusing on school nurses. There's been some work done in that area, but very little. Comments?

Dr. Susan Levine: Now I guess the question is, and I know you've probably researched this Faith, is does HHS have any power to affect this change or work with DOE? Is that one of HHS's roles? I mean if we can make it fit, it sounds like a great idea to all of us I'm sure but I think that was an issue before.

Faith Newton: It was and I asked (Nancy) about it, which is why I reworded it a little bit different way. Because it says, instead of making the real, the recommendation on whether or not there should be, it's to evaluate the need and feasibility. Is it even possible to have a cooperative effort doing HHS and DOE?

I think that falls within (Nancy) can you comment for me?

(Nancy): I think that, and whether or not we'll, you'll find out if it's feasible, but it certainly is something that can be looked at and I mean that's' the purpose for the work group to evaluate in and assess feasibility. I think it's okay, I know there's not a whole lot, I mean…

((Crosstalk))

Dr. Susan Levine: Well I mean in ones like CDC posts information on its website about pediatric MECFS or will and (Herso) we found out is involved in some pediatric types of information dissemination. I mean, I think it's an interesting area and certainly something I see in my practice where there's a great need. I would

say that not only the nurses, but I mean, you may not want to go this far but the school psychologist and the teachers. I think everybody in the school really needs to be educated but, you know.

Faith Newton: We can add that, that's fine with me and I was thinking along those lines as well. Is Vicky Whittemore still on? Because she had a couple good suggestions way back in the fall when I was thinking about this.

Dr. Vicky Whittemore: Yes, I'm on.

Faith Newton: Vicky what did you say, you, and I'm sorry but I don't remember what you were suggesting, but you thought that there was a way to do this and that you had contacted DOE. I hate to put you on the spot, but that we might be able to work with to see how we would move this forward. To see if it was feasible.

Dr. Vicky Whittemore: Right, so I don't have a contact but I previous, when I was previously working at the Tuberous Sclerosis Alliance, we had a full time staff person who did nothing but help children get the educational, get their educational needs met. For those that had special needs of any kind and she has, I mean she would be fantastic to pull into this. She's so knowledgeable and then she has contacts at the DOE who I think we could access.

Faith Newton: Okay, that would be - that would be wonderful. Still we could put together the working group then she move from there and see what it is and making sure we stay within the confines of what HHS can and can't do.

(Nancy): Yes, exactly, I just want to…

((Crosstalk))

Faith Newton: Yes, I hear you.

(Nancy): These are set - these are recommendations to the secretary of HHS.

Faith Newton: Correct.

(Nancy): I think there many, many things that can be done but can it be done, I mean, is this the best method to do it? I'm looking at the second, the first one I'm sorry, and as part of the whole issue that we've been talking about the last two days. About educating providers, I don't know how critical the Department of Education is if we aren't doing the educating of the providers. That one to me is less of a stretch, let me say. Because we, HHS has several activities now around educating health care providers, regardless of the topic of those, you know, the education, so.

Dr. Susan Levine: Are you meaning the Physicians are at the school itself, or?

(Nancy): Most schools don't have physicians.

Dr. Susan Levine: Right. Well the reason I ask, is I actually participated in a few hearings even though I'm not, I'm an adult doctor, I take care of some adolescents with MECSF. There have been physicians, pediatricians that seem to be, and they're not school doctors but they have some stake in the school or some interest, I mean I'm not sure.

(Nancy): I think most schools are lucky to have a nurse.

Dr. Susan Levine: Well maybe this is a district physician? I mean I don't know. I just remember there being a doctor who totally did not think this patients - should be allowed any kind of accommodation. The doctor, the pediatrician, I just thought that

certain pediatricians who have more to do with school policy than others, I don't know, this just happened to me.

(Nancy): Anyway I'm just saying that for the first one doesn't need as much input from the Department of Education as the second one would.

Dr. Susan Levine: Would you specifically want to say pediatrician awareness? Or does it matter, you want to leave it as physician awareness?

(Nancy): I think providers.

Dr. Susan Levine: Oh providers.

Faith Newton: Because some people go to nurse practitioners.

Dr. Susan Levine: Oh that's a good point.

(Nancy): Yes, they go to nurse practitioners, especially…

Faith Newton: They also, I can tell you right now, if they need, just like testing for processing speed and for other issues along those lines there going to see a psychologist or a psychiatrist because they need to have that testing done. That's on an MIOP. So actually changing that word to improve, you want to change it to approve…

(Nancy): Providers.

Faith Newton: Providers, awareness of their role.

(Nancy): Yes, that makes sense.

Dr. Susan Levine: Then you, I don't disagree with removing the DOE from the first, you know, paragraph.

Faith Newton: You want to take it out Sue, why?

Dr. Susan Levine: Like you just, like, you know, (Nancy) was making the point, I guess we don't need DOE in that, right, because the whole effort of HHS and educating - you know, doing education efforts.

(Nancy): I think DOE - I think that understanding what schools can do is important. It's just not a primary role. For us I think to get involved with school nurses is much more of a stretch. I think you still need to have an understanding from DOE. To me DOE is Department of Energy, so I…

Faith Newton: I got it.

(Nancy): Department of Ed.

Faith Newton: Department of Education.

Faith Newton: Yes, to approve.

Faith Newton: We need to write that out then.

(Nancy): I mean you could leave it like this…

((Crosstalk))

Faith Newton: DOE is Department of Education.

(Nancy): This isn't a recommendation, this is a work group, so I don't think it really matters that much. But I do think it's a different level of involvement with Department of Ed.

Faith Newton: It is exactly that. It's a work group that's looking at the need and the feasibility for doing this. Is it even possible? I think that's the question we're looking at answering.

(Nancy): I think the made is there. To me the real answer here is the feasibility.

Faith Newton: Okay.

(Nancy): I don't think anybody would disagree. I mean, I think it's good to get the need in there, but the feasibility is the one that.

Dr. Susan Levine: (Nancy) how do we go about finding that out before we embarked on?

(Nancy): That's what the group would do.

