CFSAC December 13, 2017 In-Person Meeting Transcript - Day 1

Coordinator: Welcome and thank you for standing by. All participants are in a listen-only mode until the question-and-answer session of today's conference. At that time if you would like to give a public comment please press star then 1.

Also today's conference is being recorded. If you have any objections you may disconnect at this time. I now would like to turn the call over to your host. Thank you. You may begin.

Man: Welcome to the (unintelligible) some logistics. The bathrooms are past the double doors to the left. But if you need any directions just ask us please.

I would like to remind you that when you please speak, speak clearly and loudly and say your name for our note taker, (Debbie) here sitting to the right.

And those listening on the phone and the HHS Live you need to have a speaker on your computer to listen to the meeting. Otherwise if you do not you have to dial the 800 number which is on the Web site and on the agenda and then click on that link for the live streaming.

Without further ado I would like to welcome Dr. Don Wright who is Acting Assistant Secretary for Health and the Director of the Office of Disease Prevention and Health Promotion.

He will give us – Don if you come up to the front. Some opening remarks on behalf of the department and then we will move into swearing in our new members who we will open the floor briefly so they can tell us a little bit about them. Dr. Wright.

Don Wright: Good morning and thank you Commander (unintelligible) for that introduction. Let me say despite the weather it is good to see all of you here. Obviously you are passionate about this topic and we appreciate your participation in today's meeting.

Also for those of you that are part of the audience thank you for being here as well as those of you that are attending virtually this very important meeting.

Let me say your input and recommendations and what you will be discussing today is very important to the Department of Health and Human Services. And more specifically to the office I lead which is the office of the Assistant Secretary for Health.

Before I get started I wanted to take just a moment and thank Commander (unintelligible), Syreeta Evans, Dr. Beth Collins Sharp and the Chair of the committee and Dr. Faith Newton I understand this is her first meeting to chair.

I know all of these individuals have worked tirelessly to ensure that today's meeting or this particular meeting is a success. I would also like to thank both the pediatric myalgic encephalomyelitis and chronic fatigue syndrome and the medical education working groups for putting together the presentations that you are going to hear. And for the recommendations that they made that were forwarded to our Acting Secretary here at HHS, Secretary Eric Hargan.

Let me say that I am pleased that the department has made some very tangible progress with the September announcement from the National Institute of Health when it awarded four grants to establish a coordinated scientific research effort on ME/CFS.

The project will award more than $7 million per year for each of five years that the project is being implemented. The four NIH grantees will come together to create a consortium of three collaborative research centers plus a data management consulting center.

NIH expects that each one of these collaborative research centers will conduct independent research but that they will not work in silos. NIH expects them to work together on several projects to create a network to help advance research on this issue.

I understand that this committee has recommended Centers of Excellence in research networks on a number of occasions of their existence. And I think this is a laudatory, maybe modest but a very significant stat from some of the work in the recommendations that you have made in the past.

Dr. Vicky Whittemore will speak more about the important project that I just described during her presentation tomorrow morning. I understand this is two day meeting.

In closing I thank you once again for exchanging ideas and engaging in honest and open dialogue with you. Thank you for the work that you do with the department as we move slowly but surely to address and unravel the mysteries of ME/CFS and to reduce its impact on so many individuals and their families.

We had a number of advisory committees within the Office of the Assistant Secretary of Health and I am just amazed at the willingness of individuals such as those of you sitting at the table to share your time, your experience, your expertise with the department to address a major issue. So again thank you for your contributions.

At this time we need to move on and swear in two new members to the committee. We have Dr. Lucinda Bateman and Ms. Amrit Shahzad will be joining the committee. So I see these two individuals if they will come to the front of the room and stand here by the flags and I will administer the oath of office.

If each of you will raise your right hand and repeat after me. I and your name do solemnly swear.

That will support and defend the Constitution of the United States. Against all enemies foreign and domestic. And I will bear truth and allegiance to the same.

That I take this obligation freely without any mental reservation or purpose of evasion. And that I will well and faithfully discharge the duties of the office of which I am about to enter. So help me God.

Welcome to the committee.

Man: Can you hear me? This is strange. The red will make (unintelligible) where you actually press it and it has to be on for people to hear you. I want to turn it over to our Chair, Faith to say a few words.

Faith Newton: Good morning and welcome everyone. We are thrilled to have you here at our in-person meeting and again a special welcome to our new members. Lucinda Bateman and Amrit Shahzad. We appreciate your time and the fact that you are willing to serve on our committee.

Don Wright: And if we could take five minutes for you guys to introduce yourself to the committee and tell us about your background. And I had a lot of questions asked me about you guys but I would rather you speak for yourself.

