

NWX-OS-OPHS-OEP-OER

**Moderator: Syreeta Evans
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10:47 am CT**

Coordinator: Good afternoon, and thank you for standing by. And welcome to the Chronic Fatigue Syndrome Advisory Committee Conference. Today's call is being recorded. If you have any objections, please disconnect at this time. Your lines have been placed in a listen-only mode until the Question-and-Answer session of today's conference. At that time, you may press Star, followed by the Number 1 to ask a question. I would now like to turn the call over to Mr. (Gustavo Seinos). Thank you, sir, you may begin.

(Gustavo Seinos): Thank you, (Michele). Welcome, everyone. I'd like to welcome the Committee Members, as well as the public. I'd like to announce we have a quick announcement that today's meeting will be Co-Chaired by two of our previous Members, (Doug Calavine) and (Dr. Newton). As you all know, (Dr. Newton) — well, you might not know, but — (Dr. Newton) was elected to be the new Chair starting our meeting our in-person meeting, which will take place in December. Dr. (Levine) will be her — her membership of the Committee has been extended, so she can Chair, along with Dr. (Newton), this meeting. But as of December, her Member Table will expire, and by then, hopefully, we will have new members. We can talk about that later. I'd also like to remind you that we have a contractor taking Minutes for this call, so please say your name before you speak, and if you are not speaking, feel free to put your phone on mute so we don't have any background noise. The Slides — you can either control them yourself, or Syreeta here in the room with me can do so. And I would like to start by having roll call. So, let me go down my list.

(Sue Levine): (Sue Levine)?

(Sue Levine): Here.

(Gustavo Seinos): (Faith Newton)? (Faith), you might be on mute. (Faye)?

(Faith Newton): Sorry, I was on mute, yes.

(Gustavo Seinos): (Dan Cook) is not here. He told me he was going to be joining late.
(Dr. Kaplan)? I think he also could be late.
(Alisa Kock) will not be joining us.
(Jose Montoya)?
(Donna Pearson)?

(Donna Pearson): Here.

(Gustavo Seinos): (Ted) from HARQ, moving out to the Ex Officios.
(Ermias) and (Beth) from CDC?

(Elizabeth Unger): (Beth) is here.

(Ermias Belay): (Ermias) is here.

(Gustavo Seinos): (Janet Maynard), FDA?

(Janet Maynard): Here.

(Gustavo Seinos): (Joe Norton), HRSA?

(Joe Norton): Here.

(Gustavo Seinos): (Michelle Shaeffer), Social Security?

(Michelle Shaeffer): I'm here, and I have also invited (James Edgerton), who's also from Social Security.

(Gustavo Seinos): Welcome, (James).

(James Edgerton): Thank you.

(Gustavo Seinos): (Becky) from (WIT-E-MONS), NIH.

(Becky): I'm here.

(Gustavo Seinos): (Drew Hermer) from (VA)?

(Drew Hermer): Present.

(Gustavo Seinos): I'd like to welcome the new, non-voting Liaison Organization. This is their first meeting. (Leah Williams), from the Massachusetts ME/CSF Association.
(Leah), you might be on mute.
(Courtney Miller) from Simmaron Research.

(Courtney Miller): Yes, I'm here.

(Gustavo Seinos): (Ben HsuBorger) from MEAction.

(Ben HsuBorger): HsuBorger. Yes, I'm here.

(Gustavo Seinos): (Ben), how do you say your last name, for everybody?

(Ben HsuBorger): The "H" is silent. So, it's SU-BORGER.

(Gustavo Seinos): Okay, welcome. And here in the room, we have myself, (Gustavo), and Syreeta Evans. And (best) (Colin Sharp) is not able to participate at the meeting at this time.
So, we also have (Carmen Sanchez) from the Department of Education?

(Faith Newton): No, (Carmen) wasn't able to join us either today or tomorrow.

- (Gustavo Seinos): Okay, well with that said, I'm going to turn it over to both Dr. (Levine) and Dr. (Newton) to welcome, and we can kick off the meeting. I'd like to remind you that, also, this is the first meeting in 2017. As you know, the meeting we held in January was actually the second meeting of last year. And I'd like to remind everybody on the call that the dates are set for the December meeting in-person, so please do not plan anything around those dates if you would like to attend the meeting. This is a new approach that we are trying here in the (OS) to make sure that we don't have any conflicts or any back-and-forth with the dates of the meeting. So, turning it over to the Co-Chairs. Ladies?
- (Sue Levine): (Gustavo), I just wanted to ask, do we have a quorum of voting members present?
- (Gustavo Seinos): We do not. We do not. We have three members.
- (Sue Levine): Because — do you anticipate we will tomorrow, or there's no way of knowing? Because we will have to, I assume we're going to have to take a vote on recommendations?
- (Gustavo Seinos): (Gary Kaplan) is going to be joining us late, and then (Cook) as well. (Alisa Koch), she might join us, or not. She's on travel. And (Jose Montoya), I emailed his assistant to find out when he declined the invite, even though you guys have known the meeting was going to be on this date, and she never responded. So, I'm really not sure where he's at or whether he will join us.
- (Sue Levine): I guess we'll have to deal. Okay.
- (Gustavo Seinos): But when, I hope that by the time — by 3:00, when (Faith) presents and if you guys vote on any of her recommendations that we will have enough members.
- (Sue Levine): Yes, as long as (Gary) and (Dan) join us.
- (Gustavo Seinos): (Dan) will for sure will join us around 2:30, 3:00 Eastern time. He...
- (Sue Levine): All right. Then we should be in good shape. (Faith), do you want to go ahead?
- (Faith Newton): Yes. We are going to start with a complete update. Actually, we're a little bit ahead of schedule. Unless you've got any comments you want to say?
- (Sue Levine): No. You know, we've got a couple of interesting presentations coming up. I know (Faith) is going to present on the Pediatric education, and I'm going to speak tomorrow about updates in medical research in ME/CFS. And then we're going to get some presentations from the new liaison organization. So, I'm very much looking forward to that. We've gotten, ahead of time, some of the presentations sent to us by Syreeta, so I've been looking at those. Looking forward to everybody's presentation.
- (Faith Newton): And the other — this is (Faith Newton) speaking. The other thing that is a little bit different is we sent out in advance (asking) about some of the different presentations, like, dealing with our Pediatric (ME/CFS), and we've gotten some comments back for when my group will (take) that information.

- (Gustavo Seinos): And is there anything else in comment? We will open the line to the general public. Only one individual in the public requested a time to speak, at 2:30. And that person will go first. After that individual speaks, we will open the line for the general public. So, this will be a different approach.
- (Faith Newton): That sounds good. We'll see how it works.
- (Sue Levine): Okay. So, shall we move forward to the first Agency Update from CDC?
- (Gustavo Seinos): Yes, we might have to take a little break. She's not here yet, but our Acting Director, (Nicole Green), might come in, and welcome everybody, and make a few announcements to the Committee. So, (Ermias), if you don't mind, in the middle of your presentation stopping for (Nicole) to give her remarks.
- (Ermias): Okay, that sounds good, (Gustavo).
- (Sue Levine): Do you want to advance...
- (Gustavo Seinos): And, (Ermias), do you want to advance your own Slides, or have Syreeta do it for you?
- (Ermias Belay): I can advance my own Slides, but I don't see the ball on this side.
- (Gustavo Seinos): Okay, she's about to do it.
- (Ermias Belay): Not seeing it yet.
- (Gustavo Seinos): Can you make it larger, Syreeta? Maybe there's an OK button, hidden?
- (Ermias Belay): I still cannot see it.
- (Gustavo Seinos): Hold on.
- Syreeta Evans: Do you have the ball now?
- (Ermias Belay): No, I do not. But you're advancing the Slides, I can see. I cannot see it.
- Gustavo: There you go. Might have it, I think. And now?
(Ermias), now?
- (Ermias Belay): Yes. No, I cannot see it. Not yet. Maybe it might be easier for you to advance it, Syreeta.
- (Gustavo Seinos): Okay.
- (Ermias Belay): Is that a better way to do it?
- (Gustavo Seinos): Yes, for the sake of time. Thank you.
- (Ermias Belay): All right. Thank you, everyone. Good afternoon. I am (Ermias Belay), the CDC Ex-Official to the CFSAC, and I'll be briefly reporting on the ME/CFS activities at the CDC since our last in-person meeting in January. Next Slide.
As many of you are aware, we've embarked on revamping the CDC Web site, and we hosted a Roundtable meeting last fall with many Stakeholders participating. And a summary of that Roundtable is now posted on our Web site. You could see the link on that first bullet.
And our new ME/CFS Web site for the general public has been cleared at CDC, and it's ready for posting within the next several weeks. However, the Web page that's intended for healthcare professionals is still under development, and it will probably take us just a little bit longer for that Web site to be available. But we are working on that. Next Slide.

In terms of communication, we had the 9th Stakeholder Engagement and Communication Call that was held on May 25th, and this is the call that we used to identify as (TICOCA), the (PICOCA) call. And the name has now been changed to Stakeholder Engagement and Communication Call to avoid confusion with other CDC calls. But it follows the same format. We are using the same line. We just changed the name.

And the last meeting – the last call that we had on May 25th, was provided – the invited speaker was Dr. (Robert Naviaux), who is a Professor of the University of California in San Diego. He was the invited speaker. And he presented on the metabolic features of ME/CFS, which was very well-received.

There were 140 phone lines that were used at the time, and multiple people may be using a single line. So, the actual number of participants may have been larger than 140. Next Slide.

And in observance of the ME/CFS Awareness Day on May 12th, we ran a feature on our Web site was jointly developed by NIH. And Dr. (Unger) also contributed to the CDC's Public Health Matters blog under the title, "America's Hidden Health Crisis: Hope for Those Who Suffer from ME/CFS," in the links for both of the Web features that are shown in this line.

The Web site, the Web feature that was developed by NIH was in the first bullet; in Public Health Matters blog under second bullet.

(Gustavo Seinos): We don't see you in that picture (Ermias); we see (Beth).

(Ermias Belay): What is that again?

(Gustavo Seinos): We don't see you in the picture. We see (Beth).

(Ermias Belay): Oh, in the picture, my camera is not on.

(Gustavo Seinos): I know. I'm talking about the picture on your Web, on the screen.

(Ermias Belay): On the screen – ha, ha, ha, ha. I was hiding behind them.

The links are that here are provided on the Slide, and the Web postings are actually accompanied by a lot of tweets and in also Facebook Web page, or posting to try to reach as many people as possible. Next Slide, please.

Some of you may be aware that our Methods paper on the Multi-Site Clinical Assessment of ME/CFS or the (ME) study was published in the American Journal of Epidemiology.

That paper – the Methods paper – was selected and featured as Editor's Choice by the Editor-in-Chief. What that means is the paper will become accessible in Open Access formats. So, it was chosen and featured by the Journal for Open Access, and it was published in April 15th issue of the Journal.

And I believe that will increase the visibility of ME/CFS and, in general, the MCAM study. If people are interested, it could be downloaded on the American Journal of Epidemiology Web site. Next Slide, please.

In terms of presentations, Dr. (Unger) participated in two meetings. And the first one you see there in the first bullet is the seventh Invest in ME Research that was held in London in the United Kingdom, and Dr. (Unger) presented under the title, "CDC Multi-Site Study and Future Plans," so, summarizing the MCAM study and plans in the future.

She also presented at the symposium on Insight into the Immunology of CFS, which was organized by the Federation of Clinical Immunology Societies. And the topic of her presentation was "The Public Health Problems of ME/CFS."

And these two presentations happened just recently. Next Slide, please.

And to briefly touch on other programmatic activities that happen at CDC, we continue to work on the Multi-Site Clinical Assessment, the ME/CFS study – the MCAM study – and the IRB protocol for the NK Cell Function Assessment, which was one portion of the study, was recently approved, and testing has been initiated to do an NK cell assessment, a function assessment.

And the Pediatric ME/CFS patients, as you probably are aware, are underrepresented in the current MCAM study. So, to supplement the MCAM contract, two contract solicitations were announced.

One for more clinics to provide data from children with ME/CFS, and the second one, for more clinics to provide data from patients with other illnesses as a comparison group for the original MCAM study that has been conducted. So, these two contracts have already been announced to supplement the MCAM study. Next Slide, please.

And our staff continues to collaborate on several CFSAC workgroups so that are shown on that first Slide. And we continue to collaborate the NIH and FDA.

Now collaboration with NIH is focused on the development of ME/CFS common data elements, which is co-funded by CDC and NINDS, and we continue to do work on that collaboration with NIH.

In our collaboration with FDA, it's focused on the development of acceptable clinical outcomes that can be used for future drug applications, or can be potentially adopted by researchers or pharmaceutical companies so that they work on their future drug applications. And we plan to share data from the MCAM study for this purpose. Next Slide, please.

And to just briefly touch on the progress we are making on the CFSAC recommendations from our last January meeting, we are continuing the dialog with the National Association of School Nurses and the Department of Education.

We are specifically consulting with the Center for Information and Resources, which is funded by the Department of Education, to draft a landing page dedicated to ME/CFS, which provides links to the CDC and the ME/CFS Web site as well as provide links to resources regarding educational plans and

services that are available from the Department of Education for students with ME/CFS.

So, that activity had taken place to follow up or meet the recommendations that were put forward by the CFSAC during our last meeting in January.

Thank you. This concludes my report.

(Sue Levine): Any questions for (Ermias)?

I wanted to know, (Ermias), is the (Bob Naviaux) interview available on your Web site?

(Ermias Belay): It's being curated for posting on our Web site. I'm not sure the voice data would be made available. (Beth), do, you know, if the voice will be available, or just the Summary? My understanding is just the Summary would be made available.

(Elizabeth Unger): Yes, we are in the process of transcribing it, and that has been, you know, just about ready to be posted. And we are — the recording is being reviewed. And it may or may not be posted, but for sure, the transcript is being prepared and should be posted in the next couple of weeks. One comment about the CDC Web page — and the reason that we proceeded with part of it and not all of it is that all of CDC is undergoing a required format update, and if we hadn't put new content up, it would look like it was a new page, even though it was just a format change. So we wanted to be sure we made the format change along with new content. And the material — the pages specifically for health care professionals — will be delayed, but it will be posted, probably in the fall.

(Sue Levine): Okay, thank you.

(Courtney Miller): This is (Courtney Miller). I have a question, if I could.

(Sue Levine): Sure. Go ahead.

(Courtney Miller): Hi, so this is (Courtney Miller) from Simmaron Research. Dr. (Belay) and Dr. (Unger), I did want to make a comment and ask a question. Thank you for a couple of things: for publishing the first paper, the Multi-Site Study, and I hope — one of my questions is what the timeline is for publishing additional findings, so far.

And then I also want to thank you for the acknowledgment and the highlight on ME Awareness Day. I think that's a first for the Federal Agencies — yours and NIH's — and for conducting the Stakeholder engagement process for reviewing the Web site. I haven't personally been part of that, but it is at least important to have that engagement in this — what was very much needed in reviewing/revising the Web site.

But my questions are more on the timeline. Do you have a goal for publishing additional findings from the Multi-Site Study? And then, on the process of developing drug development tools with the FDA, or have you (been) addressed — part of this — and Dr. (Maynard) can address it in her remarks.

Who are you working with? And are you working with any of the clinicians who have done clinical trials for our position to talk about how outcomes relate to patient care?

(Ermias Belay): Yes. This is (Ermias) again. In terms of the MCAM study and additional publications, definitely there will be publications, but the timeline may not be soon, and I will have (Beth Unger) address that.

And I'm sure the FDA will touch upon the outcome major development in their updates. But Dr. (Unger) may also have additional input on this.

(Elizabeth Unger): Yes, this is (Beth Unger). We are in the process of doing the next paper for MCAM. These are all a very high priority, and I can't really give you a timeline, because it partly depends on, you know, a combination of how long it takes to actually get it written, and then approved, and then, you know, submitted to the Journal, et cetera, et cetera.

But we are definitely proceeding on that. And then is your question about the FDA clinical endpoints, we are collaborating by providing data from the MCAM for evaluation. And we are collaborating with — and this is a very initial stage of starting to work with a group that had submitted a proposal to FDA, and Dr. (Maynard) can probably comment more fully on this.

So, we want to make sure that the data we have is used in the very best ways possible, and while the data from MCAM will be a start, there's probably additional data that will be needed, but by using the data we have, it will kind of jump start the process.

And so, as you know, MCAM data was done in collaboration with clinicians that are very experienced, and we also think that's very important. I think that answers your questions, but there may be one or two issues that I missed.

(Courtney Miller): No, that's great. Thank you very much, Dr. (Unger).

(Ben HsuBorger): Hi, this is (Ben HsuBorger). I have a question. I'm with MEAction. I have a question.

(Sue Levine): Go ahead.

(Ben HsuBorger): And so, thank you for that presentation. It was very informative, and it's good to hear that we're making progress with the CDC Web sites, and that information will be posted soon.

But I guess one question was, is there will there be any other opportunities for members of CFSAC or other ME specialists or Stakeholders to be able to see what CDC has developed and give input back into that before it's posted? Or are you just going to post it without any further feedback from Stakeholders?

(Ermias Belay): This is (Ermias Belay) again. During the Roundtable that we had, that was the intention. That's exactly what we were trying to do in — and I don't know if you participated in that or not, but we collected extensive input from different groups, including patient advocacy groups, you know, sister Federal agencies, CFS, ME/CFS researchers in professional societies, and others.

So, it's based on that input that was received at the Roundtable that we developed the Web site content. And we received very specific input and information and feedback in the Meeting before.

(Ben HsuBorger): But those Stakeholders who did give you input have not been able to see what you've produced from that. Is what you've saying that you've taken that input, but you're not engaging any Stakeholders in reviewing your Final Draft before it's posted to the Web site and finalized?

(Ermias Belay): Right. The final content is not reviewed, but again, it's based on input that we received, and we heard and accepted most of the comments and the feedback that was provided at the Roundtable meeting.

(Elizabeth Unger): This is (Beth Unger). At the CFSAC meeting, Dr. (Belay) presented in detail the process that we went through for the Web page, and what CDC's process is. We definitely are aware of the importance of collaboration in this, and that's how we came up with the Roundtable.

(Ben HsuBorger): Yes, and I thank you for that. I just, I've heard concern expressed by numerous members of ours, of people who have engaged in this process are eager to see the CDC move forward with it, but are concerned because they feel like they don't know what CDC is producing, and that once CDC puts out a final product, that it will just be there.

And if there are things that Stakeholders could give additional input into that might be tweaked or get additional feedback on, that there will be no opportunity for them to really engage in that.

In that sense, it's a one-way engagement process of getting some input, but that people are concerned that they're not being treated as true Stakeholders, and in the final product that's being produced.

(Sue Levine): Well, thank you for that. Maybe we can have time for further discussion about this.

(Donna Pearson): This is (Donna Pearson). Can I just chime in for minute? I just raised my hand. I guess we're not using that system, (Sue)?

(Sue Levine): I'm not sure. Go ahead, (Donna).

(Donna Pearson): I just wanted to know if (Ermias) or (Beth) could just explain why — we go around and around on this topic, it seems, meeting after meeting. It's clear what the Community wants. I think it's been fairly clear what the Liaisons want. Perhaps what — certainly what the Community wants, and I would imagine the Committee Members want.

Why is it there is not an opportunity to make sure that we're getting this right, when there's so many flags being raised by so many people at this point?

(Ermias Belay): Again, (Donna), this is (Ermias). Again, we heard the Community. The original Web site, the impetus to revise it and change it is exactly what you said. And that's why we had the Roundtable. We had a lot of people provide input, and

the final product is based on the input that was received from the Community.

And I think before judging it, people have to see, you know, what was finally cleared by CDC, and then, you know, give us your feedback.

But the process – we’ve made it very clear from the outset that, you know, the original Web site, we’re willing to revise it based on comments and feedback received from a lot of people, and had that Roundtable to get specific input on the process that we initiated. And again, you know, you probably have to see the final product before you make any judgement.

((Crosstalk))

(Donna Pearson): And I think everyone understands...