Faith Newton: Right.

Dr. Susan Levine: Oh so, okay.

Faith Newton: That's what I thought too, the group would figure out if it was feasible to work together.

(Nancy): Probably looking for other similar, I know that we sometimes work with Department of Education. We're doing that right now on sexual assault on college campuses. We've been working with Department of Ed on that but it's,

yes. But how do you go about doing it and are there very robust partnerships that have been developed around certain things, I don't know. There may be, but that's what I think. Look for these ways that it's been done well in other realms between health and education of kids.

Faith Newton: All right just a second, say that again because that's really important. You want to look for other ways?

(Nancy): Other parts, other places or other topics, there we go. Other topics at HHS and Department of Education have come together to develop robust plans or programs or initiatives or something like that. Where they actually work together to get policy changes in through either HHS or through Department of Ed. Because what you're really talking about here in a lot of ways are policy changes. Right?

Faith Newton: Well it could be but it also could be something as simple as sharing of information. Where…

(Nancy): Remember schools are a state, are state entities. The Department of Education is not going to go willy-nilly in and telling the state what to do.

Faith Newton: Yes, but I'm not looking at it that way. Schools, you are correct schools are state entities but what is rule here is federal rules. A 504 plan and an individual education plan is what our students, our pediatric students who have MSCSF are placed on. That's all federal guideline, that's all dictated by, USDOE.

(Nancy): Right and all I'm saying, I agree with you all I'm saying is those are policies.

Faith Newton: Yes, I agree, you're right.

(Nancy): What can Department of Ed do, for example, to influence nurses, school nurses? They would have to work with whatever policies that they can implement directly or whatever they do working with states. Around, because these are big policy issues, because they are not, they, you know, they don't do it at the, you don't go from here to the local level immediately.

Faith Newton: That makes sense to me. That's why we're back to exactly what we said. Looking at the feasibility, if this is even possible. That's what the charge of this will ultimately be. Is this possible to do this? As you said, has it been done in other areas where HHS and Department of Education have come together and how is that worked and can it be done.

(Steve): Are you talking about, this is (Steve) developing materials to give to school nurses so they have something to look at when the issue comes up? Or are you talking about something different?

Faith Newton: I don't know if we're there yet, I think we have to start at the, ultimately that's where I would like to go. I think first we have to find out if there is even a vehicle for having those conversations. Whether or not those two agencies can come together and if they have what is the protocol, the process for doing that. I think there's a whole bunch of questions that have to be answered first. Then we can go from what we would advise and what would we come up with. I don't know because we have to say as (Nancy) said, within the purview of HHS.

(Steve): The Department of Education could tell you what's necessary for an IEP or whatever it is your looking at and then HHS could develop materials to give to the Department of Education to distribute to the appropriate people. I mean…

Faith Newton: That is one thing that can be done absolutely. You know, again if it's feasible.

(Steve): Got it.

Dr. Susan Levine: I mean I think it's a great idea. I even want to join the working group, so. You know, I think it's, you know, it's all mostly investigatory type of working group for now. I mean, I think it's definitely worthwhile to find out because this problem isn't going to go away and we really need to do something about it.

Faith Newton: It's getting worse.

Dr. Susan Levine: People are very antagonistic, I find.

Faith Newton: They are very antagonistic and it's very, I feel so bad for the parents. They're going through enough as it is and to be told that your child may, you know, may not graduate, can't come to school, has to repeat the grade. They don't understand the resources that are available for them. It just is, it's just kind of heartbreaking on the parents when they're already dealing with, you know, illness/disease that they don't, that's got so many ins and outs they don't know what to do.

I mean, it is very, very difficult.

Dr. Susan Levine: Yes, no I definitely think it's worthwhile. I think it certainly be this working group certainly be something that we put on the table for next time. Then I'd like to submit for possible other working group is (Suchi) or (Aaron), if you have any ideas around which we could form a working group or any of the other ex officio's on the line. If there are working groups that you might

suggest for our members. (Nancy) you had something specific in mind, (Suchi) right?

(Nancy): Yes, this actually came from, I sent it out today, if I can find it on here, my email. This actually came about after a discussion with the ex officio's last month and I asked them if they had anything they would like for advice and help from the committee. There was lots of positive remarks around getting, forming a workgroup to give advice to the HHS agencies about good ways, not just one, but a number of ways for stakeholder engagement.

Not just from a FOCA committee, because those as you know are, have some fairly height boundaries around them that can be inhibiting. Plus, we have (Systac) already. Just what are models of stakeholder engagement particularly around research that HHS could use to get better, you know, consistent long term, sort of an infrastructure for getting patient and researcher and healthcare provider input into the research that's done. This was focused on research and getting stakeholders engagement.

Dr. Susan Levine: Would that be paired with like the NIH, you think, or?

(Nancy): Well no their research is done on MECSF. CDC at ARC at NIH, FDA doesn't do the research itself but it could probably use some of the same techniques around, sort of their approval process. Those are the main research agencies that are represented on this committee.

Dr. Susan Levine: Do any of the ex officio's, let me ask maybe Janet you think that would be a feasible partnership?

Dr. Janet Maynard: Excuse me, a feasible partnership in terms of having the different agencies engage with (Systac)?

Dr. Susan Levine: Or your agency in particular. Perhaps I just try to explore, perhaps evaluating what our stake, the stakeholders that we represent may want to have done, or what, you know, I don't know what the possibilities are, but.

(Nancy): I think what I was talking about was a work group that gave recommendations to (Systac) on how stakeholders could provide ongoing and robust input into research on CFS, I mean CFS in the department. It's not really for (Systac), it's for the agencies. (Systac) would give recommendations. Let me get the email that I sent out earlier today.

Dr. Janet Maynard: Then can she type it up.

Faith Newton: I was looking for it myself.

(Steve): I've got it right here if you need.

(Nancy): Yes, let me look so you don't have to. Here

Dr. Janet Maynard: This is Janet, just to make sure I understand, so I think this spirit is that it would be almost a way how to foster stakeholder collaborations to enhance research efforts on MECSF, is that correct.