Lucinda Bateman: My name is Lucinda Bateman. I am a traditionally trained general internal medicine specialist and have been a clinician in the field since I started practice in 1991.

And in 2000 have had a clinic, a full time clinic devoted to evaluation of fatigue and chronic fatiguing conditions. So we also have changed the focus and I now work at a non-profit clinic and research center called, the Bateman Horne Center in Salt Lake City, Utah. With hopes of moving progress forward in terms of education as well as research and clinical expertise.

Don Wright: Thank you.

Amrit Shahzad: Hi my name is Amrit Shahzad. I am trained as a physician. I came to U.S. in 1985 and I have worked in the biotech pharma industry since then. Now I am at UCSC. I am a patient of CFS and I didn't believe it was a disease when I was a physician so you live to learn.

The first item that gave me proof that I had the disease was that I had tried everything and I was still sick. So I am here to help in any which way I can.

Faith Newton: Thank you very much. I want to proceed with roll call now. You turn on your mic and say here when I read your name.

Faith Newton obviously I am here.

(Elisa).

(Elisa): I am here.

Faith Newton: Jose Montoya is not here yet. Donna Pearson.

Donna Pearson: I am here.

Faith Newton: Lucinda Bateman.

Lucinda Bateman: Present.

Faith Newton: And Amrit Shahzad.

Amrit Shahzad: Here.

Faith Newton: Thank you.

Man: So can we have the – I am going to start with the presentation.

Faith Newton: We are going to move to the update on recommendations from the January and June CFSAC meetings. The screen is going to go down so everybody can see what the recommendations are.

So while that is happening let me encourage the new members and also the new representatives on the committee to please ask questions as we are going along on any of the presentations. Just make sure you turn your mic on and identify who you are so that the note taker when we transcribe this knows who is speaking.

Don you have a question?

Don Wright: Can you hear me okay? I just want to point out that our three non-voting liaisons are actually members of the committee although I know you are trying to count for quorum. They really should be part of the roll call.

Faith Newton: And let's do that then.

Woman: We are actually not listed under attendees.

Faith Newton: We will put you on there.

Woman: Thank you.

Faith Newton: You're welcome. Non-voting members. Leah Williams. Thank you. Courtney Miller.

Courtney Miller: Here.

Faith Newton: Thank you. And Terri is it Wilder or Wilder?

Terri Wilder: It is Wilder.

Faith Newton: Thank you.

Terri Wilder: I am here.

Faith Newton: Thank you. First slide please. Next slide. Okay the first recommendation from the June meeting was that we would provide an update on the adult and pediatric ME/CFS research. That data should be an agenda item in all CFSAC meetings.

The response was the DFO which Gustavo Seinos will work with the committee chair to have that medical research on the illness presented to the committee on an annual basis.

This request will be added to the standard operating procedure for CFSAC. Tomorrow, Dr. Jose Montoya will provide an update on research for adults with ME/CFS. And Dr. (Ross Valient) will provide an update on research for young people ME/CFS.

Second recommendation from June. Developed diagnostic tools and clinical practice guidelines. CFSAC recommends that disease specific diagnostic tools be developed and validated in collaboration with disease experts.

And also that comprehensive clinical practice guidelines be developed in accordance with the IOM standards for developing trustworthy clinical practice guidelines.

The CDC response is that they recognize the importance of developing clinical practice guidelines for use by primary care physicians. These guidelines need to fulfil evidence based standards such as grade and IOM standards for developing trustworthy clinical practice guidelines and need to be developed in a collaborative and transparent manner.

CDC will develop a plan for developing these guidelines to be reviewed and supported by trans-HHS ex officio working group as soon as feasible. Updates on this process will be provided to CFSAC at each meeting.

(Unintelligible) and the ex officio member of CFSAC will provide an update on recommendation too during the CDC's presentation on Day 2.

January 2017 recommendation. Recommended that an acknowledgement of a serious educational implications of ME/CFS in children and adolescents. An ex officio member from the U.S. Department of Education be added to CFSAC.

We further recommend that this individual be well-versed in the provision of accommodations and services under Section 504 of the Civil Rights Act and the special education services under the Individuals with Disabilities in Education Act, IDEA.

OSHA response to the office on women's health will be working with the OSHA committee management officer to revise the current CFSAC charter to include an ex officio from the Department of Education.

The update is that the committee management officer advice of the ex officio from the Department of Education should be officially added when the charter is renewed.

In March, the DFO reached out to Carmen Sanchez, invited her to represent the Department of Education on CFSAC until an official appointment is made. She could not be here this morning but she will be here and she will be presenting tomorrow.