(Ben HsuBorger): So, sorry, this is just (Ben HsuBorger), just asking — so you’re saying that once the product is finally released, we will be able to give feedback on that? Who would go to, and what is that process for giving feedback, once we actually see what has been produced?

(Ermias Belay): Yes, this is (Ermias) again. Yes, we — Web sites, in my judgment, are living documents, okay? In other words, it’s not, you know, it’s not a content that’s going to be there forever.

So, based on developments that happen in the field, based on new things that we learn, and based on feedbacks that we might get, Web site would be reviewed and revised going forward into the future.

(Donna Pearson): This is (Donna Pearson). I guess I just want to go on the record as saying that I think that everyone’s goal here has been to have a Web site that works; a Web site that helps educate the medical and the (patient) caregivers, (psychiatrists) and everyone else that needs to be educated, and I know that I made some minor suggestions for simple wording that would have made a world of difference two years to (Beth Unger).

You’re telling me that we can only revise the Web site once a year. So, I’m hearing conflicting information, I have concerns, and I know I’m not getting a direct answer on why we can’t have it looked at first.

But I just want to express my concern that I think we could be proactive about this, and save ourselves a whole heck of a lot of headaches if what ends up coming out could have been easily been simply tweaked to make more people happy with it. That’s it. Thank you so much.

(Faith Newton): This is (Faith). Are there any other comments on (Ermias)’ presentation?

(Sue Levine): Okay, well, let’s move ahead to the next Agency Presentation?

(Ermias Belay): I hate to interrupt. I’m sorry guys. But we have (Nicole Green) here, the Acting Director for the Office of Women’s Health, with her remarks.

(Nicole Green): Hi guys, I apologize for being late. A meeting ran over. Which never happens. But I did want to take just a few minutes to welcome you all to the in-person meeting for CFSAC. We’re really pleased to have you here today.

I'd also like to welcome Dr. (Faith Newton) as our new Chair. Dr. (Newton) will Co-Chair today's meeting, as you all noticed, alongside our departing Chair, Dr. (Levine).

I'd like to personally thank Dr. (Levine) for her tenure as Chair and for all she does as one of the few physicians in the nation who treats ME/CFS patients. I'd also like to welcome three new non-voting members. They are located in three different areas of the country: one in New England, other in the Mid-Atlantic region, and the third is out West. We always encourage new organizations to come to the table and to bring new voices to the process. We appreciate you.

I know some of you might be wondering why there are no new members on the Committee. The nominations, not only for CFSAC, but for all of the HHS BACA Committee, including those at NIH, FDA and CDC — along with several others — are still within the HHS White House Liaison's Office. We do ask that you continue to be patient, as the new administration gets set up and running, and they're bringing a lot of new staff onboard.

(Discipline) going forward, the process will be a lot smoother. We're also waiting for the President's Nominee for the Assistant Secretary for Health to be confirmed by the Senate. And right now, we don't know exactly when that will happen. They're getting ready to go for Recess for 10 days. They'll be back for three weeks, and then they go back out on Recess until after Labor Day. So, we will see exactly how long that process will take.

But lastly, I would like to inform you that this past month, we were able to get approval to publish a report citing all the activities conducted by the Department and its Agencies around ME/CFS from 2013 to 2016.

The report was handed out in Draft Form at the last CFSAC meeting this past January. The Final version is now available on the CFSAC Web site under Presentations for January 2017 Meetings.

The Agencies will discuss their most current activities during their updates today and tomorrow. So, I just wanted to thank you all, apologize again for being late, and I look forward to a really productive meeting over the next 2-1/2 days. Thank you.

(Faith Newton): Thank you.

(Sue Levine): Thank you.

(Sue Levine): Who's the next Agency?

(Janet Maynard): This is (Janet Maynard) from...

(Ermias Belay): (Janet).

(Janet Maynard): Can you hear me okay?

(Ermias Belay): Yes.

(Janet Maynard): Okay. So, this is (Janet Maynard), and I am FDA's Ex Officio on CFSAC. And I really appreciate the opportunity to provide an update on FDA's activities related to ME/CFS strong development since our last meeting in January. I will highlight some recent FDA activities.

The first update is regarding a Pharmacy Compounding Advisory Committee meeting held on May 8, 2017. At this meeting, FDA's pharmacy compounding Advisory Committee discussed six bulk drug substances nominated for inclusion on the Section 503a bulks list.

One of these substances, NADH, was nominated in use in compounding for reducing symptoms of fatigue and ME/CFS. 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 NADH on the Section 503a bulk drug substance list. However, NADH is available as a supplement. The Committee recognized the significant unmet medical need for patients with ME/CFS and the serious nature of the disease. The second update I will provide is regarding Clinical Outcome Assessment, which are also referred to as COAs, and their use in drug development. The clinical outcomes measure a patient's symptoms, or the effects of a disease, or a condition on how a patient functions. A Patient Reported Outcome, or PRO, is one type of Clinical Outcome Assessment.

Clinical Outcomes Assessments can be used to determine whether or not a drug has been demonstrated to provide treatment benefits. These assessments are frequently used in clinical trials evaluating the safety and efficacy of a drug.

FDA has a Clinical Outcome Assessment Qualification Program. This qualification process facilitates a collaborative setting where the Clinical Outcome Assessment drug development tool Qualification Program works with the submitters in guiding Clinical Outcome Assessment development. Multiple interested parties often work together in working groups to develop the Clinical Outcome Assessment for qualification. This approach allows for shared resources and can facilitate drug development tools.

FDA has received a Clinical Outcome Assessment qualification submission for measurement of symptoms and functioning in ME/CFS. FDA is providing consultation and advice to assist with this qualification effort and recognizes the importance of Stakeholder collaboration in ME/CFS.

The Qualification Program allows multiple Stakeholders to work together to assist strong development. FDA is supportive of these efforts to assist with the development of measures to assess efficacy of drugs intended for ME/CFS.

(Beth) and (Ermias) mentioned CDC's participation in these efforts. Also (Courtney Miller) asked a question about the involvement of individuals with experience in clinical trials in these efforts.

And I agree that it's very important to engage a variety of Stakeholders when considering these issues, including patients who would really have, I think,

very important impact and input on the need for certain Clinical Outcome Assessments.

So, in conclusion, I appreciate the opportunity to provide an update on FDA's activities. We remain extremely supportive of working with interested parties on drug development for ME/CFS. Thank you.

(Faith Newton): Thank you. We have Social Security Administration?

(Courtney Miller): I'm sorry. Can I ask a question of Dr. (Maynard)? This is (Courtney Miller).

(Sue Levine): Sure. Go ahead.

(Courtney Miller): So, thank you for outlining some of that. But I do have a question about this, Is this, you know, have you selected people to be part of a Stakeholder process for Clinical Outcomes for ME/CFS that you're developing with the CDC?

Is there a timeline, is there a, you know, process for input? This is going to be essential to moving a drug development. To process them, so one question is specific to that.

And then, I really want to hear a plan, a multi-layered, sophisticated plan out of FDA for moving the clinical trial program on ME/CFS. I'm going to speak to it in my prepared comments from the perspective of Simmaron and the perspective of the wife of a patient who has been involved in a clinical trial, and who's losing access to a medicine that works.

I've got to have an aggressive plan from FDA, and I believe in collaboration with NIH, and the work of a clinical assessment that a clinical multi-site study at CDC is great input.

So, specifically on the patient outcomes, how are we proceeding in a collaborative way, in detail? Who are you working with? And I don't know what the process is to request, and maybe, like, the voting members could entertain this, but, I want to ask. And I am going to continue to ask for an aggressive program that we can see, and we can help make happen.

So, that we have a full complement of clinical trials that we need to learn what works and why, and what doesn't work, and how to bring patients out of the cycle, frankly, of having to rely on self-medication and vitamins and, you know, the latest promotions of non-FDA-approved treatments.

(Janet Maynard): This is (Janet Maynard). I really appreciate your questions and your insights you're providing. I guess that part of my response will focus on sort of drug development qualification process and program. So, this is just one way that FDA can help support drug development.

And what happens is parties or investigators who are interested in having a Clinical Outcome Assessment for whatever condition or disease submit information and plans to the FDA that we review and work with them on. But I think something that's important to highlight is that most of these endpoints, or outcome assessments, that are used in clinical trials don't go through this process.

But we think that this process is important, and can support drug development, but I wanted to be clear that the endpoint doesn't necessarily have to go through this process to be used in a study in ME/CFS. So, this is one way we can help support endpoint development and clinical trials, but it's possible that a clinical trial could also occur and go through this process. So, it's just another way we can help support drug development. In terms of the specific tool that I was mentioning today, that was — or the proposal that I was mentioning today — that was submitted to FDA. And what I think I could do is to send that out through a Web link that has information on the individual who submitted this proposal, and their specific desire to look at symptoms and functioning in ME/CFS. So, I can send that information to (Gustavo) after the meeting today so that you can have additional information about that actual proposal. And in terms of overall drug development and Stakeholder collaboration, I totally agree with what you've said. I think it's the only way we're really going to move things forward in an expedient way is to bring multiple Stakeholders to the table, and I think that involves both the Federal agencies, but also the patients themselves, the patients' families — really all the different people who are affected and devastated by this disease. So, I think it's very important that we do work together, and we are totally open to working with interested Stakeholders in collaborative ways, and I thought this was the Clinical Outcome Assessment Qualification Program was one example of how different people can come together and work together. But we are, of course, open, and if there are other avenues that should be pursued to help spur drug development in this area, because I agree, there's so much that we need to do to move things forward.

(Ben HsuBorger): Hi, thank you. This is (Ben HsuBorger) with MEAction. (Janet), I was just wondering what would be the specific mechanism, then, for involving patients or people living with ME/CFS in FDA's work on this? What would that look like?

(Janet Maynard): You mean, in terms of the overall drug development and working together to move things forward?

(Ben HsuBorger): Yes.

(Janet Maynard): Yes. You know, to be honest, I think the community has given so much helpful input to the FDA that has been extremely helpful and I think has done some catalyzing of drug development in terms of those patient programs during development meetings, and the Voices of the Patient Report that came out of that, and also helped spurred the guidance on drug development for ME/CFS.

In terms of additional similar action items, moving forward, I think that we are really working on supporting pharmaceutical companies, and also supporting the endpoint development, so I don't specifically have an area

right now where I could say, oh, sort of to help the patient community or to help them to a specific area.

But I really appreciate sort of all the support that I feel from this community, in terms of helping as those needs arise, because I do think that having input from multiple different Stakeholders is really what will make this a collaborative and successful process.

(Ben HsuBorger): Thanks, (Janet).

(Faith Newton): Are there any other questions?

(Sue Levine): Okay, so what do we have next? We have — what did you say, (Gustavo)? We're waiting for Social Security?

(James Ederington): No, I'm here. (Ederington).

(Sue Levine): Okay. Why don't you go ahead?

(James Ederington): Present.

(Gustavo Seinos): Okay, we can move the Slides for you.

(James Ederington): Okay. Sounds good. So, I guess you can just go ahead and move on to the next Slide.

So, we certainly appreciate the Chronic Fatigue Syndrome Advisory Committee to allow us to provide an update. And again, my name is (James Ederington) and I'm going to share information about our National Disability Forum. Move onto the next Slide.

Today I'm going to cover just three primary areas of NDF. That's What is the NDF? The NDF background, and How to Stay Engaged with NDF.

The National Disability Forum, or NDF — and I'm sure with so many other Government Agencies — and Social Security being no different — we love our acronyms.

NDF stands for the National Disability Forum. And NDF was the brainchild of our Executive, Gina Clemens, to give you, our Stakeholders, an opportunity to share your insights directly with the Agency policymakers and to share and discuss your diverse perspectives with each other.

In June 2014 — you can move on to the next Slide — in June of 2014, we held our first internal Steering Committee to plan NDF. And we use an internal Steering Committee to assist our Development Team evaluate topics.

In addition, to help with the feedback from the Forums, they also reviewed comments and decided on areas for further discussion. Now the purpose of the National Disability Forum is to promote an inclusive and collaborative coordinated approach to public policy issues.

NDF is designed to engage disability advocates and other public and private Stakeholders, such as yourselves, in discussions about key policy topics affecting persons with disabilities.

Now, NDF is open to anyone interested. Again, it's a public Forum. And it serves as a way to collect insight early, because we're always looking for information.

It's a complement — and certainly not a replacement — to all of activities that we already have underway, including our rule-making activities, such as the ANPRN, which is the Advance Notice of Proposed Rules Making, or NPRN, the Notice of Proposed Rulemaking. NDF just functions as a Forum to collect feedback, rather than reaching a consensus among Stakeholders.

Our meetings are held in Washington, D.C., and with the past four, including our upcoming Forum in August, it's been held at the National Education Association in Washington, D.C. And we usually hold them from 1:00 pm to 3:00 pm, only for about two hours.

Now, our Forum is designed to give speakers about 10-to-15 minutes to present their organization's position on the current topic, usually via PowerPoint. Although, during the Forum in August, we are trying something a little different, which I will discuss a little later. You can move on to the next Slide.

And since the inception of the NDF, we've held six Public Forums, with our seventh again coming this August. And we've touched on topics such as medical evidence gathering, transitioning SSA childhood – SSI childhood beneficiaries – to successful adulthood, reality of work for individuals with a disability, with a focus on impact of age, education and work experience. Also, developing and assessing medical evidence for extreme limitations and the ability to focus on task. We've also touched on exploring opportunities through telehealth and the Ticket to Work Program. You can move on to the next Slide, sorry.

Some of the past organizations that spoke during our Forums were NASCR– National Association of Security Claimant Representatives, Health and Disability Advocates, the ARC, Economic Policy Institute Justice in Aging, Legal Services of New Jersey, National Institutes of Mental Health, University of Virginia's Telehealth Center and Virginia Department of Aging and Rehabilitation Services, just to name a few.

We normally have anywhere from four-to-six panelists when we discuss – when we're having these Forums. You can move on to the next Slide.

Currently, we're developing our next Forum, titled, "Serving Individuals with Disabilities: Best Practices in the Modern-Day Workforce. We're having a group of panelists from private insurance companies, Government Agencies and Advocacy organizations to discuss their best practices, by having a Question-and-Answer session.

And we're focusing on the areas of functional assessment, identifying a clear path for individuals to return to work, utilizing decision support tools and data analytics, and developing communication strategies when implementing new policy and technology.

And to prepare for this Forum, we gather questions from a number of different components within our Agency that are focused on disability, asking

them what they would like to see, in regards to the best practices, from the Panels that I mentioned. You can move to the next Slide.

Now, after sharing all this information about the National Disability Forum, I know you want to know how can I stay engaged with NDF? And there are five major ways to stay engaged with the National Disability Forum.

One, of course, is our Web site. Our Web site is www.ssa.gov/NDF — Nancy-David-Frank. We update our site regularly with information about each of our Forums, and we include a transcript after each Forum.

Another way is IdeaScale. We use IdeaScale, which is a Cloud-based software platform. It was developed in 2009 that a number of Government Agencies picked up, including the White House. And that allows us to involve the opinions of you by collecting all your ideas and giving you a platform to vote on each of those ideas.

And if you desire, provide comments on those ideas. Like I mentioned earlier, we want to have an opportunity to share your insights directly with our Agency policymakers and each other.

Now we usually have a pre- and post-IdeaScale campaign with each Forum.

During the pre-campaign, we usually focus on questions presented to the Stakeholders to assist our speakers in shaping their presentations.

During the post-campaign, IdeaScale provides a platform for the Stakeholders to offer additional comments that they may not have been able to share during the Forum. And for those unable to attend the Forum, they can still participate using IdeaScale by reading, voting and providing comments.

Another way is our email, which you'll see up on the screen already. Our email address is nationaldisabilityforum@ssa.gov. We always monitor our email. If you have any questions of the NDF team, would like to suggest a topic, or would just like to be added to the NDF database, so you can email us again at nationaldisabilityforum@ssa.gov.

We also use LinkedIn. We co-host each NDF with the Office of Communications, and they monitor a LinkedIn page announcing each Forum for all of those that subscribe.

And lastly, are our Forums. And this is the most important aspect, our Forums. We absolutely encourage you to attend each of our Forums, either in person or via phone. If you're not currently receiving an email from our Office of Communications, the Office of External Affairs, please forward us your email so we can add you to the database and keep you updated of all the Forum activities.

We also send out Save the Date, and a formal invitation, which you can certainly share with anyone you feel may be interested in the Forum. So, having your presence, and presenting your organization to help us shape the (unintelligible), is crucial for our Disability Program.

After presentations, we offer Question-and-Answer sessions to respond to the information that was just presented. During the Forum, you may respond either on the phone, or in person, email, or even Twitter. I can say that the National Disability Forum was the first avenue in regards to using Twitter – a live Twitter account, you know, when it comes to the Agency. And you know, we really value all of our Stakeholders' voice.

We feel that engaging interested parties in Public Forums, such as the National Disability Forum, can help Social Security capture innovative ideas, ensuring that our vision for the Disability Program continues to keep pace with advances in medical technology, healthcare and the modern workplace. On behalf of myself, (James Ederington), the National Disability Forum Team, the Office of Disability Policy, the Office of Retirement and Disability Policy and, of course, the Social Security Administration, we thank you for giving us this opportunity to share the information about the Disability Forum. If you have any questions, please feel free to contact the National Disability Forum team, again, at nationaldisabilityforum@ssa.gov. Certainly open to any questions you may have.

(Sue Newton): Thank you for your presentation. I thought we'd have a half an hour before our next presentation, so if it's all right with everybody, we can open up the floor to questions for all of the Agencies, not just Social Security, if other people have questions.

Go right ahead, please.

Coordinator: Thank you. If, at this time, anybody does have a question, they may press Star, followed by the Number 1. Again, Star-1, if you do have any questions.

(Donna Pearson): This is (Donna Pearson). Are you speaking to the entire public at this point?

(Sue Newton): I think we are. Right, (Gustavo)?

(Gustavo Seinos): Yes.

(Faith Newton): Yes, I thought we were, too.

(Sue Newton): And we have a little bit of time, honestly, if anybody has any questions for any of the Agencies.

(Gustavo Seinos): We also — I'm sorry — for those on the phone — the public, listening will be unable to speak unless you follow the instructions by the Operator. We can — the Webinar, we also have a Chat box that you can email or Chat your questions, and we will read them if you want to remain anonymous, and we can answer them.

Coordinator: We do have a few questions on the audio side. Would you like to take those?

(Sue Newton): Go right ahead please, yes.

Coordinator: Thank you. (Joanna Kaiser), you may ask your question.

(Johanna Kaiser): Thank you. Before the — this is for the SSA — before the last CFSAC in January, 2017, an American with ME sent a Microsoft Word document to CFSAC with questions for the SSA and requested additional information regarding disability approvals for people with ME.

She has not yet heard – received – feedback from the SSA. These questions reflect information received from the SSA Statistics Office that showed extremely low numbers of people with ME — about 15,000 — receiving either SSI or SSDI for a primary or secondary diagnosis of ME.

This is remarkably low for a disease that affects between 1 and 2-1/2 million Americans with this disease, and a disease which has such high levels of disability. Also, information received from SSA seems to show that fewer Americans with ME/CFS were receiving SSI and SSDI in 2015 than they were in 2009.

So, the question is, did the SSA receive a copy of that Word document that was sent to CFSAC, Number 1 — and Number 2, with whom can MEAction follow up to get questions in the submitted document answered?

This has fallen into the abyss. We have heard nothing in response to the detailed questions that were submitted, and we really do need to follow up and feedback.

(Michelle Shaeffer): This is (Michelle Shaeffer) from SSI, and — hello?

(Johanna Kaiser): Hi. Thank you.

(Michelle Shaeffer): Well, if we did have information coming through like that, we would have given it to our statistical office. I don't personally remember a question like that, but was it through FOIA? Did you ask it through a FOIA question?

(Joanne Kaiser): We asked in two ways. Number 1, it was — this question was submitted to CFSAC, so (Gustavo), if you're listening, this is an issue we really need you to follow up on this.

(Gustavo Seinos): This is the questions that were submitted to us not for — if I remember correctly — the questions that were received asking SSA made it past General Comments, there were not specific instructions that required the sender to please send this to SSA for an answer. When we received those questions, if I remember correctly, back in January, they were part of the regular public comments being submitted to the Committee.