(Nancy): Say that again Janet.

Dr. Janet Maynard: My sense is the spirit of the proposal was about sort of fostering stakeholder communication and collaboration to enhance research efforts concerning MECSF. Is that correct?

(Nancy): Syreeta is putting this up on the whiteboard right now.

Donna Pearson: This is Donna can I just, you know, I sometimes get emails at work, some of us are getting emails as we're talking. I just received an email stating that, there's already a well-established process for AIDS. Why cannot that be leveraged instead of (Systac) having to like start from scratch to figure out how to do it. Another email I got was that (Lillie)…

Faith Newton: Wait a minute, Donna what are you, are you talking about the emancipation advocate community stakeholders working group or the other two?

Donna Pearson: The one that (Nancy) suggested.

Faith Newton: Okay, I just wanted to be clear.

Donna Pearson: Yes, the question is why does (Systac), why are we reinventing the wheel and taking another year and there are existing mechanisms. Something called community based participatory research. I guess which is a well-established processes for involving patients. My understanding is (Lilly Chu) is putting together panel for the ICSFME conference in the fall.

I also know that the advocacy community sent in very detailed letter, fined by a lot of organizations, including, Open Medicine Institute and Carol's organization with a whole list of recommendations on how to engage the community already. So I'm not sure what would the point of another work group about this be.

Faith Newton: Do we know about, do we know, do we have those recommendations that are specific for ACSF?

((Crosstalk))

Faith Newton: When I said here, the second sentence, the work group process would explore this comprehensively looking at models that are used successfully for other balm medical research areas, such as HIV. And explore the interaction among the patient community researchers and HHS research agencies. Then they could come up with recommendations after exploring what is already being done out there and other models.

I think I saw what policy CSF sent forward a couple months ago but I don't remember the content all that well. I just don't, if this is already done, that'd be great. I will just tell you that this is what the ex officio's asked for advice from this committee.

Carol Head: This is Carol from Salt MCFS physician. If I, yes as Donna said we and other organizations had requested, you know, what we need got, obviously there are many federal rules regulations, stipulations about how communication can occur. We struggle to understand them. We had put forward with many others, sort of our desire to be well integrated into the several processes that are going on.

I can't say that we comprehensively understood now how to move forward. I'm not sure, I'm sort of with Donna I don't know if there's any more we can do. You know, we, we're, we lack the knowledge, we recognize that there are many constraints on working directly with patient advocates and researchers external to the federal government. We struggle to understand what they are, I mean, I'd almost turn it around. We'd love to get guidance from the ex officio's on how to do it.

Again I don't know that setting up a committee would help us.

Faith Newton: Can I, this is Faith can I chime in here. I would really be interested in this. You see how these, how everybody works together. I simply don't understand it. To me this work group would just spell that out, I mean, I don't. Getting all the stakeholders involved and then seeing what they could come up with. What models are successful? I think that would give, MECSF our group some type of how do we move forward what we have been trying to move forward all these years.

Carol Head: You know Faith I agree with you on that objective. If there are those like you who have the, are interested in working on it I absolutely applaud that. I'm just not sure, well I'll leave it there.

Faith Newton: I don't know what would come out of it, but I just would be very interested in seeing what is out there and what can we do. What has worked or not worked.

Dr. Susan Levine: I think a lot of us, including myself, don't really know what is out there in terms of resources from these different agencies that could help promote MECSF research and clinical.

(Nancy): Well, and this is (Nancy), and what other diseases where the models have shown success. Such as, is the HIV is act up and all of those HIV, there's many HIV agencies, breast cancer research. I mean, so what are the successful models, how do they work, how do they look like.

Dr. Susan Levine: In other words, how have they used the agencies resources to help?

(Nancy): Or their own.

Carol Head: or their own, how do we move forward. I agree, I don't have any idea.

((Crosstalk))

Dr. Susan Levine: What has been put in the mix here? And how do we put that thought into a couple of sentences for that that wish, that.

(Nancy): Yes, so this is not…

((Crosstalk))

(Steve): Are we talking about schools or did we broaden it as a second one says.

Dr. Susan Levine: We're, now we're talking about just a general improvement.

(Nancy): We're to a third one and that's just patient advocate community.

Carol Head: Where did I put it, put a page.

Faith Newton: Number them, one, two, and three. Actually one just has two charges, that's all.

(Nancy): Does it have to be a new page?

Dr. Susan Levine: Yes, or just get it out of the way so they don't see. Just keep, there you go.

(Nancy): So this is a new, this would be a different work group. And this is the information that I, this is the idea that I sent out this morning. It was based on a conversation that I had last month with the ex officio's. So the ex officio's, you all may think, you know how it's done, but the ex officio's felt this need.

Faith Newton: It also might give us more clarity on how we go about moving this forward.

(Nancy): Is this Faith?

Faith Newton: Yes, sorry, it's Faith.

Donna Pearson: So let me ask this question, would you, would the ex officio's be just as happy to hear directly from the patient community working together to put something together. Which could probably be done in 30 days instead of waiting for, you know, a whole big process. I'm not trying to discourage anybody who wants to work on this, but if the ex officio's are asking for something the community would love to help.

Faith Newton: But you notice it's also got researchers in there.

Donna Pearson: Yes, well we, the Open Medicine Foundation which participated in this last thing is a huge research organization. Would (Ron Davis) and (Andrew Colgolnic) and I don't remember who else right now. It's huge research organization.

Faith Newton: Is it, it's Faith again. Isn't it, isn't the key point is how we work together successfully as a community.

(Nancy): Is there more than one opportunity, more than one model that could be used for different situations. For example, you know, for the internal, for the intramural research that's happening at NIH that may have a different model than the extramural research that's being planned. For the way that CDC does its research where they don't do any extramural research. Is there a different way there, so what are some different models that we could learn from.

You know, if it only took a month for the group to put it together that's good. Then we just wait for the next, we just wait for the next seat, (Systac) meeting which will be in the fall.

Dr. Susan Levine: So do we have our proposal up there already or are we still talking around ideas?

(Nancy): We put it up there, it's sitting there.

Dr. Susan Levine: Okay. It doesn't seem very clear to me, I'm sorry to say.

(Nancy): Well no that's why we're here. If you have, can you see what we wrote up there?

Dr. Susan Levine: Yes, I just.

(Nancy): That's basically what I proposed in my email this morning.

Dr. Susan Levine: Yes. The idea is to explore existing models that we could parallel or do some similar that have been successful in the past. Which HHS research efforts has been involved.

(Nancy): And which haven't been successful.

Dr. Susan Levine: Right, and sort of analyses. I mean I'm just trying to fine tune it a little bit, I'm sorry.

(Nancy): Yes, ell no that's what, and please these ideas came from ex officio's so I've been speaking but Vicky or particularly Vicky and Beth and (Suchi), (Suchi)

may have left, (Suchi)'s not feeling well, so Vicky and Beth who are the other main research agencies. Do you all have, this was originally your idea.

Dr. Vicky Whittemore: This is Vicky and I'll speak up, but I think, you know, it's certainly we've been working on this and thinking about it and certainly have received the input from the advocates but I think what challenging from our perspective is there are so many voices out there and we at NIH have to be fair about who we involve in discussions and include in any kind of committees, working groups, whatever you want to call them.

It's been difficult for us to figure out how to do that in a fair way. I know we've had a conversation with Janet at the FDA in terms of how they take nominations and select patients to be part of different things. It just still is a challenge, I think for us to understand how we can do it in an open, fair and transparent way.

Coordinator: Excuse me this is the operator, we would like to remind parties to state their name for the note taker. Thank you.

Dr. Vicky Whittemore: Sorry this is Vicky Whittemore.

Dr. Susan Levine: Are you saying Vicky that you might still suggest that, say you would be part of a certain working group that might discuss ways in which your agency has helped other stakeholders in, you know, HIV say or take some other examples. I'm just trying to word smith it into a proposal. It doesn’t have to be perfect but just, you know, so we have something that we can invite people to join for this next. I mean, to me, I think the agencies resources are underutilized by our group.

If we could learn something through working with the different agencies. I'm just not sure how to phrase that exactly or what the right way is.

Donna Pearson: This is Donna Pearson, so Vicky you're basically looking to the (Systac) as the so called experts, I guess because that's what we're supposed to be. To give guidance on how to deal with the fact that you are hearing from so many disparate, groups and different opinions, is that the gist of this?

Dr. Vicky Whittemore: The gist of it, no. The gist is if we put an - say I'm using advisory committee, but I don't mean that. Say we put a panel together of MECSF stakeholders to work with us, it's like how do we determine who should be at the table. Because there are so many voices. You know, not all the voices say the same thing. Not all the voices have the same opinions, which that's now the problem, it's just that there are so many out there.

If we would want, we would want to do it in as constructive of a way as possible and, like I said we've been working on this and thinking of different ways to integrate the stakeholders into our different activities.

Dr. Susan Levine: The priorities of the stakeholders and how they mesh with the expertise of the agencies perhaps? Or

Dr. Beth Unger: This is Beth Unger and we just went through this kind of when we put our technical development work group together and actually getting the group composed was one of the hardest parts of it. We didn't, we tried to be an inclusive as possible and gave everyone the opportunity, all the groups that we knew of, the opportunity to participate and we definitely wanted it to be open.

For research, other research groups that I've been involved in, let's just say the, for example, the Department of Defense has Gulf War Illness research

program. They have advocate participation, I don't know how they did that, I don't know how they pick those but there's an advocate representative on every grant review for example. I don't know, you know, so this was to just say this is where we're at, I mean eventually, I guess what we could all, you know, get an answer. It would be a way that the work group could do some research on this and come back and say, these are the models that we've seen and this is the one we think would work best for…

((Crosstalk))

(Nancy): Or I think you're going to need more than one model frankly, this is (Nancy). I think more than one model because.

Dr. Vicky Whittemore: There different activities going on

Faith Newton: Well and possibly, I mean possibly we don't need a work group, we just need more discussion. If the group feels as if this is something that we can work through together with the advocacy community and not need (Systac) involvement I'm fine with that too.

(Nancy): It's not just the advocates, it's also.

Faith Newton: Right, it's the entire, it's all the stakeholders, correct.

(Nancy): It's all the stakeholders and that's key and, you know, a lot, and it' also, this has been one of the problems that I've seen. Is that too often the regular primary care provider who doesn't know very much about chronic fatigue syndrome has been left out of the stakeholders? If you want those people to figure out what to do about somebody with chronic fatigue syndrome, you

need to hear from them. I think all of these things are important and it's not just about the advocates and the patients.

It's got to be a broader thing and I - you know, I think that's what you saw in some of the most successful HIV groups. I've worked a lot with the breast cancer organizations and that's what they have. That's sort of what we're talking about, so I would hope that since the ex officio's asked for this somebody's willing to take this on.

In the meantime, Vicky or Beth do you have some word tweaking that you could do to what I've got up here that would help verify.

Dr. Janet Maynard: This is Janet from FDA, I wonder if one of those things we're trying to emphasis is really the importance is sort of hearing the voice of patients and advocates as we think about these search efforts. Emphasizing sort of either stakeholder collaboration or really just making sure that things that we do are really are reflecting what's important to the patient community.

Dr. Susan Levine: Yes, I think it's important to have the conditions and researchers be involved as well. I mean it all sounds important but it almost sounds beyond the reach, it seems like too ambitious a project in a way, but I don't, I don't, know.

Dr. Beth Unger: We have clinicians and researchers and patients on this committee.

Dr. Susan Levine: Right. But on the one hand, I mean, yes it sounds like a great idea to me but Vicky is saying that maybe it doesn't have to be a working group I don't know. Maybe we could make it like a research working group to see what the possibilities are than report at the next meeting. I don't know.

Dr. Beth Unger: A research working group?