(Johanna Kaiser): And isn't (Michelle Shaeffer) on that Committee?

(Gustavo Seinos): No, (Michelle) is an Ex-Official. The Committee met — when we asked for public comment, those are shared with the voting members of the Committee. I share them sometimes, to be honest, with the Ex-Officials, but the public comment, the intention is to — the voting members to read them.

(Johanna Kaiser): You know, it would be really helpful — just as a side note to this conversation here — if this was made more clear to people with ME who have severe — well, sometimes — very difficult cognitive problems, because this is unclear. So, this was sent to CFSAC with the intention of SSA seeing this. And (Michelle), yes, we did submit — a year ago — a FOIA request which has been so far ignored.

It's been extremely frustrating to get through to somebody, so is there a way for us or MEAction to follow up with you, and send you this document, so that we could learn more and, you know, hopefully, SSA can learn more? Because this meeting really is about Americans with ME. And you know, I appreciate the presentation that was given today, but we have some very serious issues that are specific to this disease — and the disability wrought by this disease — that are, that really leave people in abject poverty, homeless, and this is the kind of support and protection we really need — in addition to just the broad support from SSA. So, how do we follow up with you?

(Michelle Shaeffer): Well, I could check on the FOIA request and see what the status is. Just we have a process to go through in order to make the request, and then they respond. There's a Division the Office of Privacy and Disclosure that answers the FOIA request, but I could check on it and see.

(Joanne Kaiser): Well, it's been a year. It's all gone into an abyss.

(Michelle Shaeffer): A year sounds a little too long, so I could check on that. Maybe if...

(Joanne Kaiser): I can get back to you and follow up offline.

(Michelle Shaeffer): Okay.

(Gustavo Seinos): I'm sorry; was the FOIA request also submitted to the CFSAC Inbox? Or was it sent directly to the SSA?

(Johanna Kaiser): It was sent directly to the SSA, and you, (Gustavo), had advised us to add to the FOIA request, but I don't know if you're aware how things appear to work to the outside public, but there was no way to do that.

(Gustavo Seinos): Okay, do me a favor, please. Can you resend to the CFSAC Inbox the email that you sent a year ago, and I will ask the Support Team to forward that email to (Michelle).

(Johanna Kaiser): I actually sent an email with this document attachment yesterday and the day before to the CFSAC Inbox, and I've received no response whatsoever. So...

((Crosstalk))

(Gustavo Seinos): Okay, if it was sent yesterday, I'm sorry, but you will not get a response right away.

(Johanna Kaiser): ...I'm certainly hoping — are you going to continue talking over me, or you going to let me speak?

(Gustavo Seinos): Go ahead.

(Johanna Kaiser): Thanks. Because I'm really sick, and it's hard to speak. You have no idea. Now I can't remember where I was. This is just wonderful.

(Gustavo Seinos): You said you sent your email yesterday.

((Crosstalk))

(Johanna Kaiser): And the day before, and it had a Word document with background information and detailed questions, and I think this would be — if this is okay with you, (Michelle) — I think this would be the most useful form of documentation on which to get feedback. Is that — would that be acceptable?

Because there's no way to — that I've found — to submit any sort of attachment. And what I was doing was referencing specific information given to myself and others by the SSA Statistics Office.

(Michelle Shaeffer): I could certainly check on it, and I'm sure that (Gustavo) could give that information to me. We have a on our SSA.gov, we have a FOIA request segment on there.

(Johanna Kaiser): I've gone there.

(Michelle Shaeffer): You've done that already, okay.

(Johanna Kaiser): That's why I said I, you know, we had made a FOIA request a year ago and received nothing more than the acknowledgment that it's been received. But I've called. No one returns the calls. Nothing has been done. It's really disappointing, because I'm really sick. I've had this for 39 years. I'm homebound, I'm bedbound, I'd say 95%.

And so, you have no idea how difficult it is to try to get any kind of response. I've going through all the recommended channels that (Gustavo) told us, that on the SSA Web site for submitting a FOIA request, and nothing.

(Michelle Shaeffer): I'm sorry. Let me check on it. It's time for me to check on it, and we'll see. What we've been trying to do at SSA is — for statistics, anyway — we've been trying to add those so that people can have access to them without having to have particular FOIA requests, but sometimes that's not always — that's something that's somewhat (new). But let me go ahead and check on it, and I can get back.

(Johanna Kaiser): Thank you. No, I appreciate that. So, just to recap, I will send that email to CFSAC and ask them to forward it to you. Is that what's being recommended in terms of the conduit?

(Michelle Shaeffer): Yes. Mm-hm.

(Johanna Kaiser): Okay...

((Crosstalk))

(Gustavo Seinos): I'm sorry, is your name (Sharon Shaw)?

(Johanna Kaiser): Excuse me?

(Gustavo Seinos): Is your name (Sharon Shaw)?

(Johanna Kaiser): No, it's (Johanna Kaiser).

(Faith Newton): Could you spell that for us, please? This is (Faith)'s document.

(Johanna Kaiser): Yes. I also spelled it when I got on this call. It's J-O-H-A-N-N-A Kaiser K-A-I-S-E-R.

(Faith Newton): Thank you very much, (Johanna). We appreciate it.

(Johanna Kaiser): (Johanna). Thank you. The last thing is that, (Michelle), I did, or others looked on the reporting tool, but you may know this already. I don't know whether you do or not, but ME/CFS is not one of categories on which one can search and get information. And I think this is indicative of the whole — of the many issues with ME/CFS and the SSA. We're just not on the radar. Does that make any sense?

(Michelle Shaeffer): Yes, I'll check and see if there's a way to search that will make it a little easier for you to try to deal with that. And then I'll check on the FOIA request and see how that goes.

(Johanna Kaiser): Okay, thank you.

(Gustavo: (Johanna), and when you resubmit your email to the CFSAC Inbox, unless you receive an email saying we have received your document, do not assume we have received them. In the past, people have submitted documents, and we have never seen them. They get lost in the mystery of IT, so if you don't mind resubmitting again and making sure that you get a response, don't assume that we saw it. Thank you.

(Johanna Kaiser): That's good to know, and how much time should we expect, like, using 24 hours? Or when is kind of the usual period of time in which we would either receive or not receive and need to send again? What do you recommend?

(Gustavo Seinos): If you don't hear from the Support Team within 24-48 hours, then feel free to call the Office of Women's Health main number — and that's for me — and then I will make sure, I will try to find out what happened.

(Johanna Kaiser): Okay, that's terrific, thank you. And this is — the other person who has been involved is (Sharon Shaw), so you're right, but, you know, there are multiple people who have been working on this, and I'm not going to list all of them. But you are referring to the right document.

(Gustavo Seinos): Okay, so we have seen (Sharon Shaw)'s email then that came yesterday, so.

(Johanna Kaiser): Okay, so you didn't see the one from the day before? That's okay. As long as you have yesterday's, it's the same document that was submitted to CFSAC in January.

(Gustavo Seinos): We received that document yesterday, and I'm getting a report from the Support Team from Mrs. Shaw at 6:23. So, we have received it. If that's what you're talking about, I can go ahead and ask the team to forward the document to (Michelle).

(Johanna Kaiser): Perfect. Then I don't need to send you anything more. That's terrific. Thank you so much.

(Gustavo Seinos): You're welcome.

(Johanna Kaiser): All right.

(Faith Newton): Thank you, (Johanna).

Coordinator: Thank you. We do have one more question. Would you like to...

(Faith Newton): Yes, go ahead.

Coordinator: Thank you. (Roberta Davis), you may ask your question.

(Roberta Davis): I saw the email about the compounding agents, and I thought that all of them had not been approved by the FDA. So I was surprised when I thought I heard (Janet Maynard) say that the NADH was now approved for ME/CFS. Did I hear that correctly? And what exactly — remind me again — what exactly it is to do for us?

(Janet Maynard): Thank you. Sorry if there was any confusion in my remarks. So, at the Pharmacy Compounding Advisory Committee, there were six drug substances discussed.

(Roberta Davis): Yes.

(Janet Maynard): One of which was had been proposed for use for — specifically it was for reducing symptoms of fatigue and ME/CFS. That was NADH. So, the Advisory Committee Members recommended not including it on the list.

(Roberta Davis): Yes. Okay, correct.

(Janet Maynard): But I think something that is a little bit complex and confusing is — so this Advisory Committee is specifically talking about the compounding of medications, which is different. So, NADH is also available as a supplement. So, that Committee was not discussing sort of use of NADH as a supplement. So, I just wanted to be clear that — so NADH is currently available as a supplement, but this Committee was discussing the compounding.

(Roberta Davis): Okay, that's what I didn't understand.

(Janet Maynard): Okay, sorry about that.

((Crosstalk))

(Roberta Davis): ...that none of them was approved for compounding, right. Okay, thank you, that's all I needed to know.

(Janet Maynard): Thank you for clarifying. Appreciate it.

(Roberta Davis): Thank you.

Coordinator: Thank you. And we do have one more question. Would you like to take that?

(Faith Newton): Of course. Go ahead.

Coordinator: (Sue Ellen TOOCH), you may ask your question.

(Sue Ellen TOOCH): Well thank you to the Committee and everyone who works on our behalf, especially the indomitable Dr. (Levine), who saved my life years ago and took me — well, I didn't have medical insurance. So I have two questions. The first one has two parts.

While I very much also appreciate the FDA pursuing new drug options, I'd like to know when the United States is going to get serious and fund a rituximab study here in the United States.

As far as I'm aware, I'm the only PWC who has had more than 50 — that's 5-0 — treatments, which cause a temporary remission of some of the worst of the symptoms. I want to make sure to be clear; it's not a cure. I am not well, by any means, but I do have some quality of life and a bit more human functionality at certain times.

So, there's two parts of the question will be: when will this be applied in clinical trials here, as they are now being undertaken in Norway with Dr. (Pflug), and also now in Europe, I understand.

And the second part of that question is why isn't anyone looking to reverse engineer this b-cell agonist, to discover the originating mechanism to prevent

and limit progression and fatalities and, tragically, ever-increasing prevalence in children. The autism prevalence is now off the charts.

And my second question is are you intending to fund the (Microbe) Discovery Project at Columbia? They've reduced substantially; they're (off) from 20 million that they asked myself and (John Sterling), who was then the CEO of the CAA, back in the early 2000s, and now they're only requesting 5 million for their groundbreaking work.

(Faith Newton): Now who are you directing those questions at?

(Sue Ellen TOOCH): Anybody in this group (unintelligible).

(Faith Newton): Let me answer the best I can. There are — tomorrow I will be presenting some discussion on new medical research on ME/CFS, and I hope it will give some insight into the answers to those questions.

The work is very interesting, and it's mostly going on in Europe, as you say, on rituximab and ME/CFS. Probably the drug will not turn out to be for everybody, and we're trying to determine which subgroups it will be most appropriate for.

There — you know, there is — people have submitted various groups around the country. CFS/ME research groups have submitted grants to the NIH to get funded, hopefully, for Centers of Excellence, and some of those Centers will likely undertake clinical trials using rituximab or similar b-cell-depleting therapies.

But the question — you know, we just don't have the dollars. But I think, certainly, that it looks like a very promising approach to a subgroup of ME/CFS patients yet to be determined.

And I'm sure the Microbiome Project would take as much money as we can throw out them. It's just a matter of getting, you know, money to them.

They're doing very good work. Anyone else want to make any comments?

(Vicky Whittemore): This is (Vicky Whittemore) at NIH, if I could comment.

(Sue Levine): Sure, go ahead, (Vicky).

(Vicky Whittemore): Yes, just want to comment that I recently was at the Invest in (unintelligible) in England, and had the opportunity to talk to the Norwegian investigators who are doing the rituximab clinical trial.

And they are — the status there is that they will be seeing their last patient in the trial in September, and so, then, unblinding, or being able — they will be able to look at all the data and see who was actually receiving rituximab, and who was on placebo, and beginning in October.

And part of what they are very interested in, because it's clear to date that there are clear responders, there are clear non-responders, and that there are people in the middle. And so, they are very interested in trying to understand what those different groups are.

And they will make their data available to the regulatory agents — meaning FDA and NIH — when their data is available, and we will, I think, be able at that time to take a look and see what next steps might be.

As you are probably aware in the United States, clinical trials are either funded directly from the company that has the intervention they want to test, or are funded through NIH grants.

So, what it would require from NIH to support a clinical trial would be investigators coming together to submit a grant application to NIH for the clinical trial. We are — NIH will not initiate the trial. It needs to be investigators coming together to put together a clinical trial application that would go through peer review.

And just one other clarification. The collaborative — ME/CFS collaborative centers that we're hoping to fund — at least in this initial five years, we're not proposing to support clinical trials, but rather to get a better understanding of the causes of ME/CFS, such that in the next, potentially, five years down the road, we could begin to subtype and really tailor clinical trials to meet the needs of individuals with ME/CFS.

So, I just wanted to make those clarifications.

(Sue Levine): Thanks, (Vicky), thanks.

Any other questions for — I see we're coming up on about 1:30, and we'd like to certainly give enough time to Simmaron. Okay. Someone else?

(Dan HsuBorger): Yes, this is (Dan HsuBorger). I just had one question for Social Security Administration. The previous presentation that was given, back in January, was about a training program, ME/CFS, and I was curious to know what its status — what the status of the training program was — and when we could possibly see the content that has been developed for that.

(Michelle Shaeffer): This is (Michelle Shaeffer) again. I'm glad you asked about the training program. It's a continuing medical education program on ME/CFS that we have, and it's rolled out now, and the doctors who work at SSI have been taking the training. We've been getting some pretty good feedback from that, so that seems to be going pretty well.

(Dan HsuBorger): Is it open to access? Can the members at CFSAC see what it is that people are being trained in, and does the content — I guess my specific question would be does the content in the training reflect the IOM (criteria) that was developed?

(Michelle Shaeffer): Yes. It's primarily based upon our Social Security ruling and, of course, that coordinates with, you know, the other protocol — we mention those specifically in our Social Security ruling, so that is, the emphasis there is on that.

As far as seeing the video, I'd have to ask another component within our Agency about that. This isn't generally available to the public. It's on a special training format for the, you know, for the continuing medical education.

((Crosstalk))

(Dan HsuBorger): ...available to CFSAC?

(Michelle Shaeffer): Yes, I would have to ask about that, like I said.

(Sue Levine): I think what we would like to know, if I'm saying this correctly, is we'd like to know what criteria you base your decision on, more or less, to grant benefits for ME/CFS patients.

I know at one point it was very elevated EBV titer, like some crazy amount – 1-to-2560. But since IOM came out with new criteria, have you revised your criteria for disability?

(Michelle Shaeffer): Well, we still follow our Social Security Ruling that we have.

(Sue Levine): I guess we're trying to figure out more specifically what that is. What your specific components are.

(Donna Pearson): This is (Donna). We were actually given a copy of that, (Sue). I think it was two years ago. I don't think they've changed anything since then. So, maybe we could, maybe (Gustavo) could pull it out or something?

(Sue Levine): Okay. Fair enough. All right. Why don't we continue? (Faith), is that okay? Are you on board with continuing with Simmaron Research's presentation?

(Faith Newton): Yes, let's keep this on time that way.

(Sue Levine): All right. Okay. Okay, (Courtney), go ahead.

(Courtney Miller): Hi. Okay. So, you guys have the Slides up. I think I've lost my Internet connection. So,

(Faith Newton) That happened to me too.

(Courtney Miller): So, hopefully I can track with you. But so, I want to — my name is (Courtney Miller). I'm President of the Board of Simmaron Research. I wanted to go through our goals, our mission and some of our accomplishments so that you can get a little bit of our perspective.

So, Simmaron's goals are really to redefine ME/CFS through scientific discovery to determine diagnostic markers, to identify scientific characteristics of subsets of ME/CFS patients — which is where we believe the researches into the disease needs to go.

Push through research that can lead to potential treatments that we will be driven. Our work and our advocacy is driven on a desire and the need to develop treatments for patients.

Hopefully, we'll do this work through marrying the clinical and scientific expertise, try to bring translational research to bear, and the goal is obviously to improve the lives and the health of patients. Next Slide.

Our mission is really to play a key role in the scientific research that will lead to better diagnostics and treatments on this disease. We do it through funding and coordinating pilot studies that can helpfully lead to diagnostic markers, patient subsets' treatments.

And we believe strongly in publishing peer-reviewed findings and sharing the resources — the results — as openly as we can. And we won't get there if we

don't collaborate with those who have the expertise and the tools we need in our disease. The next Slide.

So, the history of Simmaron is that we were founded in 2011 by a group of ME/CFS patients in northern Nevada. We focus on harnessing the 30-year clinical expertise of Dr. (Daniel Peterson), who is one of our core scientific advisors.

And through his work, we have access to well-characterized patient populations for studies. He has a wealth of data yet to be mined, and an unmatched biobank of samples from this – the duration of this 30-year clinical history. So, next Slide.

How we function is really that we are a Foundation of volunteers. The Board is volunteer; our data operations – some of our operations – are volunteer. What we fund is research staff. So, we fund the Research Manager, Coordinators to do work on particular studies, and interns, to help with things ranging from data mining to, you know, sort of data organization. And we fund some collaborators to do studies that we believe are strategic to our goals. The prime example of that are the spinal fluid studies that I'll touch on in a second. And for other collaborations, many of which are multi-site, multi-clinical, you know, many clinical sites participating, we will staff our end of the work for the sort of data side of it. Next Slide.

So, we have a small Scientific Advisory Board led by Dr. (Daniel Peterson), and it includes Dr. (Mady Hornig) at Columbia University's Center for Infection and Immunity; Dr. (Constance Knotts) at (Copa) Healthcare — what many long-time patients will remember as this Wisconsin Viral — and Dr. (Maureen Hanson) at Cornell University. Next Slide.

So, our scope — in the years since our founding, we have funded probably a little more than \$1 million worth of research work. Our scientific advisors, and Dr. (Daniel Peterson), in particular — his collaborations have helped publish 15 peer reviewed articles in those six years.

We have provided expert input into certain processes of — run by government agencies, so the FDA, the NIH, the Institute of Medicine, the CDC — where Dr. Peterson is one of the clinical sites collaborating in the multi-site study — and so, along with them, we have strong collaborations with Columbia University, worked with (Precious) University in Australia, (Binney), Albany, University of Nevada, Reno, and when it was sort of active, the (KON-A-PA-CHE-GA) Initiative. Next Slide.

So, what I would point to as our accomplishments is helping — largely helping — to drive a strategic focus on immunology and its role in ME/CSF. Over the last five years, a substantial amount of effort has gone into identifying immunological impacts.

What I will call a signature spinal fluid studies are really designed to figure out the immunological implications on neurology. So, we've started to publish findings on those, and we'd hope to continue that. And most of our

publications — ones where we're collaborating, or where we've, you know, provided the funding — establish scientific bases for different subsets.

So, everything from the Columbia study in (blood) that identified as shorter duration versus longer duration, immunological profile, (Keller)'s spinal fluid study, that was just published, identifies the difference between the what the collaborators called classical versus atypical cases of ME/CFS

And the Microbiome Study, that Columbia has just published the first finding on, identified differences between ME patients with and without irritable bowel syndrome. Next Slide. So, you can move to the next Slide as well.

We have published three collaborative manuscripts in the last two months, and I'll just pick these for reason, a little bit. So we conducted a spinal fluid study with Columbia University that compared ME patients with patients with MS and with healthy controls.

The first set of findings was published back in 2015, right around the time that the Institute of Medicine Pathways to Prevention studies were published.

A second finding from that study is that there's a clear distinction in immunological markers and cytokine patterns between classical patients and those that had some atypical identification.

And what, just in basics, what that was was some number of patients who had, after years of having ME/CFS, gone on to develop cancers, certain kinds, or had a different path to getting ME/CFS, like a blood transfusion, or some other not-normal or not-common way of contracting the disease. So, that paper was published two months ago – three months ago. If you go to the next Slide.

Dr. (Peterson)'s clinical site is one of the collaborators in the CDC Multi-Site Study, and what I mostly want to add about that study is that — and I took a quote from the publication.

Right, that study was really designed in a collaborative way with the clinicians who are among the top experts in the country on this (disease). So, it is, from the ground up, a look at what those clinicians believe are the classic representative cases of the disease.

And so, we're eager for more publications, and I believe from our perspective, it's — look, it's the largest study being conducted in this country, and I think it's changing the perspective of the disease both on the outside and on the inside at CDC. Next Slide.

So, we were one of four sites as well in the Microbiome Study which was just published by Columbia just last month, and basically, looks at, you know, (ME mutations), but divides them based on the bacteria profiled in fecal matter. There's a difference between any patients who have symptoms of irritable bowel syndrome and those who do not. As well as differences, there's the controls. So, last Slide, I think.

As my comments earlier in the meeting suggest, we do believe that treatment for patients is the most pressing unmet need and that we have to all be engaged in a plan to build the field of evidence-based treatments, collaboratively.

Treatment trials are all but nonexistent. Everyone listening to this call, everyone who has the disease, everyone in the room knows that. But we need to move to studying the responders, as the description of the rituximab trial in Norway is doing. We need to be part of that study — to study the responders to Ampligen, to cidofovir, to rituximab, to antivirals to monoclonal antibodies; we need to be doing more work.

Simmaron can do its part, but I think everybody on this Committee and in the Federal Agencies have a part to do, and we have to move that plan on much faster than a five-year timeline.

So, that's our presentation. The last Slide is just where you can find more about what we're doing. And we're grateful to be able to be on this Committee, and thank the Committee and Federal Agencies for the work they are doing. It's very important. I can take questions, if you'd like.

(Faith Newton): Thank you. Sure, any questions? Thank you.

(Gustavo Seinos): Why don't we take — (Sue) and (Faith), we can either take questions at the end, after the three Agencies report, or we can do it right after.

(Sue Levine): That might be a good idea, because then people will have a chance to think about their questions.

(Faith Newton): Yes, I would agree, let's go to the next one and then they have time to think about what they want to talk.

(Sue Levine): Now we have Massachusetts. Go ahead.

(Leah Williams): Hi. Can you hear me?

(Gustavo Seinos): Yes, we can.

(Leah Williams): This is (Leah Williams) from the MASS CFIDS Association. And we are the delighted and honored to be part of CFSAC. If you could go to the first Slide. So, I should first explain our name. We're using an older name for ME/CFS, which is Chronic Fatigue and Immune Dysfunction Syndrome. We were founded in 1985, and that was the name that was current then. We are talking about changing our name, but we haven't quite gotten there yet. For one thing, the name seems to be a moving target. So, we are a patient services organization, primarily, and our mission is to improve the lives affected by ME/CFS and FM. Advancing awareness, care, treatment and research. We're a 501c3 in Massachusetts, and we're, I think, one of few really active sort of local or regional patient organizations. Most of our members live in Massachusetts, although some of them live in New England, and we do have people all over the world. We are an all-volunteer organization. We have (nine members). Four of our Board members are not patients; the remaining five are. And we think it's really important to have both of those on our Board.

The patients, of course, have a much closer personal relationship with the illness, and the non-patients have a little bit more energy to work on some of our projects. We have about 20 active volunteers as well.

We focus on three things: patient services, education and awareness, and then in the last few years we've started doing a fair amount of advocacy work. You can go to the next Slide, please.

So, for patient services, one of our most popular ones is a physicians' referral service. We get about approximately 150 requests a year in Massachusetts in surrounding States, and we try to connect people with doctors who have some expertise or who are sympathetic and supportive. This is a very difficult project, because there are so few doctors, and the ones that we know are, most of them, at the end of their careers and starting to retire.

And so, for us, we feel like it's educating physicians, and just making sure there are more physicians who can treat patients is really important. We wish that when people ask us for a referral we could easily give them a referral and that we had many doctors to refer to, but we just don't.

The second thing that we do is we have a Disability Handbook that we wrote, and we provide that handbook, and we give personal counseling and guidance on how to get disability services.

We also have a contact list through our Web site. We get about 200 requests a year. Most of them are for patient services. And then we also have support groups, and we sponsor and support three in-patient support groups. We used to have almost 20; those have sort of, I think – years, as people have gone to more online sources of support, but we feel those are very important to have some in-person interaction. You can go to the next Slide, please.

Next Slide, please.

For education and awareness we have a Web site that we completed redesigned in 2015 to make it mobile-friendly and to also update the content, some of which was quite old.

We're very proud of this Web site. We think it's a really good resource. We've vetted everything very carefully before we put it on our Web site. And we have pages for different categories, so we have a Pediatrics page, we have a Disability page, we have an FM page; so if you get a chance to go look at our Web site, that would be great.

We sent out an email newsletter approximately monthly to about 1600 recipients. When MASS CFIDS first started in 1985, we sent out a physical newsletter to probably about 1000 people, and that's been replaced by this email newsletter in the last about five years ago.

We have events – in-person events; we do one or two per year. The last one, last November we had Tony Komaroff speak about the IACFS/ME conference in Florida. And the next one, we have somebody coming from the Open Medicine Foundation to speak.

And these events also are very important for people to be — the ones who are not homebound — to be able to gather together, and both listen to a presentation, but also meet other people to have somebody to talk to in person.

And so those events we have found have been very, very useful for the community unity. We also have a Facebook page, which we update frequently with current activities. You can go to the next Slide, please. In addition to events that are sort of focused on our members, we are also trying to increase education and awareness at the local and regional level. And so this year we made an effort to obtain State and City Proclamations. So we did get a Proclamation from the Commonwealth of Massachusetts for ME Awareness Day on May 12th. And the picture on the right there is a bunch of us at the Office of the Senate President, Stan Rosenberg, and the Lieutenant Governor, Karyn Polito, actually showed up. She's on the left-hand side of the Proclamation that she's holding there.

And we thought that this would be a photo-op only, but in fact, we spent quite a lot of time with her staff member, and then, with the Lieutenant Governor, herself, describing our situation and how few resources we have. And it seemed like a really important meeting, and we think that's going to lead to some more activity on the State level.

In conjunction with these Proclamations, we also did Media outreach, so we had press releases that were published in various local newspapers. We've also had a big effort educating school nurses. There's an annual school — or there's several — annual nurse conferences in Massachusetts where we've had booths. We've done that about five or six times, and we have quite a few people stopping by.

Many of these nurses talk to us and then say, you know, that sounds like a lot like a student I have. I need to get more information about this. And so, this is, of course, a drop in the bucket, but hopefully will lead to better awareness among school nurses, who would be the first people to see students with this illness. We also have — there's a State-wide school nurse newsletter, and we've been able to submit items to that over the last few months.

We've also just recently started meeting with the local or HHS Regional Office, and the Massachusetts Department of Public Health. It was a meeting yesterday, in fact, with the Department of Public Health.

And these are projects that try to promote more education about ME/CFS to community health centers, including the school-based ones, and other organizations that are overseen by the Department of Public Health and HHS in Massachusetts. I think — can you go to the next Slide, please?

And then, in addition, we have done public testimony at CFSAC meetings, and we've also participated in two CFSAC working groups. We've participated

in the CDC's technical development workgroup and Stakeholder meeting in 2016.

We have, as one of our Board Members, Dr. (Alan Gurwitt), who has been a co-author of several primers, the IACFS/ME Primer for Clinical Practitioners in 2012 and 2014, and then there's a new Pediatric Primer that was just published in *Frontiers in Pediatrics*, which is Open Access, so anybody who wants to can download that and take a look at it.

We've also just very recently established a Patient-Partner relationship with a medical research group at Beth Israel Deaconess, and we will have a meeting with them probably in about a month to try to understand how we can support their research.

And this is a new research group. They have not been doing any ME/CFS research before, but they have a group of people who are very committed to finding resources and continuing that research.

I think they submitted an application to the NIH call. I don't know, I don't think those have been decided yet. But if they got one, that would be very exciting for us. You can go to the next Slide, please.

And then, on advocacy. So, this is a more recent effort over the last two years. And we have been doing Congressional visits, so we visited the Congressional offices in Washington, D.C. in February, 2016, February, 2017, March this year, and May this year.

The upper right-hand corner is a picture of (Carol Head) and (Emily Taylor) from SMCI. Then Elizabeth Warren, Senator from Massachusetts, and I'm on the right there, if you're curious what I look like.

This was a Meet and Greet, where we had about two or three minutes with her to explain our cause, and she is amazing. She's energetic. She has something intelligent to say to every group that talks to her. And then we got this wonderful picture to put on our Web site.

We were part of getting the Congressional briefing that happened in May of 2017. I remember (Rifka Soloman) made the initial contract with Senator Ed Markey at a Town Hall that he held. And that led to his willingness to be an advocate for ME/CFS and to sponsor the Congressional Briefing that was held in May. And of course, that was part of a much bigger group of meetings with Representatives in Washington.

And then, if you go to the next Slide.

Additional advocacy efforts; (Charmian Proskauer), who is our President, is current Chair of the U.S. Action Working Group monthly meetings where they coordinate various advocacy efforts.

We've also had a lot of local districts visit, so in May, as part of the big push, we coordinated visits to local offices in seven of the nine Congressional Districts in Massachusetts.

And then we also participated in the Millions Missing. There have been two events in Boston in May and September of 2016, and the one in September, we had outside the HHS building, and that led to meeting some of the officials the District 1 Office of HHS, and that has led to an ongoing collaboration with them, which we hope will be really useful. If you can go to the next Slide.

So, this is a little bit about me. I am the parent of two children who have ME/CFS. They both had a pretty typical onset. My son was 12. He had a perfectly normal (unintelligible) infection, and just never got well again. He got sicker and sicker over a few years. He was really unable to attend high school. High School was unable to figure out how to deal with him, and then he effectively dropped out.

Did a GED, took a lot of online college-level classes, and is now actually at U Mass Amherst. He just finished his first year there. He's 21 now.

So, he's a little behind schedule, but we're very happy that he's recovered enough that he can attend college. He is not well, though. He has about, he says, about 60% of the energy of a normal 21-year-old. And he's managing college by understanding that he has five good hours a day. He spends those on going to classes, and doing his homework, and nothing else; and then he just sleeps and rests the rest of the time.

Which sounds kind of awful for a college student, but for him, it's actually a huge improvement over where he was five years ago.

My daughter, who is now 18, also got sick when she was 12 at a similar progress of the illness. She had a viral infection. We happened to know it was (adenovirus), but it doesn't really matter. She's too sick to attend high school right now, but is taking online classes and hopes to actually get a high school diploma, probably sometime in the next year.

She is hoping to go to college, and we'll just see. We've had experiences with five different school systems – or schools; two different school systems.

Some have been very supportive. Some have really not wanted to deal with us and wished we would go away. And some have been openly hostile.

And I was interested in the question from the working group on pediatrics, which is, do you think things have improved, versus stayed the same, or gotten worse over the last few years? And in our experience, things have definitely gotten worse. We feel like schools are much less willing to listen, and be supportive, and help accommodate what our kids need to get an education.

Of course, we've been to many, many, many doctors, a few of whom have been supportive; most of whom have been either dismissive or unhelpful in various ways. We wish, you know, that there were treatments, but really there's not much that doctors can do.

At the moment, I feel optimistic, since my son is in college and my daughter is finishing high school. But I really don't know what the future looks like for them.

For my own, for myself, I have a Ph.D in Physical Chemistry from MIT, and I work for a small contract research company doing research on air pollution. I've been very fortunate, in that my company is flexible, and I've been able to work part time. I don't know how I could have had a full-time job and dealt with the illness that my kids were dealing with. If you can go to the next Slide. Next Slide, please.

And so, our goals for being on CFSAC as a liaison – my personal goal is to be a voice for children with ME/CFS and their parents. I think there may be some other parents on this Committee, but probably nobody who's had young children with the illness.

And for MASS CFIDS, I think our goals are probably the same as everybody else's, which is that we would like to work towards having research funding that's commensurate with the burden of this illness.

We'd like to have CDC to put correct and helpful information on their Web site. We'd like the ICD 11 to have, you know, a good and useful definition of ME/CFS, and not have it over in the "Uncategorized" illnesses.

We'd like clinical practitioners and educators to know what ME/CFS is, and be able to deal with it appropriately, and we would want all patients to receive compassion and respect from medical, legal and educational professionals.

And so that's my last Slide. I want to thank you, again, for letting us join the Committee, and we hope to have a very productive two-year appointment. Thank you.

(Sue Levine): Thank you, (Leah).

(Faith Newton): Thank you. That was an excellent presentation. Does anybody have any questions for (Leah)?

(Gustavo Seinos): No, we're going to wait until the end, remember?

(Faith Newton): Sorry, (Gustavo), you're right.

(Gustavo Seinos): (Ben), you're up next.

(Ben HsuBorger): All right, thank you. My name is (Ben) — (Gustavo), are you going to pull up the PowerPoint?

((Crosstalk))

(Gustavo Seinos): Yes, we're working on it. Give us a few seconds.

(Ben HsuBorger): (Leah), I just want to say it was a real pleasure to meet you and your son in May on Capitol Hill, along with all the ME/CFS (unintelligible); one of the — it's been real exciting over this past year to see the different advocacy groups collaborate together.

(Leah): Yes, thank you. That was a great event. We were really happy to be there.

(Ben HsuBorger): You have some real powerhouse members who are doing great things who have been involved with MEAction and others, but we're cheering you on in all the stuff you're doing in Massachusetts.

(Leah): Thank you.

(Ben HsuBorger): All right. So, (Gustavo), do I have control over this, or are you going to advance the Slides for me?

(Gustavo Seinos): We're going to do it for you. It didn't seem to work earlier on.

(Ben HsuBorger): Okay. Great. So, hello everyone. My name is (Ben HsuBorger). I'm the Managing Director of MEAction. We're a registered nonprofit in the State of New Jersey. And I'm also a person who has lived with ME for the past 12 years. Next Slide, please, (Gustavo). Great.

So, I want to take the time to tell you a little bit about who MEAction is and what we do. We describe ourselves as an international network of patients, empowering each other to fight for health equality for myalgic encephalomyelitis.

We are — as I said, a registered nonprofit in the State of New Jersey. We really work — and our major presence is in the U.S., but we also work as a network all over the world.

And this is a picture of a few of our US. Advocates who've come out. We, actually, a pretty young organization, so we were founded in 2015 by two women living with ME, Jennifer Brea and Beth Mazur.

And they had a vision to build a new space within the advocacy landscape, and try to take the new digital tools that were out there, and help the community have a stronger voice, be more open, be more connected, and really take some tools and lessons from other advocacy communities and groups and apply them to the ME community.

So, in a relatively short amount of time, we've built our digital presence, just in the past two years, to 10,000 email subscribers in the U.S. And we have about double that, globally. We have about 13,000 followers on social media. And then that's just kind of the first step of people getting connected to us, but as you can see, a lot of those people then start volunteering on projects with us to work to achieve health equality throughout the world, really.

And what I love about these pictures and the many people that I've gotten to know in my past year working with MEAction is their individual — there's so many individual stories here.

And I look at them and see all the — what they've suffered and what they've accomplished together, but then we're taking those individual stories and building them into a public story that we can speak up and tell people, to make sure people understand this neglected public health crisis of ME.

And we do really see this through the lens of through a social movement lens, and we try to root ourselves in that tradition — we do our work. Next Slide, please.

So, we're a network, but we also describe ourselves as digital platform, and a variety of different patient advocates — even other organizations — can come and use our platform to accomplish some of their advocacy goals. Now one of the questions — whenever I say we're a digital platform, probably the first questions I get is what is a digital platform? What does that mean? How does it work?

And the short answer is it can work a lot of different ways. You know, there are lots of different platforms. Uber is a platform. Facebook, Google, Yelp — they're basically new ways of taking technological tools to bring together users online and allow them to do things that they wouldn't be able to do without those tools.

So, I could take up a long time giving you many different examples of all the many different things we've been trying, kind of trying and experimenting with over the past two years to empower the ME community. But I'm going to stick with just two.

The first one's going to be ways that our digital platform has supported a very large-scale campaign. And the second one is going to be more about the ways our platform can support a very intimate and targeted working group. Next Slide, please, (Gustavo).

So, the Millions Missing Campaign. (Leah) mentioned this, in her presentation. You may have heard of this or, hopefully, seen this around this past May, or in previous years. Millions Missing is one of our largest campaigns for public awareness and bringing attention to this public health crisis.

In the past year, we've been able to hold 19 separate rallies across the country, and we've received local and national media attention. Now, we've brought together local activists from cities across the U.S., including Atlanta, Boston, Chicago and Dallas, New York, San Francisco, Washington, D.C., and many others.

They use this campaign, primarily centered around urging public health officials, to ramp up funding for ME/CFS research, clinical trials. And while this has become a very large campaign, with thousands of people participating, it actually all started with one person.

We didn't design this. One individual, a woman living with ME in North Carolina, came to us with an idea. And she was obsessed about the state of the crisis, the state of clinical care, and the lack of research funding, and she wanted to do a protest in D.C. And so we became a platform for her to help organize, connect with other people, and this idea really took off.

People — we found a kind of untapped desire within the community to express and make themselves known, make the voice known; that this is a serious issue that needs to be taken seriously.

And so, what started with one person, we able to bring a lot of other people around with a variety of different skills and experience to create a massive campaign for people to be involved with, and develop a grassroots network. Next Slide, please, (Gustavo).

So, Millions Missing, you know, has been very successful for us, in terms of getting public attention, but we also — I mean, I could probably spend all day talking about some of the different shoot-off effects from Millions Missing. But I think the larger point is that we were able to — we then took and harnessed that momentum and people coming towards us, new people getting involved who'd never done anything before, long-time experienced advocates in the community, and focus that energy and momentum to very specific goals.

So, through an extensive, two-part community collaboration process, we developed this set of demands for Health and Human Services. And we talked very specifically about what is it that we, as a patient community, want to see. What are we looking for.

And based off of that, we were very grateful to be able to meet with the former Assistant Secretary of Health, and had several meetings with her to discuss the current situation and talk about some areas that we thought that the ball could be moved forward.

And some of those, specifically, were talking about CFSAC and, you know, we were asked at that point about this CFSAC Charter and the importance of renewing it. And we strongly believe in the need for this body, and the importance and criticalness for — and we also lobbied for an additional patient caregiver voting seat to be on this Committee, because we think that's an important voice that needs to be heard and represented at this table.

Other ways that we got — that we took things from Millions Missing, we took the grassroots networks and, then, also directed, them mobilized them as constituent advocates to contact last fall to 55 members of Congress to write a letter to NIH Director Francis Collins about ME/CFS, and have been doing a variety of Congressional things, activities along with the fall, then the ME/CFS initiative this past May.

We met with — we had 75 different meetings with Members of Congress to communicate the importance of funding, research, and treatment and education for this disease.

And also, a lot of things at the State level, too, so that as we kind of brought people — done public awareness campaigns that bring people out of the woodwork, develop new networks, and get people working together, people have been doing, taking action. Not just looking for action at the Federal level, but at their State and local level, as well.

So, (Leah) talked about what MASS CFID and Massachusetts activists had been doing in Massachusetts, getting resolutions. We've also been doing, there's been work doing that in California, in Georgia, in Illinois, and in various cities around the country. And so, we're excited to build on that effort of trying to educate public officials on this disease and set the ground for further change.

All right and I guess next Slide please (Gustavo). So that kind of one way that we are able to kind of take the snowball effect of, you know, what I love is people sending emails to my inbox and saying that are usually titled, you know, I have this crazy idea I love to do and they kind of can take off from there. And we've run different campaigns based upon them and been able to do things that more than any one person could do just by themselves. But we've also been doing a lot of stuff kind of quietly behind the scenes. We bring together groups of patient volunteers into virtual working groups to work on specific areas that they identify as important to them. So you'll see the, pictures you see there the screenshots of a video conferencing service that we use actually, that hold different calls from patients around the country. And a lot of times you'll see them laying in bed, speaking in bed to each other and working on various projects.