Dr. Susan Levine: Well I mean that this working group would be comprised of people who would investigate other models, other disease models and how, you know.

Dr. Beth Unger: Right, but it wouldn't just include researchers.

Dr. Susan Levine: No, I didn't mean it that way exactly. I guess like investigatory type of.

Dr. Beth Unger: Right, but then so you could come forward, I mean, recommendations can come out of this.

Dr. Susan Levine: I just don't even know how to word smith, I guess it's the end of the day, I don't know how to word smith what your trying to say. I kind of, I have the gist of what I think you're trying to accomplish with it, but I'm not sure how to write it up in a way of a proposal exactly right now.

Dr. Beth Unger: Well would it be, I'll take a stab at it, investigate models by which MECSF stakeholders can productively be involved, I'm not sure productively is the right word there but, in discussions around research and research priorities. I guess that's what I'm trying, that's what I would be interested in. I'm not sure you need the word productively in there.

Dr. Susan Levine: Can generate a productive discussion, I don't know.

Dr. Beth Unger: Can be involved, I mean just

Dr. Susan Levine: That's good. Yes.

(Steve): Effectively involved.

Dr. Beth Unger: Yes, that's a better word.

(Steve): (Steve).

Faith Newton: This is Faith why don't you put in there, I think Vicky you were the one who said it. Models that look at a fair and transparent way to effectively involve, I don't know, again I'm tired too, so I don't know if I can word smith it.

Dr. Susan Levine: Do we want to look, research and clinical priorities? In MECFS.

Faith Newton: Yes, that's a good idea.

Dr. Susan Levine: Using…

((Crosstalk))

(Nancy): What do you mean by clinical priorities?

Dr. Susan Levine: Well I guess bedside, I mean I'm talking about more, what is needed for patient care, I don't know how to.

(Nancy): I think that's a, if we're talking about the research agency that's a really different topic. I would just certainly.

Dr. Susan Levine: Well, it feeds into what we ultimately want to give the clinicians tools, by which they can help patients, I guess that's where I'm getting at. I know you guys are directly involved in patient care but the research priorities revolve around what, you know, from bench to bedside type of thing.

(Nancy): Right, and I think that's involved in research. That's what research.

Dr. Susan Levine: It's implied, that's your saying.

(Nancy): Right.

Dr. Susan Levine: Okay.

(Nancy): Take out in clinical, yes, because. Maybe say and research

Faith Newton: Okay and research.

(Nancy): Projects or project efforts.

Faith Newton: Research efforts that involve all of the stakeholders in a fair and transparent.

(Nancy): Well of course it would be fair.

Faith Newton: Well right, but that's what, I'm using Vicky's terminology. Fair and transparent and I want to say way but.

(Nancy): I think transparent is a very good word to add in there. I think that.

Faith Newton: We legally have to do everything fair and transparent.

(Nancy): Well right I got that, it doesn't hurt to remind people.

Faith Newton: Right. This is Faith by the way talking

Dr. Susan Levine: Do we want to say anything about, use the word agencies and mention you guys or?

(Nancy): Oh that's a good idea.

Dr. Susan Levine: That's what we're trying to, we're sort of trying to marry the stakeholders with the agencies in a way.

(Nancy): Involved in discussion just to get no, let's see.

(Steve): Discussions with.

(Nancy): Discussions with, well it's not the discussions, it's around HHS research priorities. Yes, put HHS, there you go. Did that make sense?

Dr. Susan Levine: I think the last part of that sentence is kind of redundant sounding but I know you want to use the word transparent. But I don't like to use the word stakeholder again. It just makes it sound awkward I think.

(Nancy): Just say, that are fair and transparent.

Faith Newton: Fair and transparent, period.

Dr. Susan Levine: That are fair and transparent.

(Nancy): Yes, just go from, yes. And then just go to fair and transparent.

Dr. Susan Levine: Now I think that we've sufficiently ambiguous for now until we really decide. I think it's a great idea.

(Nancy): Vicky are you good with this?

Dr. Vicky Whittemore: Yes, I think this is fine.

(Nancy): I mean you wrote it.

Faith Newton: Let's hope.

(Nancy): Yes.

Faith Newton: Can you, let me ask a question, where it says, investigate miles by which MECSF stakeholders, can you put in there or is this redundant. And agencies can effectively involve and discussion around HHS priorities because we're looking at both groups and having them work together.

(Nancy): And HHS agencies?

Faith Newton: Or just agencies.

(Nancy): No, you want it to be HHS.

Faith Newton: Okay, and HHS agencies.

(Nancy): You don’t give recommendations to the secretary about (unintelligible).

Faith Newton: Oh okay. That makes sense. This is Faith again.

(Nancy): Donna does this address some of your issues?

Donna Pearson: Yes it does, thank you.

(Nancy): Are you comfortable with it?

Donna Pearson: Age wants it, we sure as heck want to provide it.

Faith Newton: I definitely am interested in this. This would be very interesting.

(Nancy): That's Faith.

Faith Newton: Yes, I am not leading two working groups.

Dr. Susan Levine: I know, I was just going to say, how you could do that.

Faith Newton: Not happening. You don't have a…

((Crosstalk))

(Nancy): Do not do that.

Faith Newton: I have a bad arm break and I'm literally in rehab three times a week for my dominant arm so I can do one but I'm not going to do two.

(Nancy): Can we get one, some of the researchers on the committee to lead this?

Dr. Susan Levine: How about you Dane?

Dane Cook: I'm considering it, I'm just looking at my schedule.

(Nancy): The other, I mean.

Dane Cook: I really like this idea, yes I was a little surprised people didn't jump right on it. I think this is something we've all been asking for, for years, is to be involved in the process. Creating a process to get that involvement I think is great idea.

(Nancy): Another person that might be really good for this is Carol. I'm - we talked, we called her up and told.

Dr. Susan Levine: Is she still on, as we volunteer her?

Carol Head: I am on.

((Crosstalk))

Dr. Susan Levine: You could be co-chairs.