And one of the projects we recently worked on was very proud of was after in 2017 after NIH put out their RFA for ME/CFS Collaborative Research Centers in which they strongly encourage the plan researchers to establish partnerships with patient groups and solicit their inputs as part of their research plan. So when we saw that we thought well, you know, we don't we – maybe there's a role that ME action can play to help researchers think about how to better involve patients in this process. And so we brought together some experienced advocates particularly led by (Jenny Spotilla) and some – and a variety of other volunteers who all came to gather. All of these people were people that (TFF). And they did a literature review of what are the best practices and patient engagement in the medical field and research fields in general.

And they started to put things together, develop a document that we then made publicly available to all researchers. And we sent it out directly to 29 different researchers around the country, made it publicly available online. And so these are another way that we try to work is not just kind of doing big things to get attention and get awareness but look at specifically where areas where we can move the ball forward. And you can - you've heard comments from me today and asking questions about patient engagement. That's something that's really important for us and that we want to see - that we see as important for all federal agencies, all research communities. If we're going to work together we have to bring the patients as a true stakeholder in the process. Next Slide please (Gustavo).

So finally what are we hope to contribute and achieve during our term on CFSAC? Well I think our goals are, they're the same as many of you. And just like all of you and the reason we are so excited to be on this committee as well as because we want to be recommendations and invites made to the assistant secretary of health that can be improved and implemented to change the situation this public health case crisis for people with ME. And we recognize this is a complex, a series of urgent crisis. And there are a lot of different voices that are going to be needed to tackle this.

We need scientists. We need doctors. We need public officials in a range of organizations working together and listening to each other. But it's also important I have to say that we remember the people living with this disease each and every day are in some sense the experts. And they are the ones who have the most important stake in this discussion.

And so we, you know, are encouraged by the work the CFSAC has done and we look to find ways using our platform to keep the community engaged and constructively involved in this process. And that's how we think we can accomplish systematic change. And this is a picture of one of our activists in Georgia. She's wiped out because she had just spoken - presented in the capital in Georgia on ME/CFS.

And for me this picture kind of represents, you know no matter how knocked down we are by this disease we're still here and we're going to be there. And we want to be in the public square being a part of the solution. And so we thank you for the opportunity to be involved. And our final Slide is - and that's just our - a Web site where you can find us at meaction.net if you have - and if you have any questions for me you can always also email at ben@meaction.net. Thank you very much.

(Gustavo): We're going to go ahead and all the new nonvoting members we will add to your Web site a link to your Web site tool the Safe Side Web site so people can also go directly from the Safe Side Web site.

(Faith): That's an excellent idea (Gustavo).

(Gustavo): But anyway I - should we go ahead and open the - we have ten minutes before public comments. We could some - (Save) and (Susan) we can open the lines now so not only members of the community can ask questions of the three nonvoting members but also the public.

Dr. Susan Levine: How long do we have for that (Gustavo), 10 minutes?

(Gustavo): Until 3:00 when...

(Faith): Okay. Sure that sounds fine yes.

Dr. Susan Levine: Yes that works.

((Crosstalk))

Dr. Susan Levine: Yes I...

(Gustavo): No, no, not yet. (Unintelligible).

- Dr. Susan Levine: So the agenda I have is (unintelligible) time so it's moved to 3:00 or am I looking at the wrong day?
- (Gustavo): You might be looking at the wrong day. We have public comments at 2:30.
- Dr. Susan Levine: Okay.
- (Gustavo): So we can open the lines to the public to ask questions to the three new nonvoting members or we can open the lines now to ask questions to you or talk about their experience about pediatric and ME/CFS.
- Dr. Susan Levine: Actually what I'd like to do is open the line so that any – the public can ask the nonvoting members questions as well.
- (Gustavo): Okay.
- ((Crosstalk))
- (Gustavo): Operator can we then go ahead and give instructions to the public?
- Coordinator: Thank you sir. Once again if you do would like to ask a question or you have any comments you may press Star 1. Again that is Star 1. Please unmute your phones and state your first and last name when prompted. Again please press Star 1 on your phones to ask a question. (Hillary Johnson) you may go ahead.
- (Hillary Johnson): Yes thank you yes it's (Hillary Johnson) to the conversation. I was very interested in Vicky Whittemore's comment about clinical trials. She explained the FDA does not fund clinical trials and that funding for clinical trials may be achieved by applying to the NIH. But she's –she notes that the US government's NIH program which is, you know, looking into ME/CFS right now is not going to pay for clinical trial for at least till that study, the current study is completed. They'll be looking at subsets, et cetera. Only after that will they be interested in funding clinical trials.
- So if you look at your calendar those - we're talking about a first clinical trial being funded by NIH in year 2023. That's about 50 years since, 40 to 50 years since this epidemic of ME began in the United States and around the world. I think someone who is say 65, you know, clinical trials are going to be funded essentially by the time they're 70, 75. I just wanted to point this out to people who've been listening that year 2023, that's the first clinical trial that NIH may consider supporting.
- I also wanted to welcome Courtney Miller. I'm very glad she's on CFSAC. And I appreciated all her comments about the (unintelligible) of clinical trials and the absence of clinical trials. And so I'll leave it there. Thank you very much.
- Vicky Whittemore: This is Vicky Whittemore. May I comment?
- (Hillary Johnson): Sure. Go ahead.
- Vicky Whittemore: So let me clarify what I said. What I said was that within the collaborative research centers we will not - the RFAs specifically said that clinical trials were outside the scope of these applications and the centers. And that's largely because of the funding we have available as well as we believe the need to do the basic research. That's not to say that NIH will not fund or

consider clinical trials until after these five years of funding. Investigators are open to talk to NIH staff and submit applications for clinical trials at any time. So they are not necessarily linked. And we welcome anyone who would like to talk to us about submitting an application for clinical trial to contact us and discuss it with us.

Dr. Susan Levine: Thank you Vicky. Any other comments?

Coordinator: We have a few more questions. Would you like to take those?

Dr. Susan Levine: Yes please.

Coordinator: Thank you. Carol Head you may go ahead.

Carol Head: Hi. Thank you for this time, just a couple brief comments. I'm Carol Head, the President of Solve ME/CFS Initiative. And I'm really thrilled to see the three new organizations in the nonvoting seat suite, worked with all of them and I have enormous respect for the work of all three groups and are delighted that you'll continue the forward movement and perhaps even be able to accelerate the forward movement for CFSAC.

I do hope that CFSAC will continue at each meeting to methodically follow-up on previous recommendations made by CFSAC and pursue next steps when the recommendations were not accepted. This was a new approach that had – this is nascent and but having not seen (unintelligible) the standard operating procedures that I know (Donna Kirsten) has worked on I do hope that that's included in them. I think it's very important that continuity from meeting to meeting when we're only meeting twice a year to follow-up on previous recommendations.

And at the CFSAC meeting in January our organization had enumerated some specific changes that we would look into each of these CFSAC agencies to consider as we work to ameliorate this urgent public health crisis. And we as an organization will continue to follow-up with those CFSAC agencies directly. And I hope and talk that folks in the ad hoc position on CFSAC are open to that.

You know, on a different note I do think that the expanded role for the trans-NIH working group that I hope Vicky will be talking about today will be an effective way to address many of the issues that have been raised in CFSAC as there's a plan I believe to include other agencies in that trans-NIH working group and also patient organization. So I'm looking forward to hearing more about that. I think that could be a powerful tool for accelerating change regarding this disease.

So in short we'll continue to have an active voice and advocacy with the federal agencies. And kudos to the three new agencies who have three new organizations that have a seat at the table. You're all doing terrific work. Thank you.

Dr. Susan Levine: Thank you Carol. Was there someone else that wanted to speak up?

Coordinator: We do have one more question. That comes from Terri Wilder. You may go ahead.

Terri Wilder: Hi. Good afternoon. This is Terri Wilder, a person living with ME and I'm also an activist with ME Action. Thank you (Jen) for a great presentation. I just want to (Jen), you know, it's important for groups like MEAction to be at the table from my personal experience I - to tell everyone that when I first came to MEAction I was very, very sick. And through working with them they were able to link me to care which I think is a really important conversation to have in CFSAC about this kind of piece of linked care that needs to be explored more particularly around social services and case managers being educated about our illness.

I'll just close by saying that while Ben was only able to give a couple examples of what ME Action has been able to do I want to make sure everybody is aware of new kind of Webinar series that's been started which we refer to as Teach-ins which is kind of as a shout out to Act Up because they do teach-ins to train their own membership on important issues. Our next teach-ins will be on Saturday, July 8 at 1 o'clock Eastern Standard Time. And it will focus on something that's been mentioned which is activism at a local level.

And one of the reasons why we put that together is that we're starting to see movement kind of past federal and national activism and that people are really starting to kind of think globally but act locally. And so we have people literally from all around the world who will be talking about their successes at a local level. I will be presenting because people are very interested to hear about what happened to in New York State when we were able to work with our New York State health commissioner to get a dear colleague letter sent out to over 85,000 physicians and other medical providers across the state of New York on ME. So thank you again for accepting ME Action and we look forward to working with everyone.

Dr. Susan Levin: Thank you.

Coordinator: We do have one more question. Would you like to take that?

Dr. Susan Levin: Yes we've got time. Yes okay.

Coordinator: (Mark Hamenson) you may go ahead.

(Mark Hamenson): Yes my son has severe ME. He's home comatose so I can't work and I have to stay home and take care of him two days a week or my wife does. So it's a very severe disease as everyone knows. Norway tracks MECSF. Does CDC even track it as a disease?

Woman: (Unintelligible).

(Mark Hamenson): If not what does it take to do it because it's a neglected responsibility if it's (unintelligible) major epidemic more common than Ebola, Zika, polio, West Nile all combined. So just (unintelligible) track and if it's not, you know, we're looking at maybes California can start tracking it and we could send news to all MDs in California, all schools in California to inform them. But

CDC needs to be tracking this. Do they have a comprehensive tracking of this disease?

Woman: Beth Unger are you on?

Dr. Beth Unger: I am.

Woman: Or (Ermeus)'s?

Dr. Beth Unger: (Ermeus) are you – would you like to comment?

(Ermeus): This is (Ermeus) from CDC. I don't know what's meant by tracking. If what the speaker meant by tracking as having a reportable disease those diseases that are reportable are tracked by states primarily. Making diseases reportable is a state law, not a federal law. And states have to make them reportable in their – within their own jurisdiction. But apart from that what we have done as you're probably aware over time is two spaces studies to try to pin down the incidence and the prevalence of CFS and characterize the (A list) using different approaches, different studies the multi-site study being one of them and most recent one that has yielded a lot of information as a lot of people have talked about. And in addition there is an effort that's going on with the national surveys that are under CDC control. This includes the behavioral risk factor survey that's conducted every pretty much on a rolling basis.

And there's a question that Dr. Unger could specify the details, specific questions added about Chronic Fatigue Syndrome ME/CFS to try (unintelligible) the number of people at least in that survey who've been diagnosed or identified as having ME/CFS. That would give us an idea of how many people out there have been diagnosed as ME/CFS.

The big issue as you probably would agree are not the cases that are diagnosed but the cases that are missed. And different studies indicate that a large proportion of suspected or two ME/CFS cases are not even diagnosed. And that's one of the reasons why CDC emphasizes provider education, awareness creation so that, you know, ME/CFS would be – would be on the forefront of physicians thinking when they're seeing patients. I'm not sure if that addresses your answer. I don't know Beth do you want anything to this?

(Mark Hamenson): Well instead of CDC tracking it comprehensively which would make a lot of sense to me so we have to have every state do it so we could start with California or Massachusetts, Georgia other leading states, is that the approach? Or right now there's a thing called disease maps.org that went from 800 people listed worldwide a year ago to 3500 now and it helps people contact each other. But that's like .1% self-reporting. Why do we have to self-report? You think you'd come up with a CDC driven procedure. And if that's not possible due to bureaucracy then do we have to do it at the state level?

(Ermeus): It's not a bureaucracy issue. It's just CDC cannot mandate anybody to report diseases. We're not – these are state regulations, state laws. And that has to go through each one of the states. But again it depends on what the purpose of tracking is because, you know, again as I said the – what personally I'd

worry about is the ME/CFS cases that are not even diagnosed in putting all our efforts so that those patients would be diagnosed and receive the care they need.

(Mark Hamenson): Was the thing all right, you know, for example you shut down – there's been hospitals shutdown in London and Los Angeles and, you know, outbreaks in upstate New York and (Tahoe) area. And it can happen anywhere so you can miss a whole cluster. What happens if you sent down a major hospital University or DC? If you're not tracking it how do you know? Isn't that CDC's job (unintelligible) disease and then there can be clusters to – so for example Palo Alto for example has a high (unintelligible). They have high ME/CFS incidents in that general area it seems to me because there's a lot of people I know there. Maybe they're related. If 10% is suicide related ME/CFS it wouldn't shock me. And so if you don't track it how would you know? So, you know, it's more injured (unintelligible).

Dr. Beth Unger: No. This is Beth.

((Crosstalk))

(Ermeus): All right this...

Dr. Beth Unger: I will just to add on to what (Ermeus) has said. At one point CDC did conduct some population-based surveys in order to understand the burden to get an estimate of the burden of the disease in the US. That's not a trend with time but that's where a lot of the data about how common ME/CFS is in the population and what the burden, what the economic burden is and the barriers to health care.

We felt at that point that as (Ermeus) has indicated that the next important thing was documenting and providing clinicians, better tools to understand the illness and be able to diagnose it because that was the biggest problem that we heard when we talked with patients, patient advocates. Now we have discussed, you know, the difficulties of doing any kind of a registry or any kind of surveillance. It is correct we can – CDC cannot make a case, make a particular illness a reportable. We did try to interest the BRSFF which is the survey that Dr. (Boulet) mentioned and we had a couple of states do agree to include the question in their survey. But the value of self-reported illnesses is very difficult I mean even on a survey.

And so we do feel the most important thing is understanding this illness, coming up with treatments and providing all the tools that are necessary in order to do that. So we – that's where we've been focusing. But I understand your question.

(Mark Hamenson): Well I mean you track Ebola, you track Zika. You track AIDS do you not? And yet seems this is not tracked to the degree those are. Those are reportable diseases most likely (unintelligible).

(Ermeus): This is (Ermeus) again. Those diseases are again tracked by state and I can't over emphasize that. Unless states track them physicians are accountable...

Dr. Beth Unger: Yes.

(Ermeus): ...for their states because their license come from the states and diseases that reportable are reported to the states.

(Mark Hamenson): So we have (unintelligible) 50 states instead of being efficient and doing it nationally. Okay so that's just bizarre, doesn't make any rational sense. But if that's the way it is we'll change 50 states.

Dr. Beth Unger: Okay (unintelligible).

(Gustavo): Well somebody who used to work for the – at the local department of health – this is (Gustavo) in the Office of AIDS for the District of Columbia right after grad school. The CDC staff is correct that so (Ermeus) and Beth are correct. We use to report AIDS cases in the district and HHV incident to the CDC like most jurisdiction does. The CDC personally does not gather this data when it's reported directly from each of the states and the jurisdiction including Puerto Rico, the District of Columbia, the Virgin Islands. So this is something that has to be dealt with at the state level, not so much at the federal level.

Dr. Sue Levine: I mean I just – may I just make a quick comment? And I know we want to move on. It's Sue Levine.

(Mark Hamenson): Right.

Dr. Sue Levine: I know a lot of organizations including Solve ME are interested in creating patient registries and in so doing, you know, track patients annually, track normal controls. And to try to determine something about the natural history of the illness and possibly combine that information with tissue, you know, banking tissue from the general body and the brain. And I know Vicky Whittemore was at Invest in ME in ME said that there - there's that kind of movement afoot in Europe where they're, you know, creating a tissue brain bank that will obviously track clinical information on ME/CFS patients. So it's not as if no one has thought of that. It's just and we think it's very important but I think it's a matter also of, you know, limited resources and people want to focus on treatment and another stuff first. But that's not to say this is not important as well. But, you know, people...

(Mark Hamenson): Well yes.

Dr. Sue Levine: ...have talked about it yes.

((Crosstalk))

Ben Hsuborger: This is Ben Hsuborger I with MEAction. I just want to jump into this discussion to say I appreciate the clarification around what CDC can and can't do. And obviously data quality is really important because one of the concerns that I see with the CDC that CDC could do something about with data tracking is that the way the CDC has modified the ICD-10 CM is to put ME/CFS in the same ICD code as chronic fatigue. And so then, you know, the two get - come together, that muddles the water with medical records. Any other tracking that you do through that that – so that seems to be something that the CDC could do especially with the new ICD-11 coming out is making sure that ME/CFS is distinguished from chronic fatigue because we all know

as part of CFSAC that those two things are not the same. But if we don't start tracking them in different ways we're going to continue to collect bad data.

Dr. Sue Levine: I agree.

(Mark Hamenson): Thank you.

Dr. Sue Levine: No I think that we can have a long discussion about this. And I think...

(Mark Hamenson): We...

((Crosstalk))

Dr. Sue Levine: ...once we develop biomarkers that will be, you know, become helpful as well. What do you say (Faith), should we move on with the pediatric education workgroup?

(Faith): Yes that's fine.

((Crosstalk))

(Ermeus): Before we move on we have one individual, the only person who requested to provide public comments at 2:30 and, you know...

Dr. Sue Levine: Sure.

(Faith): Oh yes.

(Ermeus): ...our apologies to Miss (Mahano) who is probably waiting to be given instruction from the operator as to how to provide comments. And after her comments we can open the floor to the public to answer or talk about any of the four questions and Syreeta have put on the screen for the public to see. (Faith) these are the ones that were developed by your workgroup and we thought would be a good idea for everybody to see them for those who did not receive them via the listserv. So operator...

(Faith): Yes.

(Ermeus): ...if you can open the line for Miss (Mahano) or if she's on the line.

Coordinator: Yes Miss (Mahano) your line is open.

(Mahano): Hello. Can you hear me?

(Ermeus): Yes ma'am. You'll have five minutes.

(Mahano): Thank you.

(Ermeus): Thank you.

(Mahano): Good afternoon. Today I would like to highlight the imperative need for pediatric specialists to manage ME. If I refer to it as ME/CFS apologies. Some of you will understand I hope. My sons are in their mid-20s and have had ME since 2005 sudden onset and 2006 gradual onset. They both are housebound and partially bedbound because of this disease.

The issues surrounding pediatric MA patients are of great concern to me. As we all know there are far too few specialists who work with adult ME/CFS patients. Even fewer specialists work with pediatric ME patients. The newly released pediatric primer is a positive step but the fact of the matter is that there are far too few qualified specialists willing and are able to take on pediatric patients. And this situation is not acceptable.

I asked well-known specialists in the United States with some of the key concerns are. The response rate was about 70% so not all those who responded answered every question. My first question was if they required post exertional worsening of symptoms a.k.a. PEMS as a mandatory symptom to diagnose ME/CFS or ME.

I was quite taken aback that only four out of seven of those who responded required post exertional worsening of symptoms. One out of seven did not give a clear-cut answer. And to my great distress two out of seven said they do not require it to make a diagnosis of ME. Not requiring post exertional worsening in order to make a diagnosis of ME concerns me. What disease are these practitioners really looking at?

I next asked if their practices accepted pediatric aged patients? Fifty-seven percent said yes, 29% said yes but only those over about 15 years of age. Fourteen percent do not accept pediatric patients. Of those who do accept pediatric aged patients 43% specified they have been seeing them for 24 years or more, twenty-nine percent said they have always seen them. I was also curious about the percentage of pediatric patients in each practice. Pediatric patients comprise 10% or fewer of the patients in most practices. In fact it is in only one practice accepting pediatric patients that 90% to 95% of patients have ME with post exertional worsening of symptoms. And fully 1/3 to 1/2 of those are pediatric patients. The practitioners (unintelligible) even though they are now adults. Think about it. Only one specialist sees pediatric ME/CFS patients full-time and he can't take on any more patients. If that sounds as though it isn't enough to adequately deal with the pediatric ME population you are right. It's nowhere near enough. So because one full-time specialist isn't enough I asked the specialist about factors that limit taking on more pediatric patients and about unique challenges regarding pediatric ME patients.

Limiting factors include the time needed per patient because of the complexity of the disease, not being able to take on any more patients of any age, not being trained in pediatric medicine, the practice being based in an adult only hospital, there's no one in the area to transition adults age patients to, the ever-increasing insurance company administrative demands, lack of administrative and/or nursing health due in part to the inability to hire medical help because of low reimbursement rates due to the time needed per patient and the complexity of disease and as Dr. (Peter Ro) noted "NIH funding provides support from studies on pathophysiology and mechanisms for clinical trials and very little funding for clinical research. Having funding would bring financial support that could highly or other helpers," thus freeing up practitioners time to take on more patients and train additional practitioners.

Pediatric ME patients face many challenges. In addition to the typical changes that occur as one grows up ME impacts academic life, their family including siblings, friends, social activities, self-esteem, quest for acceptance and for far too many the severity of ME can greatly impact their ability to become independent. Among other challenges the complexity of treating pediatric patients with ME is compounded by the overlap of comorbidities. Additionally pediatric patients may not know how to assess or verbalize their symptoms in part because they don't know what normal is for the growth period they are in and/or because of the length of time they been sick or because cognitive impairment may limit their ability to provide descriptions. Given that in most practices pediatric patients make up only 10% of the patients and that there's only one practitioner working full-time with pediatric ME patients it is abundantly clear that pediatric patients are even more underserved than the adult ME patient population. The number of practitioners who can accurately diagnose ME in pediatric patients and can treat symptoms must be increased dramatically.

These practitioners must be well-educated about this disease and must understand the unique challenges faced by pediatric patients and their families. The practitioners must be supportive of the patients and families. They need to work closely with them on myriad issues involving things like activities, school, insurance, learning to live within their energy resources and so on. These issues take quite a bit of time all of which is in addition to the time required during appointments to appropriately care for patients. In closing I want to express my sincere thanks to all those who provided such thorough responses to my questions. I would like to note that those who responded felt it was very important to highlight the critical need for more pediatric ME specialists. So I add their voices to my request that as this committee discusses medical education you also thoughtfully consider the unique needs of our pediatric population and the imperative needs for more pediatric ME specialists. Thank you.

(Gustavo): Thank you.

(Faith): Thank you (Denise).

(Gustavo): (Faith) I'm going to turn it over to you and ask the operator to open the lines for any other comments regarding the four questions on the Webinar.

Coordinator: Thank you. Once again if you do have any questions or comments you may press Star 1. Carol Head you may go ahead.

Carol Head: Hi. This is Carol again of FMTI and I want to respond to the issue that was discussed just a couple moments ago about prevalence of the disease. And I'm bringing it up because Sue Levine was kind enough to mention our patient registry. But I really want to be clear about what our registry can and cannot do.

First off it really is we are waiting to do a launch when - till we have the common data elements project that the work being done by CDC and NIH. We want to launch our new registry with common data elements so that it will become a resource to all researchers everywhere. But my point is that it really is not, it cannot be and was never designed to be a statistically significant set of individuals with ME/CFS and therefore could not be used to estimate prevalence of the disease in the United States. And if you'll bear with me just for a moment I mean this is such an important issue for us. And I hope staffs and (RES) at the CDC you can understand the misperception of many of us about how a prevalence study would occur to push it back to the states is an enormous burden on patient organizations and including all of us who were on the call here. And we don't have the resources to do it. You know, the - as I understand the mission of the CDC it is to protect the health of Americans and because the CDC had done an estimate of the prevalence of ME/CFS many, many years ago I hope you can understand why many of us would still hope that you would do that again. We, you know, again you've raised many of the challenges about doing a statistically rigorous prevalence study, you know what is the definition of the disease? Most patients are not diagnosed and, you know, we don't yet have (unintelligible). And at the same time, you know we continue in this circular loop of because we don't have X we can't get Y because we don't have X. And really the way to break through that is to proceed. You know, Ben's suggestion that about changing the ICD code so that we finally separate out ME from the very generic chronic fatigue is critically important. What work the CDC might be able to do is to instigate a prevalence study, you know, how, can you advise us on how to work through this issue with the various states. We have to find a way to work through the circular chicken egg problem that we have year after year after year. So I just I wanted to say that. I know that we're all aware of this. It's just how do we move forward on understanding prevalence? And I - just part of my comment here is I just wanted to mistake to correct a potentially mistaken perception that our registry would be able to assist in that. Thanks so much.

(Faith): Thank you Carol.

Coordinator: We do have another question. Would you like to take that?

(Faith): Yes please.

Coordinator: (Sue Ellen Tritt) you may go ahead.

(Sue Ellen Tritt): Yes I'm grateful for the opportunity, just wanted to address brief briefly pediatric Question on Number 2. In my many decades of advocacy the proper diagnosis that it's not behavioral is essential with children especially, understanding their limitations and the need to help them compensate for their limitations. Also forcing medications for behavioral issues as a panacea Adderall and Ritalin as - and I was given Ritalin -- it's horrendous -- it's damaging and it's a disgrace in our company that this is being done

wholesale to our children. Ignoring the progression and the fatal (unintelligible) progressions.

For instance just one example is children are highly subject to heatstroke. And that's not even mentioned in the schools. And there are children dying from it. A lot of the, you'll see these football players. I'm sure that's an issue. Charter schools being implemented will further cripple any efforts to get help for special needs children. That's - that I see is another tragedy coming on us if we don't stop it and not enough doctors to refer children to. In my advocacy it's very frustrating. A lot of parents will beg me who can I send my kids to? I don't even have a name to send them to.

Also the last - then lastly my in-person testimony to the CFSAA back in October 2000 I coined the term that this is an economic war. And it's very sad for me to see that it's even more so 17 years later. So it's incredibly tragic to see that children's symptoms are the only thing that is being treated because of the enormous amount of profit with (unintelligible) instead of focusing on the testing the mechanism to avoid progressive – progression and fatality. So I'm going to try to hope that someone's listening. As I said this is 17 years later. It's, you know I'd like not to be frustrated if I'm still by another miracle here in another 17 years. So I hope they'll be due attention in the agencies that need to look into this.

And just lastly the prevalence in military children is more than double in the general population. Doesn't it seem like it needs attention as well folks? Just wondering.

(Faith): Thank you very much for your comments. I think some of them might be addressed in the PowerPoint that I'm going to do shortly. And I can I have your name again please? I missed it at the beginning.

Coordinator: It was (Sue Ellen Tritt).

(Faith): Yes. Thank you.

Coordinator: Thank you. We do have one more question. Would you like to take that?

(Faith): Yes I would think you.

Coordinator: Thank you. Wilhelmina Jenkins you may ask your question.

Wilhelmina Jenkins: Good afternoon. My name is Wilhelmina Jenkins and I wanted to address Question Number 4. I'm a person who's been ill with ME/CFS since 1983 but my daughter became ill with this disease in 1991 as a sophomore in high school. She is an example of Number 4. She's doing much better now and is functioning very well but that was after many, many years of making serious adjustments to a lifestyle as well as good medical care and that's one thing I would like to emphasize first.

When she became ill we were not sure that she would be able to finish high school. She was dysfunctional. She was failing classes because she could not stay awake. She was nauseated. She could not get from place to place.

We had to do a number of very aggressive things. The first thing that was important was the fact that she was able to be diagnosed very quickly. Early diagnosis is key in this illness especially for young people. If they continue with the illness and do not know what's going on they could not learn how to function as some of us adults have learned how to at least continue our lives with this illness.

My daughter was able to get a very quick diagnosis because I already had the illness. I had all the information, particularly Dr. Bell's great information about pediatrics and this illness. Most young people and their parents have no information about how this affects young people.

I read Dr. Bell's information over and over again when we went to a wonderful doctor here in Atlanta who has been treating us ever since and came to him. He already knew about Dr. Bell. And he knew to throw everything that he possibly could to make my daughter more functional into her treatment plan and to completely adjust everything that she did functional. That was immediately. That was within six months of her getting ill.

We were lucky to find that doctor and it's already been mentioned earlier there are very few doctors that do treat pediatric cases. We were lucky. The first doctor that we went to was a terrible experience. My daughter had a blood pressure of 60/40. That doctor recommended a psychiatrist. We walked out. And we're fortunate enough to find our current doctor who was knowledgeable.

Getting knowledgeable doctors for young people with this illness is key to them being able to have any kind of success in living an adjusted but full life with this illness. She also had adjust her school schedule and we encounter teachers who were very reluctant to believe that she was ill. We had to learn how to work around those teachers, find teachers that she could work with, completely adjust her schedule. First period was off the table. Some teachers were off the table. We had to work constantly with her school to make sure that she could be a success.

When she completed high school she could not go away to college. There was no hope for that. She went to a college just a few blocks away from where we live because my husband was a professor there. She was able to go there, go to a class. I could drive her a few blocks to class. She could go to class. She could not both walk up the steps and learn at the same time. So she had first floor classes, jumped back in the car, went home, took medicine, food, rested and rehydrated.

With that kind of an effort and eliminating our social life all together she was able to succeed in college. She's now much better. She was one of the lucky ones who after having her first child became much healthier. But she would not have been able to get to the point of being functional in the world without a very early diagnosis.

We are African-Americans and I would be very surprised if there were any doctors that could point a large number of African-American students out who have this illness yet we know they're there. With African-Americans it's a particular problem because for many African-Americans particularly in urban areas expectations are already low. So when this illness crushes those expectations in those students people are always very ready to say, "Oh they aren't trying, they're lazy, they have school phobia. They just want to drop out."

This is not the case. Nobody that I've ever seen works this hard as young people with this illness to try to have some kind of a life. They want to have the same kind of life as their friends. They have to adjust.

I have a grandson who asks my daughter, "Why don't you tell funny stories about high school and college like other people's parents?" The reason is there are no funny stories. She gave up her life of funny stories and focused entirely on trying to hold on as hard as she could to the core of her life. She had me. She had her father. She had the people at her school who believed that she was seriously ill and her own fierce determination and our absolutely wonderful doctor Dr. Richard Prokesch here in Atlanta. Without those things she would not have the life that she has now.

All young people need a good doctor who is familiar with pediatric ME/CFS and who's able to work as hard as they can as hard as our doctor did to make sure that they are able to work as well as possible under the circumstances. It's a tragic thing. I think any parent who has a child with this illness can tell you that there's nothing as heartbreaking.

I've been disabled with this illness since 1987 but nothing that ever happened to me broke up my heart the way watching my daughter become ill with this as a sophomore in high school did. It broke my heart entirely. We need support as parents with this illness. We need a lot of support. We need all schools to understand that this is a serious illness and speaking for the African-American community we are terribly underdiagnosed. I would love to see this committee or the CDC or whoever is able to do this treat this as an under treatise illness within the African-American community. That will affect so many young people who at this point are just thrown away, treated as people who are not living up to what they could do. People are not trying as hard as they could.

I know this committee can do that. I know that the CDC and HHS have done things for underserved communities before. The young people who are African-Americans who have this illness deserve to be treated with care and respect to make sure that they can participate and be a part of this country in a way that everyone else wants to be. They have skills to contribute. They have perspectives to contribute. They have intelligence to contribute. Please

do the kind of things that will make sure that they get early diagnosis, quick treatments, understanding treatments from their schools and all the support that they need to become the most active and participatory people in the society that they can be.

It's not easy. It's good. It's not going to be easy for them. It's not easy to for the doctors. We'll need to give everybody the support that they need in order to do this. I know there are many, many young people out there just like my daughter. I have nightmares about the idea of a young person whose family has perhaps never had a child go to college who's been getting all As all through middle school and suddenly in the middle of high school begins to get Fs and whose parents go to a counselor who doesn't know anything about this illness who says, "Well they just look lazy to me. They're falling asleep, they're not showing up for class. Maybe he's just not college material."

This is not true. We need to make sure that all of our students get the kind of support and care they need both from medicine and from their schools. Thank you.

(Gustavo): Thank you so much. (Faith) I think we're ready. We did already – we're ready to start your present after those comments.

(Faith): Okay that sounds good if you would just bring it up. And you can yes go to the next Slide. Working group members of this group Robin Curtis from CDC, Kent Friedman, a patient advocate, (Alisa Dock), CFSAC member, Beth Mattey is I - hopefully I've got the correct title, Executive Director of the National Association of School Nurses, Carmen Sanchez who's with US DOE specifically with Parent Information Centers, Beth again, Vicky Whittemore with NINDS and a special (unintelligible) a group working with us who has in a school psychology who has treated...

(Gustavo): (Unintelligible) your phone I'm sorry.

(Faith): ...excuse me who has treated in schools gotten services for students that have ME/CFS. Okay our next Slide.

(Gustavo): (Faith) if you don't mind getting closer to your phone.

(Faith): Can you hear me or no?

(Gustavo): Yes now we can hear you better. Thanks.

(Faith): Okay sorry. Are you good now? All right update on the January 2017 recommendations. (Gustavo) can you hear me?

(Gustavo): Yes we're good.

(Faith): All right.

(Gustavo): Just needing you to speak louder.

(Faith): Okay the CDC was to coordinate with US DOE Office of Education to disseminate information on pediatric ME/CFS to our Parent Information Centers. For those of you who may not have any background each state has a Parent Information Center and parents can go to those Parent Information Centers to get information about how your son or daughter with ME/CFS

could qualify for services in the schools. The parent information centers are done by state since each state's rules and laws are a little bit different when it comes to applying for special education services. So progress has been made. They are designing a landing page on the CDC Pediatric Web site that's going to link all of the parent information center hubs. So that - they're moving along on that and that's - from Robin Curtis had a conversation with me last week or an email with me last that said that this is coming along nicely.

So hopefully will happen is the parents get on the Parent Information Center site they will see that if they have a child that has ME/CFS they can automatically connect to the CDC Pediatric Web site. And the same thing will be true if they're on the CDC Web site they can see that they can get information about schools from the Parent Information Centers.

So the next step would include developing a Webinar around Pediatric ME/CFS that hopefully will be used on the Parent Information Center hub so that they have that access to that information. Next Slide. The CDC and the School Nurses Association is working together to involve a series of Webinars on ME/CFS to be distributed to all school nurses nationwide. Again they're finalizing the Web page content on the Web pages similar to the Parent Information Centers, the NAS and which is our Association of School Nurses would also have that link to this CDC Web site under the parent information hub. So that way it's triangulated and parents regardless of where they go can find out information that they need.

Also our school nurses will now have that information about ME/CFS that they can use when they have students that come in their office who's parents may not know what's wrong with them or maybe they need to refer them to a physician to find out what's going on or that child may need help in staying in school and how do we go about giving them those resources. The next steps would be to work on a Webinar by the parents and the nurses about what ME/CFS is and what kinds of support that we can provide in the school. Next Slide.

The next recommendation was given the implications of pediatric ME/CFS it was suggested that one position on the committee's roster would be an educator from the US Department of Education well versed in special education services. The recommendation was made for Carmen Sanchez to serve on the CFSAC as an ex-aficionado. We are waiting for the new member to be appointed to CFSAC as (Gustavo) said at the beginning of this meeting. Once they are confirmed there will be a formal recommendation to appoint Ms. Sanchez. And unfortunately due to a prior commitment she could not participate with us today and tomorrow. Next Slide please.

Okay suggestions then were our group was working on a two-pronged approach. We want to educate both our parents and our schools simultaneously about services and support that students that have ME/CFS

can get. So what materials can we offer them, how do we how do we go about doing this?

I've worked with the CDC before on their fact sheet. The pediatrics Web site has got some great information on there. They are in the process of updating it. I also have a fact sheet that I've put up here that you'll see in the next couple of Slides. It's just something that's informative.

Just a comment CDC has to have language in a certain way. So while those of us that may be working with other organizations across the country we can say things a little bit differently. So the CDC has to use that particular language and it has to be approved. So we're looking at what kinds of accommodations and modifications are needed with children with ME/CFS. And we're going to have that available on the Parent Information Center hub before the states. Next Slide please.

So this fact is something that I've developed that is that I've used for many years. It gets updated frequently. So the first page just so you get an idea of what would be the symptoms on the left-hand side. So this is something that we would distribute to schools, to school nurses as well as the parents. It can also go to teachers, administrators in schools. So you have information about the illness. It's right now been lined up with most recently the version of the primer, the new primer for ME/CFS diagnosis and management of young people that just came out in the last two weeks or so. The second, go to the next Slide please. So your next Slide has educational implications. So this discussed what you would see with a child that has ME/CFS in school. Some can attend school part time. Some are bed bound. Some can attend daily. It tells you what happens with schoolwork, the fact that they need accommodations. It also gives you some information about how it affects our students in school, your intellectual reasoning or the language ability is not affected all right. So if they need to take advanced classes they should do so. We talked about brain fog and the ability that they are confused or forgetful at points in time depending on how sick they are.

It also goes on different ways that the illness can manifest itself in the classroom such as distractibility or they can't complete an assignment or they can't retrieve information learned the day before. So you have all that information on this page as well as some resources. Here on information centers up here Massachusetts CFIDS/ME which spoke a little while ago is up here Solve ME/CFS, et cetera, and then lastly the primer that was just came out. Next Slide please.

Perhaps most useful to educators and the parents this goes over materials instruction how do we teach students a little bit differently who have ME/CFS and then logistical and administrative accommodations that we can make. These are all things that you can put in an individual education plan IEP or a 504 plan in the school for parents. Next Slide please.

Top part of this last Slide is assessment is how do we test our students that have ME/CFS, what we do about giving them curriculum? And then very lastly as suggested by the working groups were some psychological tests and procedures that may contribute or help support the pace for a students to be on an IETF or a 504 plan. Please note that this is not required however some testing especially when you're looking at different tests like the (waste) or the repeatable battery for assessment of neurological status, the (RVAN) can give supporting information to parents and to the schools about why this child needs the services that they need. Next Slide please.

Future issues of this working group. We look at that parents need some type of fact-based documentation about ME/CFS we need to be able to have them take those accommodations and modifications and get them to school. So whether that goes up on the Parent Information Center site or the school nurses that's something that needs to be determined. The results of a lot of discussion about why spread inconsistency among states and school districts about the documentation that they need for an IEP which the categories for our students that have ME/CFS falls under is other health impaired.

So what recommendations can we make, how do we get we - I was listening to carefully when you said, you know, your one child ended up dropping out of high school. I am adamant about how do we get those supports for our children so that they do not have to drop out of high school? How do we get them through high school, through middle school, through elementary school so that they can be successful and graduate and go to college if they're well enough to do so? Next Slide please.

Initial valuations for our students that have ME/CFS is going to take 45 days. So early request for an evaluation in your school district is critical. Here is something else that I hear a lot of. I've done a lot of advocacy work in New York, PA, Maryland. My husband does that as well in the Midwest. And I want to point out this statement very carefully.

Schools may not receive to complete an evaluation as long as the parents put that evaluation or that request in writing. So if you as a parent have a child that has ME/CFS you are – you can simply state it we are requesting that our child be evaluated for special services. Language is extremely important all right. And parents do have the opportunity to monitor that evaluation process as it occurs. Next Slide please.

Data that we get for parents so that their child can get their services are from parent teacher interview surveys, attendance records, medical records, any psychological testing that can be formed performed by the school psychologist. And again as I said before not required but can be useful especially if you were looking at short-term memory deficits. That's where it's going to show up. It'll also show up in slow processing speed. And that's - usually that information's very helpful to an IETF team or a 504 plan team in diagnosing what kinds of support you need for children.

Parents have the right to see all data -- testing results and documentation that's used in decision-making about their child. And a lot of times parents don't know that. It is (unintelligible) that information and to make sure that you do have it. Next Slide please.

Once the school has gathered that information and analyzed that documentation the next step is that there is an eligibility meeting scheduled with parents. Parents are always included in the eligibility meeting. I would highly recommend that you bring a parent advocate with you. You can get that from your Parent Information Center Web site through your state. The school has two provide written documentation on what the basis of that recommendation is. Are they going to approve or disapprove special services?

Being denied for an IET does not mean a child is denied for an IO 504 plan. The standards are very, very different. It is very technical for parents. So again as I stated a little bit earlier a parent advocate is very capable of interpreting the test results for you. It is highly recommended that you contact your Parent Information Center Web site through your state and you get that information.