(Nancy): Well she doesn't have to do anything, but I'm just saying this, I think Carol would be a, this is one of the things you do.

Carol Head: Thank you (Nancy), I have to pass on this. I just don't have the bandwidth for this.

(Nancy): Yes, you're so what?

Carol Head: I just don't have the bandwidth for it.

(Nancy): Yes, I got you. Well you know since you are an organizational rep if there's somebody else from your organization that would be okay. Just saying.

((Crosstalk))

(Nancy): We all, both of our, all of our work groups in the past have benefited by having people that are volunteering and are not members so that's okay too, so.

Carol Head: You know, and I just got an email from someone who's not on (Systac) who I think would be terrific on this. Can we bring on non - well obviously we have a precedence for bringing on non-staff members for these working groups, so. You might want to reach out to (Courtney Miller).

(Nancy): Okay. She maybe on the phone. She got volunteered to.

Carol Head: I want to reiterate the same thing. If your folks are interested in working in the pediatrics, please reach out to me.

(Nancy): I think we need it. I think we need a chair who is a member.

Dane Cook: I'll do it, this is Dane.

(Nancy): All right Dane thank you. You're a wonderful gentleman.

Donna Pearson: I'll serve on it, Donna Pearson.

Dane Cook: Thank you Donna. I'm looking forward to many helpful members.

Dr. Susan Levine: Does anybody have any ideas for another working group? Or is that all, right for now?

(Nancy): I think if we have two unless if somebody’s got a big one to propose.

Dr. Susan Levine: I'm just asking, I realize that two is fine.

(Nancy): I think two is also maybe the max.

Dr. Susan Levine: Right, but I mean if we didn't reach enough interest in both I just want to make sure that, you know. That we have hopefully equal and similar involvement in both.

(Nancy): Yes, do we have members for both groups. Okay so Faith's going to be the chair for the first one.

Faith Newton: Right, we'll send out, (Nancy), I'll send you an email, maybe Syreeta can send out something.

(Nancy): All right thank you.

Faith Newton: You're welcome.

(Nancy): Certainly people can be involved in both. Also if we can and we need primarily for these work groups to be led by members of (Systac) but we certainly want to get input from and input from non-members. We're totally open to that. It's just we need to make sure that this is a (Systac) member run process. If you have, if you are on the phone, if you are not a member of (Systac) and you're interested in participating send me an email and the (Systac) mail box or to Dane or to Faith.

Sue can get, if you've got Sue's email, you can send it to there too. We'll constitute these.

Faith Newton: (Nancy) I have a question for you. Do we have any idea if we're going to under (unintelligible) have in terms of planning and what I'm going to be

doing? If we are going to have that solved earlier, like in September or October. Or are we moving towards November, December, do you have any idea?

(Nancy): I don't know yet. I would think it's more likely after the election than before the election but who knows.

Faith Newton: Should have thought about that. I hear you.

(Nancy): Yes, the, as you know. The problem with October 1, is it's the end of the fiscal year. Or beginning of the new fiscal year and if we don't have a budget passed by that time then we cannot have a meeting. We are loads to create meetings right around October 1, or right on October 1 or shortly after because they get canceled and I think we had that happen. If we have that happen, or it was another meeting. Yes, it was another meeting I was involved in that got canceled. That's the main thing.

We won't have it around the first two weeks of October I'm here to tell you. We'll either do it in late September or after the first couple weeks in October. That make sense? It will be an in person meeting.

Faith Newton: Yes, all right so late September or mid to late October.

(Nancy): Or November.

Faith Newton: Or November.

(Nancy): Yes.

Faith Newton: Will we have, who's on? When's the IACSFN conference? Does anybody know off the top of their head?

Dr. Susan Levine: The end of October.

Faith Newton: End of October okay.

Dr. Jose Montoya: (Nancy), this is Jose Montoya. Now that the just this one - kind of like a statement and something for the group. Now that the ION the NIH, CDC, FDA, and other major government organizations recognize MECSF. As a (unintelligible) worthwhile of being researched and understood and in my view this is the greatest scientific challenge of the 21st century.

Major funding is ultimately required to really make a difference short and long term. I really would like the safe sack committee explores ad recommends what are the other avenues separate from the NIH that can be explored for the level of funding that we need. You know, which is in the order of, order of hundreds of millions of dollars. I think that several people who have commented on this, to the (pediat) have alluded to the fact that for other diseases, and I know and I am aware of the mechanisms are different.

But for other diseases and other organ issues, you know, hundreds of millions of dollars can be put in place for those processes, for those diseases. I really would like to Safe Sack takes us see a shot of this. That somehow in a thoughtful, careful way we come up and I'd be happy to share this, to committee. Come up with recommendations that this is really badly needed, originally needed separate from how it can be done.

One thing is the concept that this disease really needs literally hundreds of millions of dollars now so that a major difference can be made in a five, ten-

year period. It is going to take time from when you do the research to the time that the outcome of that research gets done and polished. It's going to be five, ten-year period. If we start, the longer we wait and they, very low funding is placed, that is going to be worse in terms of timing.

Dr. Susan Levine: Your proposing a diff - another working group, Jose, or?

Dr. Jose Montoya: I'm not sure Susan, maybe yes to would be that. I just, you know, I hate to see on the Safe Sack and see things happening very slow or not happening and I think that what I can see at the 35 thousand view is that, I'm happy and is refreshing and is wonderful to see ION, HIH, CDC, FDA everyone align around. This is finally something that needs to be researched. But the funds are going to take, how many years to really come at the level that the disease needs and deserves.

I wonder if, because Safe Sack has that advisor capacity that something that is carefully thought and analyzed be put together where we said, beautiful what has happened at the NIH. Wonderful what is coming out of the NIH, but also, you know, presidential funds, congressional funds are really needed badly originally. It's true, it's not Zika, you know, producing the micro (unintelligible) it's not Ebola killing patients.

Patients really lives have been completely I hold for decades. It's really painful to see these patients in clinic every week here at Stanford.