Next Slide please. Lastly there is nothing in the federal (IDEA) law that requires that students undergo psychological testing for ME/CFS. However there as I said before there are several tests that could be beneficial for those accommodations. Next Slide.

So recommendations from this group that we will discuss I think tomorrow afternoon (Gustavo) -- I'm not sure if we're doing it this afternoon or tomorrow afternoon -- but recommendations to HHS create parent specific fact sheets and facts sheets for school personnel on ME/CFS. Again although I gave you samples here the government has to use language that is plain language for references for parents so they cannot look similar to what I've done.

Secondly an ME/CFS sheet on the eligibility process for IEPs and for 504 plans I think would also be very useful for parents. Second recommendation is that I think we need to start having at each of our CSITAC meetings an update on pediatric ME/CFS research at each of the staff meeting. I think that's critical given the number of children now that have been diagnosed with ME/CFS. Next Slide. We're done. Questions or comments from either the public or members of the CFSAC CFS committee?

Coordinator: If you'd like to ask a question over the phone please press Star 1.

(Faith): Do we have any questions out there?

Coordinator: No questions over the phones. Any...

Ben Hsuborger: Hi. This is Ben Hsuborger. I just had one question. The information that you presented on Slides 3 and 4 about the landing page I was wondering if is that information that's being put together is it going to be aligned with the

pediatric primer that was just published, just wanted to confirm (unintelligible).

(Faith): It is already aligned with the primer that was published. I was one of the contributing authors on that primer and it was already vetted by one of the authors on that primer so it is aligned.

Ben Hsuborger: Great. Thank you.

(Faith): You're welcome. Someone else?

Coordinator: We have a question from the phone.

(Faith): Go ahead.

Coordinator: (Mary Kimmeth) your line is open. Mary your line is open. Please check your mute button or pick up your handset.

(Mary Kimmeth): Thank you. Thanks for the opportunity to ask questions. I wanted to follow-up on Ben's question. I appreciate that the material that you showed us on the accommodations information, et cetera, is already aligned. There's also information on the pediatric on the CF CDC Pediatric Web site. Will that information also be aligned with the primer?

(Faith): That's a question that would have to be asked of (Ermeus) or Beth.

(Mary Kimmeth) Okay.

(Faith): And the...

Dr. Beth Unger: This is Beth. The primer just became available but (Faith)'s group has reviewed not (unintelligible) in mind but the Web site in general. So I think that it's, you know, unless there's something new it should be aligned.

(Mary Kimmeth) So for instance the primer requires PEM whereas the Web site right now is based on (Facuda) not surprisingly since it's been there so – for a while. So there are some aspects of it that could use some updating I would think. If it's useful I can send some comments to you directly.

Dr. Beth Unger: We are in the process of revising it with the IOM criteria yes.

(Mary Kimmeth) Okay.

Dr. Beth Unger: Yes.

(Mary Kimmeth): Yes, thank you.

(Faith): (Mary) go ahead and send that please. That would be useful. You may have but...

((Crosstalk))

(Faith): I may not have seen it.

(Mary Kimmeth) Thanks.

Coordinator: Any other questions, comments or concerns?

(Gustavo): (Faith) these recommendations to HHS are they specific to – I have a question. I mean I know that the committee has not voted on it. I'm not sure I think Gary and Dane Cook are already on so we have a quorum. Let me confirm that Gary and Dane. Are you guys on?

Dr. Gary Kaplan: This is Gary. I'm here.

Dr. Dane Cook: This is Dane. I'm here.

- (Gustavo): Okay welcome both. So (Faith) I have a question and I don't quite understand two and three. Standardize updates on PGS like ME/CFS research at each CFSAC meeting. Can you expand on that?
- (Faith): Yes what I would like to see -- Sue Levine is doing it at this meeting -- but I would just like to see an update on what research...
- (Gustavo): Oh, okay.
- (Faith): ...On what research has come out so that everybody is aware of just what's going on with pediatrics. We tend to overlook that. And I think we're seeing a lot more students getting ME/CFS and we need to start dealing with it. So just similar to what Sue's doing just an update on what...
- (Gustavo): Okay.
- ((Crosstalk))
- (Faith): ...the (ratios) because that's happened.
- (Gustavo): So this is a standing item you'd like to see on the agenda?
- (Faith): Correct.
- (Gustavo): And Number 3?
- (Faith): This is more if Carmen Sanchez gets approved as the ex-officio I'd like to see some updates on what the school implementations of ME/CFS are...
- (Gustavo): Okay.
- ((Crosstalk))
- (Faith): ...for the (unintelligible) the Department of Education.
- (Gustavo): Okay. And Number 1 Bullet 2 I -- this is something that I don't see HHS doing because we don't do the IVP and the 504 plans.
- (Faith): Yes you're right. As I read it I thought about that and I said, you know, what this is a recommendation for CDC. It really isn't a recommendation for HHS.
- (Gustavo): No, no but even CDC the CDC doesn't to the IEP in the 504 type of plan.
- (Faith): Oh you mean Letter B?
- (Gustavo): Yes, 1B.
- (Faith): That's true. That would have to be on -- you're correct. That has to be on the Parent Information Center Website, the PIC.
- (Gustavo): Okay.
- (Faith): That will be (alone). So that needs to be reworded and I'll reword it.
- (Gustavo): So I have a suggestion. We have a break at 3'45. And we break now from 3:30 to 3:45, come back at 3:45 if that's possible so the committee can vote on these because unless you guys want to go ahead and understand each of these recommendations to either approve or disapprove change and delete them -- do what you guys usually do.
- (Faith): That works for me. Let me in the meantime revise them during that 15-minute break. And can I send them straight away to you (Gustavo)?
- (Gustavo): Yes and then to Syreeta and I and we'll...
- (Faith): All right.
- (Gustavo): ...manage to load them up.

(Faith): All right let me do that.

Dr. Gary Kaplan: All right (Gustavo)?

(Gustavo): Yes sir?

Dr. Gary Kaplan: Yes this is Gary. Number 2, standardized update on pediatric ME/CFS research or the CFSAC CFS meeting I would love to see that expanded to standardized update on research at ME/CFS. The problem...

((Crosstalk))

(Faith): I actually...

Dr. Gary Kaplan: ...not just the pediatrics.

(Faith): ...already said that.

(Gustavo): Well we can discuss that when – if you guys approve it or disapprove it. But the issue that I have is that right now the one due in the - this update its Sue Levine. This is her last meeting as her term expire. And we are not sure whether or not we'll get a physician as the new member of the committee that is capable unless Dr. Montoya wants to do it at the next meeting to give an update on both pediatric and adult. That's the issue that I see with that. So you...

((Crosstalk))

Dr. Gary Kaplan: (Unintelligible) the concern it would certain be certainly something that we'd love to – I think it would be something that would be of service to the community and useful to enter into the notes.

(Faith): I also don't know if it has to be somebody on CFSAC that...

(Gustavo): Yes you're right. I was thinking we do have funding for to invite speakers and contractors to speak. So that would be something that me as the CFO we have to work through our administrative process unless somebody wants to do it for free. But anyway we can talk about that when you guys are ready to vote. So is everybody okay with taking the break now and coming back at 3:45?

Woman: Yes that makes sense.

(Faith): That works.

Woman: Yes.

(Faith): Thank you.

(Gustavo): So you think about these in the next 15 minutes and then we'll reconvene at 3:45.

(Faith): Thank you.

(Gustavo): Welcome back everyone. So Syreeta has put on a whiteboard on the screen so you all can see in either revise, draft or leave as it is the recommendations drafted by (Faith)'s work group. So now open the floor for comments.

Dr. Gary Kaplan: Hi. This is Gary. Who's going to create the patient specific fact sheet? Hello?

(Gustavo): Yes. I imagine this would be something for the CDC. Therefore (Ermeus) what do you think?

Dr. Beth Unger: This is Beth and we do have a patient fact sheet for and one for schools that we developed in conjunction with the community. And (Faith) was involved in the preparation of those. We did share them with the pediatric workgroup so it's – I'm not sure what additional, you know, I guess it could be modified but we do have that. And I'm not sure if the committee – if the (Faith)'s committee wanted something that to be available at the HHS level like from CFSAC itself.

Dr. Gary Kaplan: The problem with the recommendation as it's written is that there's no – I'm not sure what I'm voting on. There's no action plan and I don't know if I'm – what I'm approving. Are you directing somebody to do something or are we directing the committee to come back to us with that and then we'll approve it and then how does it get distributed of course? So I'm not sure what I'm voting for on that first one. I agree with it conceptually but I'm not sure how it happens and where it goes.

Dr. Beth Unger: And this is Beth. And I would say this is part of the problem that the committee has had that CFSAC CFS is supposed to be advising Health and Human Services. And that is different than advising CDC. I mean it's HHS can advise CDC or tell CDC but it's a little complicated I guess.

(Gustavo): (Faith) are you on? Might be on mute. We'll let's – I don't know where (Faith) is. Let's move on to the second one which is something that we could easily do. And I guess that would befall on me and probably will be incorporated into the SOP which we will talk about tomorrow about having a standardize update on both pediatric and adult ME/CFS update and research at each meeting. And the other one is contingent upon whether or not Carmen Sanchez joins the committee as an ex-officio which is something I have not worked on because we still don't even have new members and are still waiting for the new administration to approve them. So I don't even want to add more work that is just going to sit in limbo. But this is something to be done once Carmen is on the committee, not necessarily Carmen but the Department of Education so Beth or somebody from there.

Dr. Gary Kaplan: So it strikes me that this last one is really about agreeing to create an ex-official seat for the Department of Education for this purpose. Is that not correct?

(Gustavo): Yes and that was recommended last at the January meeting in...

Dr. Gary Kaplan: Is there any need for us to take action on it?

(Gustavo): No. It's a recommendation which we say we would do. However Gary I don't want to send Carmen's name forward until we have new members because nothing is really moving as fast as we would like them to with the new administration. In other words the most important thing we need at this time for this committee is new members. We have to extend the three members - - Dane, Sue and yourself. So you guys would participate at that this meeting because we are not having – we're not getting the response that we would

like from the people here who approve members for the committee as fast as we would like to. So I think that's more important than have – then bringing a new ex-official to the committee.

Dr. Gary Kaplan: Understood. So it strikes me at this point in time there's actually nothing we can move on on these.

(Gustavo): I mean the second one is something that could be suggested or voted upon because it's something that I myself as the CFO can do which is find somebody at every meeting that will provide an update to the members and the community on ME/CFS updates.

Dr. Sue Levine: Yes I mean it's Sue. You could even have, you know, Catherine Rowe from New Zealand on Skype or, you know, you could have other...

(Gustavo): But we can have you as a guest speaker.

Dr. Sue Levine: Yes, yes. But I know the pediatricians are harder to come by who do ME/CFS. That's why I was, you know...

(Gustavo): Oh this lady is a - deals with pediatrics only...

Dr. Sue Levine: Yes.

(Gustavo): ...the person you mentioned?

Dr. Sue Levine: Yes.

(Gustavo): Okay.

Dr. Sue Levine: Yes so, you know, I think – and that's certainly worth. And I think the public would like to know updates in general so I think that's a good feature so it doesn't always have to be provided by a member of CFSAC updates.

(Gustavo): Yes.

Dr. Sue Levine: So I think that's certainly true. The other two recommendations are little more difficult to grapple with. I agree.

Dr. Gary Kaplan: So I would propose that research updates on ME/CFS in the pediatric and adult population become a - an agenda items on all CFSAC CFS meetings moving forward.

Dr. Sue Levine: Okay I second that.

(Gustavo): Remember that Gary because Syreeta has to type it. Oh they haven't voted up on yet so that was second by Sue proposed by Gary. Sue you have to call a vote.

Dr. Sue Levine: Yes let's – well we're waiting for (Faith) right?

(Gustavo): I don't know where she went.

Dr. Sue Levine: Yes it's possible. I know I had a few little computer glitches myself so I can...

(Faith): And you might want to add...

Dr. Sue Levine: We might need her to do the quorum is that right or do we...

(Faith): Well (Faith) got on but you'll need a (unintelligible) I recall calling back in.

Dr. Sue Levine: Okay.

(Gustavo): She's rejoining. Let's give her a few minutes.

Woman: (Michelle) I'm sorry, can you check on Donna Pearson? She says she cannot – we can't hear her and she's speaking.

Coordinator: If she could get Star 1.
Woman: Okay.
(Gustavo): (Donna) can you press Star 1 for the operator to grab you?
Donna Pearson: Are you there?
Coordinator: Okay the line is open.
Donna Pearson: Okay you can hear me now?
Dr. Sue Levine: Yes.
Donna Pearson: I'm wondering how many other people have that problem coming back in because we don't hear very many voices.
Dr. Sue Levine: Maybe (Faith) does. We're waiting for her to make some comments. We're you going to say something Donna or...
Donna Pearson: Well I was going to mention something to (Faith) before but it was about the fact sheet. I'll just...

Ben Hsuborger: (Gustavo) this is Ben Hsuborger. I was wondering while we're waiting if you could give us a little preview of I know we're talking about the SOP tomorrow but give sort of a (vote) of how that conversation will go? So are you looking to finalize an SOP tomorrow? What...

((Crosstalk))
(Faith): All right this is (Faith). I'm back on finally.
(Gustavo): I'm sorry (Faith). Let me answer a question quickly that Ben asked. Ben this was proposed at the last meeting. I drafted something between the last meeting on last week when I send it to everybody. I think you received it. I just want to have a discussion about it, make sure then we all clear and we can finalize it. And then it will be standard not only for me but for somebody else to come in and be the DFO should I ever leave this position which is, you know, happens. So I said it's a standard - it's in SOP that all the other committees within (OASH) have in place just for the very same reason in case you get a – a committee gets a new DFO and that person needs to find out what needs to get done and how to put a meeting together and what happens before and after the meeting.
Ben Hsuborger: Thank you.
(Gustavo): All right (Faith)? So (Faith) we have a question about will
(Faith): I heard...
(Gustavo): Go ahead.
(Faith): Go ahead. That point...
(Gustavo): We were going to revised the second one by Dr. Kaplan made a suggestion but we didn't have a quorum to vote on it.
(Faith): Dr. Kaplan what was your suggestion?

Dr. Gary Kaplan: Oh it was revising the standardized updates on pediatrics to say that research updates on adult and pediatric ME/CFS the research be included as an agenda items on all CFSAC meetings moving forward.

Dr. Sue Levine: Slow down.
(Faith): (Unintelligible).

Dr. Sue Levine: Gary you spoke faster than they can type.

Dr. Gary Kaplan: Okay. So the proposal is that research updates on adult and pediatric ME/CFS research.

(Faith): Go ahead.

Woman: Yes?

Dr. Gary Kaplan: ...be an agenda item at all CFSAC meetings.

(Gustavo): So that's the change from Bullet Number 2 (Faith).

(Faith): Correct. And that makes sense.

Dr. Gary Kaplan: And edit that so it's – I'm not research update. So just eliminate the first research, capitalize the UN updates.

Donna Pearson: So this is (Donna). While she's typing number one, I have a couple questions. Number one, who prepares these research updates and presents them? And number two with this be more appropriate for the SOP rather than as a recommendation to HHS unless we're acting for someone from HHS to bring these research updates to CFSAC?

(Gustavo): I you referring to the first one?

Donna Pearson: I am referring to we're adding time to the agenda for research updates so that'll be part of our standard agenda.

(Gustavo): Yes.

Donna Pearson: Are we asking someone from HHS to put something together and present it? What exactly are we asking other than...

((Crosstalk))

(Gustavo): You are – what we have discussed so far Donna is that we – you are asking HHS to have a pediatric and adult research update on research on ME/CFS at every meeting.

Donna Pearson: Presented by who?

(Gustavo): That hasn't been discussed but I assume that it's not somebody from the committee. Right now we have Sue Levine then it would be up to me to find somebody as a suggestion or the help with - of the chair to have that person in the agenda.

Woman: Is that okay Donna?

Donna Pearson: Yes I understand what you're saying now. So it's up to the chair...

((Crosstalk))

(Gustavo): So it will be a standing agenda item like we have agency updates and nonvoting organization updates.

Donna Pearson: Right.

Woman: Does that make sense?

Donna Pearson: Yes except we don't...
(Faith): Great.
Donna Pearson: ...have a research - but we don't have a research expert serving so...
(Faith): No and so...
Dr. Sue Levine: We're going to make an outside person I think.
(Faith): I would agree. It's probably going to have to be an outside person. But it's not something I can do. It's going to have to be an outside person.
Man: But (Dave) can do it because he has...
(Faith): Well...
Man: ...lots of spare time.
(Dave): I unfortunately will be gone by the time it comes around.
Man: Ah, but we can bring people in...
((Crosstalk))
Man: ...without them having to be on the committee.
(Dave): That's true. That is true.
(Courtney): This is (Courtney). Can you hear me?
(Gustavo): Yes.
Woman: Yes.
(Faith): Yes go ahead Courtney.
Courtney: So this might be crazy but who couldn't the NIH give us a research update on what research has happened? I mean I assume we're talking about published findings.
Dr. Sue Levine: Or maybe they could provide what studies were funded and like an update on, you know, what they've done so far. That's a good idea.
Courtney: Well they do their own update on their activities to...
Dr. Sue Levine: Right.
Courtney: ...hopefully increases research right which we want to keep.
Dr. Sue Levine: But then we'd know about...
((Crosstalk))
Dr. Sue Levine: ...what new research projects have been submitted and might not be published yet although I'm not sure that that could be divulged but yes.
Dr. Gary Kaplan: Well they're two different things though. So if you've got one person giving an update on what's been recently funded that's one thing. The other is what research has been completed and what the conclusions of is another.
Dr. Sue Levine: But some of these studies...
Woman: And I...
Dr. Sue Levine: ...have been like five year Gary like the Vanderbilt studies on IV saline for instance...
Dr. Gary Kaplan: Yes.
Dr. Sue Levine: ...there's little updates provided on their Web site that presumably are not confidential that might be interesting that the general public might not be aware of but that, you know, I think that might be interesting to have the NIH perhaps be a resource anyway.

Dr. Gary Kaplan: I think it'd be interesting to have both but...

Courtney: Yes I don't want to limit it to just NIH.

Dr. Sue Levine: Right.

Courtney: I'm with Gary. I would like to see both as well.

Dr. Sue Levine: Do we need to wordsmith that recommendation any differently than if we want to do that or I mean it's still an update. I mean does - I don't know if you had to add anything to the recommendation the way it stands because we're getting ready to vote on this.

Courtney: I think it's fine. I'm not sure what everybody...

Woman: Sure.

Dr. Sue Levine: I think it's fine.

Dr. Gary Kaplan: It's fine.

(Gustavo): So on the second one what do you guys want to do about it? It is...

Dr. Sue Levine: I'm not sure Gustavo that (Faith) and knows that we weren't sure how to do - whether, you know, whether to table Recommendations 1 and 3. Remember we had the discussion just now and she wasn't on the line?

(Gustavo): Yes.

Dr. Sue Levine: I'm not sure if you know what I mean.

(Gustavo): Yes.

Dr. Sue Levine: So...

(Faith): Yes.

Dr. Gary Kaplan: Also why don't we vote on these things one at a time? That's why it's done.

(Faith): Yes let's finish the one that we're currently working on first.

Dr. Sue Levine: Yes. Okay let's call a vote.

(Faith): Call a vote call...

Woman: And this?

(Gustavo): Yes. And this becomes this.

(Faith): Gustavo do you call that or does Sue or I call it?

(Gustavo): The chair does that. You or Sue can do it.

Dr. Sue Levine: Yes. Let me...

(Faith): Go ahead Sue.

Dr. Sue Levine: I'm just waiting for them because she's seems to still be writing it out. That's why I'm hesitating. I'm not sure she's finished writing it, you know, on the whiteboard here.

Woman: I'm finished.

Dr. Sue Levine: Okay thank you.

Woman: You're welcome.

Dr. Gary Kaplan: And actually I think we're actually going to do this, it is the recommendation of the committee that updates on adults.

Woman: But yes.

Dr. Sue Levine: Okay. That makes...