(Nancy): Jose I totally get your concern and your big picture view. (Systac) makes recommendations to the secretary. That's what's the charter says and (Systac) has made multiple times recommendations for large increases in funding. In HHS for secretary, for MECSF research.

We can't, and the secretary is forbidden by law to go to congress. That's for the advocates and that's for researchers, such as you to do. We cannot do that. We're forbidden. The, all the secretary can do is around the recommendations for research and the agencies here within HHS. The president, we can, the presidential budget, we have input in that, we just have, we just got a little introduction to that process this morning. It's, they are now, just now giving input into FY18 budget.

That's a little difficult because it's after the election and we don't know what the new administration is going to be or what that priority is going to be. You could recommend to the secretary to include inform, to include in the presidential budget but that's sort of already been recommended. Given that there's been, I don t know, I think we counted once, there's like seven recommendations for it from out of (Systac) for increased funding.

Dr. Jose Montoya: Can we take that for the next cycle then?

(Nancy): I beg your pardon?

Dr. Jose Montoya: Can we take then this to the next cycle, to the next meeting or cycle.

(Nancy): I mean, yes, I mean I don't know if another work group, I mean you can make that recommendation today if you want. As long as we have a quorum but as, you know, I don t know what else the work group would do. I think Vicky is already talked about the tough, she mentioned that yesterday and then again today the very difficult budget cycle that NIH is on right now. Because of things I don't understand if it's about this that and the other.

The budget process and the federal government is very complicated and so certainly it is here as well. I am no expert but so that's just my, I'm not sure

that the work group could do any more than has already been done by this committee.

Dr. Jose Montoya: I really…

Dr. Susan Levine: I think it's good Jose put that on the record. I think unfortunately, you know, that.

(Nancy): Remember yesterday we made a recommendation for a 60-million-dollar budget.

Dr. Jose Montoya: Right, but that was because it was to the NIH, right. What I am proposing on the table, formally recommend or formally proposing is that we as a committee suggest or recommend that the other avenues of where larger and more immediate funds can be put into the disease right. You know, it has been 35 years, very little has been accomplished. Not just because, you know, the disease was start to be psychological was one of the reasons because research perhaps even half of the rigor that was another reason. The finding was not there, another reason.

That was because the decisions really complex. There are many phenotypes and one patient is different now and in a few weeks and in a few months so it is a hard thing to deal with medically and scientifically. That called for heavy funding around really good people and good group. How long it's going to take for that level of funding to arrive, so I think it's an obligation, as fast as a committee to say, so regardless of the obstacles out there to get those funds.

You know, if we go back to early 80s when HIV was even thought to be punishment of god. Look at what all the activism and the resistance to put those funds into HIV was there. It was thanks to those patient's and other

things that happened back in the early 80s. It took only three years, March of 84 to discover that it was the HI virus and in 85 a year late there was a psychological test for the diagnosis, and so on.

Then 95 the cocktails, the protease inhibitors came into place and those lives were saved. It was because of the funds and the research that was behind. I think there is somehow if we see this picture, if we as a committee see that we really need that level of funding, like now. Then we should say so. That the mechanism or avenues that are within the legal frame, you know, this committee can only advise that part or that part.

Whatever it is legal and appropriate I think we should say so regardless of how difficult that can be accomplished.

(Nancy): Well I guess.

Dane Cook: This is Dane, Jose can you clarify, for me at least how that is different from our previous recommendations asking for funding that's commensurate with the magnitude and impact of the disease?

Dr. Jose Montoya: That we go further. I am aware that we made a recommendation yesterday for the 60 million dollars for the NIH for the Centers of Excellent. I am aware that we have asked for level of funding…

((Crosstalk))

Dr. Susan Levine: I think he is referring to another, further back recommendation, right?

Dane Cook: Yes.

Dr. Susan Levine: That just an open ended one for greater funding, commensurate with the disease burden.

Dr. Gary Kaplan: Jose would you, I'm very intrigued by what you're saying and wondering if the next step past the Centers of Excellence is to produce a road map that talks about the deficiencies in research in this field. Proposal, a white paper essentially proposing a road map for studies that need to be conducted and areas of, for areas of advancing the research most rapidly.

Is, so I'm trying to do this on the fly, but essentially it's a white paper that creates a road map that says, here's the areas of most fruitful research at this point in time. Here's areas we thing should be funded and by here's the price tag.

Dr. Jose Montoya: Right, but that is slightly different, Gary that I think is strategy. On the previous comment that, how is this different from what has been recommended before, is that, there are two things that I see different. One I don't know when that recommendation was made but I think this is a historical moment with this disease. Where entities like ION. NIH, FDA, CDC publicly are acknowledging that this disease is real and needs to be researched, understood and have treatments available in a relatively short period of time. I think that, that's unique for 2015.

Second is somewhat different before or more specifically because we are now saying look at the presidential funds. I mean the office of the president appears to have the autonomy to say, we're going to dedicate five hundred million dollars for brain research, for example. I think that happened during this term, during this presidency.

I think that we should attach that general good recommendation that was made before but take advantage of the historical moment that we are living through of this government agencies coming forward publicly. If they would have studied the disease and point to specific mechanisms where those hundreds of millions of dollars can be immediately allocated to MECSF.

Dr. Gary Kaplan: Thank you

((Crosstalk))

Dr. Susan Levine: Jose are you saying more like a recommendation than a proposal right? You're saying to add, to reiterate the recommendation or strengthen it, or?

Dr. Jose Montoya: I honestly don't know the mechanisms of this thing but it's like yes. I think that we can.

Dr. Susan Levine: I don't disagree, I just don't know what the right, you know, if it's legal so to speak, or how can we do that.

Dr. Gary Kaplan: We can make any recommendation we want it just goes to the secretary but at least were on record. We have the institute of medicine

((Crosstalk))

Dr. Susan Levine: We have like about two more minutes on air too.

Dr. Gary Kaplan: Oh we might not be able to do it right now, but.

Dr. Susan Levine: I mean, I'm all for doing that, I just don't know, you know, it doesn't sound like we have enough time to vote this minute because we haven't put it on. We haven't crafted that recommend, I mean.