(Faith): Yes that makes sense Gary...

(Gustavo): It is the...

((Crosstalk))

(Faith): ...or whoever said that.

Woman: The committee.

(Gustavo): The committee that - is that fine Gary?

Dr. Gary Kaplan: Yes.

Dr. Sue Levine: Okay if we're finished with that let me call a vote on that recommendation.
Okay. Who agrees, say your name please.

Donna Pearson: Donna.

Dr. Gary Kaplan: Gary yes?

(Faith): Faith yes.

(Dave): (Dave) yes.

Dr. Sue Levine: Sue yes.

Woman: (Unintelligible).

Dr. Sue Levine: Has everybody cast a vote?

(Gustavo): Sounds like everybody said yes.

(Faith): Yes everybody said yes Sue.

Dr. Sue Levine: Great, okay. Now in the interest of time we have on the agenda still too for me to provide that update we were just talking about. Do we want to discuss a little further these other two recommendations?

(Faith): I've heard of what - part of what (Gustavo) and Beth said so let me talk to the states. For the third recommendation we charge Carmen Sanchez or what - whoever the representative is going to be is not going to prove (unintelligible) a third recommendation (unintelligible) to these tables okay? So let's just table that because we're not to that point yet.

(Gustavo): So delete it (unintelligible) for now? I know delete it from the whiteboard. That's what I mean.

(Faith): I can't see the white - well I can't see the whiteboard. Can you read it to me?

(Gustavo): Characterize update on school implications of pediatric ME/CFS annually at the CFSAC meeting. It's basically the same as the last one but it would be something the Department of Education would do. Well you came up with the recommendation so you know what it is.

(Faith): Right. It was something that the - I wanted the Department of Education to do is what is going on in education and could we update a little on the cases of what's going on with ME/CFS. And Carmen or whoever represents the...

(Gustavo): Yes.

(Faith): ...Department of Education would be able to do that.

Dr. Sue Levine: So right now you want to table that recommendation?

(Faith): I would just because you don't have an ex-officio member that's going to...

Dr. Sue Levine: I see.

(Faith): ...(unintelligible) that because that's...

((Crosstalk))

Dr. Sue Levine: Right makes - okay.

(Faith): So I would wish we table it.

Dr. Sue Levine: Okay and folks what did we decide on the fact sheets? We decided to just hold up on that for now?

(Faith): Yes we need to hold up off on it to see what the CDC and the Parent Information Center and the school nurses are linking on their platform.

Donna Pearson: (Faith) this is Donna. Can I say one thing about that?

(Faith): Yes.

Donna Pearson: So this school fact sheet I think you're the one that - the ones that you showed you actually wrote those yourself?

(Faith): Yes.

Donna Pearson: So like...

(Faith): But they're different than what's on the Web site.

Donna Pearson: Okay yes those were great. I only – I wanted to point out a few things. And one of them was that it said that it's a diagnosis of exclusion. And IOM has made it clear that we should no longer call it diagnosis of exclusion.

(Faith): Okay.

Donna Pearson: I think that's one of the reasons that some people get thrown in to the CFSAC category. And the second thing just a terminology thing but it talks about you used the term illness on that first page and are you really trying to change the narrative to use the term disease which was a big thing that came up on the under the IOM report?

(Faith): And you are correct and I'm surprised I didn't pick up on it. Thank you.

Donna Pearson: Not a problem.

(Faith): You're welcome Donna.

Donna Pearson: Those were great though.

(Faith): Thanks. So (Gustavo) let's table that until they get some more progress on where they are with the CDC the school nurse, school associates and school nurses and the Parent Information Center.

(Gustavo): Okay are you going to continue because I don't want this to be lost for the next meeting? Are you going to continue your pediatric committee so these can be included at the December meeting to...

(Faith): Yes.

(Gustavo): ...should things go faster with this office having new members come on board?

(Faith): Yes I am. I would like to continue it. That way if we get the ex-officio member on board and the new members we can hopefully finish up this working group in December.

(Gustavo): Okay perfect. So for the purpose of this exercise I'm going to ask Syreeta to delete then the second – the first bullet. And this is one of the

- recommendations and we'll send forward to the secretary and, you know, and provide a response which is easy to do. None of delete I want to...
- Dr. Sue Levine: So I know I'm doing this kind of prematurely but one of the things we usually discuss at the end of the second day in the meeting is groups for next year for next, you know, not next year but for the next six months. So I want you guys to think about continuing with the – usually we don't do more than two workgroups so we - so I want you to think about it overnight. We're going to perhaps keep the pediatric one growing for at least one more session. And then Gary think about we probably will is that right, keep the medical (unintelligible).
- (Gustavo): Well the problem with that one is that Gary's the chair and his term is expiring just like you and Dane.
- Dr. Sue Levine: So let's may be think overnight of how we deal with that or who we pass the torch to. I don't know...
- Dr. Gary Kaplan: So the medical education one were supposed to – we are giving an interim report tomorrow...
- Dr. Sue Levine: Yes.
- Dr. Gary Kaplan: ...but we'll so the expectation is that we'll have a definitive report for the committee at next meeting. When is it approximately?
- Dr. Sue Levine: December I think.
- (Gustavo): December...
- Woman: Thirteenth and 14th.
- (Gustavo): ...13 and 14 and (unintelligible).
- (Faith): Thirteenth and Fourteenth.
- Dr. Gary Kaplan: Okay so that's going to pass because my term was extended to November I believe.
- (Gustavo): Yes.
- Dr. Gary Kaplan: Okay so I'm going to have to hand it off to somebody for presentation unless you want me as a non-member of the committee to do the presentation at that time and somebody else will have to pick it up after that. Whatever works for you is fine by me.
- (Gustavo): I'll find out if a non-voting member can present from our committee management officer. But if not, you know, somebody else can present. But I would like for you to work on it until your term is expired.
- Dr. Gary Kaplan: Oh I plan to. That was my expectation.
- (Gustavo): Okay thank you.
- Dr. Gary Kaplan: My plan is to finish it and just really hand it over to you so...
- (Faith): If you would be nice if you could present on it so hopefully we can do that.
- (Gustavo): So well I guess this has passed. This recommendation has passed so we can move on to if nobody else has any questions to Sue's presentation.
- Dr. Sue Levine: Now (Faith) are you doing – what did we decide on about the updated pediatrics?

(Faith): I thought you were doing at.
Dr. Sue Levine: No I didn't...
((Crosstalk))
(Faith): It was a miscommunication on both...
Dr. Sue Levine: No. I mean I don't know why I thought that too. I thought that either you or you were getting...
(Faith): Right. And we tried...
Dr. Sue Levine: ...(unintelligible) role. I'm sorry.
(Gustavo): Sue that was...
(Faith): Right.
(Gustavo): ...in the email between you and (Faith). And the last email was that you were going to do it because the person you had in mind could not.
Dr. Sue Levine: Right, right.
(Faith): Right.
Dr. Sue Levine: Okay. All right. So I'm going to present some – my presentation is entitled new research and ME/CFS. And it's largely taken from but not exclusively from the Invest in ME meeting that took place in London earlier this month. And okay next Slide please. Okay the major categories I'm going to discuss are tissue brain bank, common data elements, microbiome metabolome and autoimmunity. Next Slide.
Okay first we're going to talk a little bit about the idea of tissue brain bank. And my– I've just taken out important elements from this whole idea. There's a lot more that goes into it. But (McCaw) and others from the London School of Hygiene and Tropical Medicine together with NIAID have sought to establish a postmortem brain and tissue bank for the study of ME/CFS. And what they thought about is establishing a specific donor program that involves several elements which are important in processing tissue after the death of a subject. The main thing is rapid collection to ensure integrity of the specimen and processing. Next Slide.
And presumably in advance of the death of a ME/CFS subject and a normal control or whoever else has volunteered to be a donor supplemental clinical laboratory and self-assessment data would've been collected from each of the potential subjects. The idea was to incorporate this potential tissue brain bank in an existing bio bank that's already been set up and is up and going. For instance those have been set up to study Alzheimer's patients and those with Creutzfeldt-Jakob Disease which is a slow virus that affects the brain. It's a prion. Now potential donors would've access to a Web page and follow instructions from that Web page. Next Slide.
The goals of such an endeavor would be to establish a cohort of well-characterized controls in ME/CFS patients to help identify potential biomarkers and retrieve high-quality pathological samples and then to hopefully disseminate this resource globally so that researcher's questions around the world could learn new information about this disease. Next Slide.

Next I'm going to move on to common data elements. And this is a project that's ongoing now. And the whole idea of it is written about in this reference I've stated here, Lenny Jason and Beth Unger and others have tried to determine at least what are the minimum data elements that most clinical projects, clinical research projects should have in them, what assessment tools should we be using so that there's a commonality we – that everybody speaks the same language that we're more or less collecting the same data. And of course I didn't prepare adequately for the pediatric portion of this but of course this – and we are currently assessing pediatric tools for this kind of project. For instance I happen to be on the NIH Sleep Common Data Elements Project that is meeting monthly by phone. And we're looking at pediatric sleep questionnaires, separate questionnaires for teenagers and for children with ME/CFS. So that's certainly part of our process right now. So once again the idea here is to collect research in a sort of homogenous way so that there's less variability in the data and of course trying to decide as subgroups like once again I'm in the sleep sub group. There's an autonomic assessment subgroup, a fatigue and pain sub group, what are the critical elements that should be included as we go forward into new types of research that are done on this disease?

Next Slide. Next Slide. Okay, all right I mean among the first things that you think about when you're designing a study is what type of study are you going to have -- case controls -- and that means that's probably the more common type of study where you have an age and sex matched case-control pair. And those people are more or less from the same geographic region and have other commonalities like ethnicity and, you know, basal metabolic index. So they're matched pretty similarly, the case control study. The other types of studies are longitudinal studies where you're obviously following people over a period of time. Other things to include which may seem obvious are the demographics, age race ethnicity duration of illness as we saw earlier that's being looked at very closely and disability status. What case definition should be used, should we have used more than one Canadian and (feds) or limit ourselves to one case definition when enrolling subjects for the study?

And other types of consideration would be the types and severity, frequency and severity of the case defining symptoms like sleep, how severe are the sleep issues that the subject faces. Of course within that there's problems because within the sleep you can find – sorry I think we're jumping ahead a tiny bit. I – let me just linger on this one a little bit because I think it's important particularly with ME/CFS patient's because there could be a period of time when the person subject with ME/CFS has worse sleep issues and they're not – they're looking for the right medication and then those

symptoms improve perhaps related to – taking the medication. And so again the medication has to be taken into account.

And also just the variability of the symptoms with this illness that just occurs kind of whimsically has to be taken into account. So I think this poses more of a challenge than in a lot of other illnesses where within that same subject to there's a lot of variability of and of the frequency and severity of the symptoms that we consider core to this illness. So I think that's a particular challenge. That's why we take multiple samples on patients over a period of time to try to determine that. Okay next Slide.

And then of course we use self-report scales that many people are familiar with on this committee, VSF 36, the sickness impact profile, various sleep studies. We do functional assessments. And what are the best ones? Now we're looking at the gold standard of the two day cardiopulmonary exercise test. Maybe there's – there will be shortcuts to better assess the objective to objectify the system of post exertional malaise.

We look at (Alastatic) loads like heart rate variability, body mass index, 24-hour urinary cortisol. We look at the HPA axis for instance cortisol levels, adrenal cortical levels. We look at immune function and natural (killer) self-studies and various cytokines. Next Slide.

And as we proceed into an age of improved technological assessment (unintelligible) we're looking at (synthetic) activity, various imaging studies, functional MRI spec scans which are expensive. So those studies would probably be limited. But the new age is the last couple of years have brought us genomic and transcriptomic studies, genome-wide assessment studies, whole genome sequencing, epigenetic studies, prodemic studies that better define markers for this disease.

Once again I'm feeling bad that I didn't do any pediatric, look at what's going on in pediatrics. But I'm guessing so for those studies that I know of had been looking at these in children. We've mostly been focusing on adults 18 and over but there's no reason why these types of studies could not be carried out on pediatric or adolescent age patients. Next Slide.

Okay next is the microbiome. Many of you have heard about it. There have been several studies published recently on the micro biome. Once again at the Invest in ME conference Professor Carding at the Institute of Food research in the UK published something and that sort of reaffirms that the idea that the break-in gut mucosal the so-called leaky guts promotes inflammation in the body and that there's a back and forth of microorganisms between the gut environment into the systemic circulation. And that adds to inflammation and that there's a link perhaps between cognitive function and the composition of the gut microbiome. Next.

One study found that 77% of ME/CFS patients demonstrate small intestinal overgrowth. Further examination not only of the bacterial species of the gut

but the viral species of the gut I think will provide some unique insights into the gut – the abnormalities in the microbiome that we won't be seeing. Next. Okay so finally the metabolome. And this the metabolome relates to changes in metabolism that have been observed in ME/CFS patients. Of course (Bob Navio) published something about this and so did (Flu Ginemella). And what they found is the (Flu Ginemella) diminished number of amino acids that fuel oxidative metabolism via the TCA cycle. And what that means is that the normal Krebs cycle that we - our bodies utilize to metabolize carbohydrates are improper, not working properly. There's an impairment of a key enzyme called pyruvate dehydrogenase. Next.

An adequate generation of ATP by oxidative plus (florazation) causes switch to more anaerobic less efficient metabolism by the body and diminished glucose oxidation and increased anaerobic metabolism so with increased use of amino acids which is not a normal way that the TCA cycle works. So the theory is that dysregulation of this pyruvate dehydrogenase enzyme is one mechanism which goes awry. Next Slide.

Other studies namely the (Navio) study have showed improper fatty acid metabolism. And lastly so this PDH dependent metabolism is important in perhaps contributing to the post exertional malaise but may not be so obvious when the ME/CFS subject is at rest. So I think in conclusion where the new studies seem to be going is looking at ways in which we can better study ME/CFS patients, the idea of groups of clinicians and researchers working together, collecting samples and deciding what the best collection tools and scales are to draw an accurate profile of this very heterogeneous illness.

I think although we're still studying looking for infectious causes etiologies of ME/CFS there's more emphasis now on maybe underlying biochemistry, the genetics of the individual who gets ME/CFS and, you know, more about the sort of sequelae of long term of having this illness for a long time how that affects the body. And, you know, the complexity of it is certainly being realized.

Once again I apologize for not having really delved into the pediatric issues. I did attend the Florida IE/CFS conference and I think, you know, certainly Peter Rowe of course is doing some interesting studies looking at ways in which he can make patients function better, adolescents function better with various physical therapy exercises and, you know, changes in diet so forth. I think in general he would agree that adolescents with this illness have many autonomic symptoms such as POTS. And certainly I've seen that and mast cell activation disorder and so forth that may be more prevalent in the younger adolescent subgroups.

But anyway I think there's a lot of new and interesting research going on and, you know, hopefully to continue in the future. Any questions? That's the end of my presentation.

Ben Hsuborger: Thank you. This is Ben Hsuborger. I had a question on Slide 7 when you talked about the common data elements project. You mentioned that your case definition and I guess I was a little unclear. Are you saying that choice a case definition as part of the CDE initiative? I was under the impression...

Coordinator: And to ask a question over the phone please press Star followed by the Number 1.

Dr. Sue Levine: That might have been confusing and I'm sorry to sort of mix apples and oranges. I think I was even though there is an ongoing project with the NIH, you know, looking at common data elements I think that was just an idea that was brought out at the London symposium. And maybe a Vicky could comment on that a little bit because I know she was there. But it's more, you know, I think that's an element of what one decides when one's putting together an outline for doing a study design, you know, which case – how will I recruit my patients, which case definition criteria will they have to meet, you know, in order to be eligible for the study? That's you're right and it's not per se part of the NIH initiative but I think it's a question that, you know, just has to be asked.

Dr. Beth Unger: Yes. This is Beth Unger from CDC. Could I comment?

Dr. Sue Levine: Yes.

Dr. Beth Unger: Yes the Common Data Element Initiative is a joint project from NINDS and CDC. And indeed case definition isn't a specification. Instead we are trying to gather ways of measuring all of the various ways to characterize patients. And there's a, you know, whole list of workgroups that are going on for each characterization. And I think part of what Dr. (unintelligible) different paper which commented on information that should be provided in a research report. Now common data elements will simplify and standardize the way this research information is provided. But one of the most important things about all of this is that it's not sufficient just to say which case definition you're using. Rather you need to really indicate how you measured it, what sort of process did you go through to say that patients met the case definition because there's all different kinds of approaches to that and you can end up with different results depending on how you apply even with the same case definition.

Ben Hsuborger: Thank you.

Coordinator: (Unintelligible) phone from (Roberta Davis).

(Roberta Davis): Hi.

Coordinator: Your line is open.

(Roberta Davis): Actually no I didn't press that. I think that was from the last section and it never went through. So no, I'm sorry I didn't mean to press that.

Coordinator: No other questions over the phone.

Dr. Sue Levine: Thank you. Well (Faith) I'll, you know, I'll just say that so for tomorrow we have – what we have in our agenda for tomorrow?

((Crosstalk))

(Gustavo): (Unintelligible) presenting. And I'm sure a lot of people would want to hear about their RFA that they have released for ME/ CFS.

Dr. Sue Levine: And we have Gary's presentation.

(Faith): Gary's - yes Gary's working for presenting (unintelligible).

Dr. Sue Levine: Yes.

(Gustavo): And then we have a presentation from HRSA and HARQ. And I don't think – well we'll see what the VA has to say if they're doing any research on. So that leaves war syndrome or anything related or similar to ME/CFS.

((Crosstalk))

Dr. Gary Kaplan: And then we want to give you a heads up. I will probably not sign until about 1:00, 1:30 tomorrow because I'm traveling. So I'm going to have to be doing this from outside my office.

Woman: Okay Gary thanks.

Woman: Okay thank you Gary for letting us know.

(Gustavo): And then we'll...

Woman: I just wanted...

(Gustavo): And then we'll talk about the SOP that I would have – I would like a few guys at least take a look at it. It's about only three to four pages and provide me with comments.

Woman: Sure that sounds good. I also want echo what Sue said earlier. We do need to make sure before going to (unintelligible) all those working groups is that how we're going to continue?

Dr. Sue Levine: Yes, yes will I understand you guys are in flux also with the new administration but yes.

Woman: Right.

Dr. Sue Levine: And but we've put enough effort into it at so far we – I think all of us agree that we'd be happy to continue helping if, you know, the need arose...

((Crosstalk))

Coordinator: We have another question over the phone.

Dr. Sue Levine: Go ahead yes.

Coordinator: (Sue Ellen Tritt) your line is open.

(Sue Ellen Tritt): Yes thank you, wonderful presentation as always Dr. Levine. I just have three quick questions if it would be prudent to correct also from PWCs for this study what treatments they have undergone and what type of medications they have had. In my case I had antiviral. I had antibiotic and I had rituximab. So you might want to keep and track that as well.

The second thing would be what other diagnoses had the patient had. For instance they tried to fix my dis-regulated high hematocrit and threw me into

IPB. So that might be – and that’s why it ended up with Rituximab. So that might be important to have in the database.

And the third would be possibly collecting familial data. My former support group in New York and the NJCFSA put of paper out on the genetic predispositions. And that might be very interesting, you know, since you’re collecting data to just add that as well possibly.

Dr. Sue Levine: All terrific ideas (Sue). What can I say. Thank you. All right (Gustavo).

(Gustavo): Well you have to...

Dr. Sue Levine: And (Faith).

(Gustavo): You have a motion to end the meeting.

(Faith): Okay. I hereby do a motion to end the meeting and continue tomorrow. Anybody second that?

Dr. Gary Kaplan: Gary second.

(Faith): Thank you. All in favor say I.

Man: Aye.

Man: Aye.

(Faith): Aye. We will meet again tomorrow at 12 noon.

Dr. Sue Levine: Okay thanks everybody.

(Faith): Thank you.

(Gustavo): Thank you.

Woman: Thank you. Bye.

Dr. Gary Kaplan: Thank you.

Man: Thank you.

Coordinator: That concludes today’s conference call. Thank you for participating. You may disconnect at this time.

END