Dr. Gary Kaplan: I think it would be a good idea to do a sub group or a work group to look at the research needs. Start with the IOM and the P2P and what people know and actually come up with a budget for it.

(Nancy): Isn't that what, this is (Nancy). Isn't that what the NIH is doing right now?

Dr. Gary Kaplan: I don't know what the NIH is doing.

(Nancy): I think that's there - I think that's what their trying to do now. Don't want to recreate.

Faith Newton: Yes, that's correct.

Dr. Jose Montoya: I proposed based on what (Nancy) said, that we as a committee recommend that presidential funds be looked at in the order of 100 million dollars a year for MECSF research.

(Nancy): That recommendation along those lines, some more, some less has been made, four or five times before.

Dr. Susan Levine: Well like Jose says, where in a new historical moment. That has some power to it, I think. I just don't know how we can do that this minute, on this phone call. That's what I'm worried about.

Carol Head: This is Carol and I, you know, we all have hoped that this - the dial in report the P2P would be that historical moment and we've seen, you know, obviously

new developments particularly at NIH and I just, I think the jury is out on whether or not our own federal government will genuinely grasp the gravity of this and find a way to get this done, you know. It's an interesting position were in and all of us are in. That we both can see the bureaucratic hurdles to funding this and yet, you know, part of being part of an organization that's complex and has lots of rules as understanding how to bend the rules so that they work towards justice.

It is an issue of justice and CSF patients. We have not yet seen other than (Francis Collin)'s statement which stands and you know, again I hang my hat off to him. That's what we've seen that could actually be something that takes the federal government way from the long standing pattern of putting this disease aside and really focusing on it. Time will tell and time needs to tell within 12 months. It's very unclear that if we're actually going to see the kind of, you know, (unintelligible) in funding for this disease that's only just.

I try to remain optimistic but it's getting tougher and tougher as each moment goes by. I would also say we'll have an administrative shift here. We don’t know who will be in any of the roles or any of the individuals who were on Safe Sack or who manage any of these issues. We may be starting over again with a new secretary of health and services.

I'm feeling a sense of, you know, we all feel a sense of urgency because we know of the suffering of these patients. You add on to that the administrative change that’s coming in seven months and it's, you know, tougher to remain optimistic and there are more and more individuals who are talking about sort of, you know, seeing, you know, the act up model.

It may be that, that kind of activism is what really finally gets public opinion to the place where something breaks loose. That's what's needed. Nothing is broken loose yet, so that's my feeling.

Donna Pearson: Well said Carol.

(Steve): Well speaking from the IACFS perspective. This is (Steve) again, obviously funding is the major problem. I think Dr. (Montoya) hit it on the head. Unless the government is willing to put money up we won't see the private owners to put money up. We really need to do something and there's no harm in making a recommendation to, that it needs funding at such and such a level. I do think we have to set out the justifications for it so it stands as a decent, rather than a something blowing in the wind but a strong paper and case for it.

Dr. Jose Montoya: Okay, volunteer to chair that group, Jose Montoya.

(Steve): I'd be glad to be on the group with you Jose, not sure what help I'd be but I'd be glad to be there. (Steve).

(Nancy): This is (Nancy). If you could send, sort of your like, one sentence or two sentence charge to me and then other people who are interested in participating, just send your name to me. I'll get that back, we can send that out so people can be interested, can let you know if they want to participate.

Dr. Jose Montoya: Great.

(Nancy): Okay? That work.

Dr. Susan Levine: Sounds good (Nancy). Any other comments from anybody.

Faith Newton: Yes, I would like to especially thank the advocates that worked on the, both working groups. I thought the working groups and the Safe Sac numbers that did were exceptionally well done. I thought they were succinct, I thought they were clear. I know, because we have a lot of patients that are ill but I just wanted to say, I think we need to say a big thank you to those people that put in all of their time and effort.

Dr. Susan Levine: I completely agree.

Faith Newton: This is Faith by the way, I keep forgetting to tell you guys that.

Dr. Susan Levine: Well thanks for another great session everybody. I look forward to reviewing the working group suggestions and you know, getting people involved in the next set of working group meetings.

(Steve): I look forward to not doing this on the telephone next time.

Dr. Susan Levine: I agree, I think the inn person is much better.

(Steve): Absolutely.

Dr. Gary Kaplan: I agree.

Dr. Jose Montoya: Thank you (Nancy) and Sue, Jose Montoya.

Dr. Susan Levine: Thanks, Jose, thank you for everybody's input.

(Steve): Thank you everybody, you bet.

Dr. Gary Kaplan: Sue, everybody thank you. Really actually very productive useful meeting, I appreciate everybody's hard work.

(Nancy): I think it was too and I want to thank everybody for all their hard work. I really personally like the developing the work groups, I mean developing the recommendations out of the work groups. I think that's a very valuable process and I think we all learn from it and I think it's more, it helps the agencies and the secretary as well. Thank you very much. For your participation it's very hard to do this on a webinar for ten hours so we appreciate your commitment to this task.

Dr. Gary Kaplan: It's only been ten hours, it just flew by.

(Nancy): Did Sue make a motion to adjourn?

(Nancy): She's got to do that, or somebody does.

Faith Newton: All right I'll say it. This is Faith can we have a motion to adjourn?

Dr. Gary Kaplan: This is Gary I will second it.

Dr. Susan Levine: Yes, me to. Thanks.

Faith Newton: Oh and thank Syreeta.

Dr. Gary Kaplan: Yes, thank you Syreeta.

Dr. Susan Levine: Thank you.

Dr. Jose Montoya: Thank you Syreeta.

Syreeta Evans: You're welcome.

(Steve): See you guys in the fall.

Dr. Gary Kaplan: Bye.

Dr. Susan Levine: Okay.

(Nancy): We'll be there.

Dr. Susan Levine: Oh my goodness.

Coordinator: This does conclude today's conference call. Thank you for your participation. All parties may disconnect at this time.

END