CDC response. ME/CFS program fully agrees with the recommendations. My apologies I skipped ahead here. And is working towards implementation. CDC has implemented the correspondence with Carmen Sanchez Department of Ed and with (Basmati) National Association of School Nurses to plan next steps. Progress will be included in CDC's reports of CFSAC.

CDC and the International Association of School Nurses collaborate to develop and disseminate educational materials on ME/CFS as it affects children and adolescents. That slide was out of order.

So that was one of the recommendations from January that we develop and disseminate educational materials on ME/CFS for nurses and adolescents. I am going to go back okay.

The CDC agreed and we are working towards that with Basmati and with Carmen. You will get an update on that during our working group presentation tomorrow. Gustavo.

Gustavo Seinos: So I wanted to present this table to the committee because we had had a lot of questions about the vacancies and the number of individuals and when their terms expire.

As you know the charter calls for 13 members. We so far have Faith, (Elisa), Donna, Jose Montoya, Lucinda. The new member who couldn't be here today is (unintelligible).

I am not sure if you guys know her but she is known in the research community on ME/CFS. She is in Europe and couldn't attend the meeting in person but she will be hopefully our next meeting in the summer.

And then Amrit. So we have one, two, three, four, five, six vacancies. The column to the right represent the three fields of areas that the committee is supposed to be made up of.

We have one vacant position for a patient or a caregiver. Then we have one vacant position for clinician. And you will see we have the most vacancies for then under researcher.

Next year, early next year come January I will draft a federal register notice calling for applications to have this committee hopefully fulfilled by the summer. Some things are beyond the control of the Office of Women. So we only can inquire about our nominations.

When you see the federal register notice comes out what I would like for you to know and the community is that when you apply for example. We have a federal register notice asking for a clinician. You cannot apply if you don't have any clinical background. We are looking for specific fields. People in specific fields.

And that has been the issue in the past in which we put out – at least as long as I have been at DFO. We put out a federal register notice asking for somebody with a specific background and we get individuals that don't necessarily meets the need.

The process I wanted to make sure and clear to everyone is that the ex officios review these applications and they rank them. And then we nominate them and put them forward to the secretary. We do not pick individuals. The secretary does. We just put their name forward.

My understanding and this has never been shared in the past with the committee but I want to be open and clear. And these are the vacancies we have.

And when the Federal Register notice comes out we will try to meet those vacant positions as long as the individual meet the requirement that we are looking for. Any questions?

Donna?

Donna Pearson: Donna. Just to be clear. The patient/caregiver actually is a little bit more expanded than just patient or caregiver. I think if I recall, the charter states you need to have some experience related to assisting patients or volunteering or something like that.

So you don't have to be a direct caregiver. ???

Faith Newton: That is correct. Courtney?

Courtney Miller: So are there nominations that were already submitted for some of these positions?

Gustavo Seinos: So the last Federal Register notice we put out was in the summer. And we received nominations for researcher and we received nominations individuals that didn't have the background or the knowledge in the area we were looking for.

So only Amrit and Dr. Bateman was sent forward. And they were sent forward to the Secretary after they were ranked by the ex officios.

Courtney Miller: So you haven't posted the patient caregiver, the clinician (unintelligible).
Gustavo Seinos: Like I said this is going to happen in January after this meeting.

Faith Newton: If I could jump in with just a bit of explanation. Since the last appointment of members there were two I believe or maybe even three calls for new members.

And they all went through the process and I believe that among – the situation occurred where one of them was – one of the calls was for a researcher and some of the applicants were not researchers.

But there were other individuals who submitted their names who were nominated and are not seated today or not appointed today. I think that is what you were wondering. Is if there were people who were nominated that were not accepted. Their nomination was not accepted at some point during the process.

Courtney Miller: Yes I think the patient one, has been vacant for quite a while. So I just curious why. I know there are applications in, nominations in for it. So I just want to move that one. All of them but that one I know is kind of sitting out there. And so we are going to retake nominations for that position?

Gustavo Seinos: All those vacant positions we are going to – once we print the register notice we will receive applications and then the ex officio will rank them and then they will be sent forward to the secretary.

(Elisa)?

(Elisa): Yes (Elisa) here. I just wondered since they are – thank you for sharing this but it looks like there were two big pushes to get members, you know, in 2014 and then again in 2017 and thank you for doing that.

Do you – besides issuing this notification or call do you also approach individuals directly and ask them whether they would like to be involved in this?

Gustavo Seinos: I mean we could.

(Elisa): I mean I would think maybe given the number that might be a good thing to try.

Gustavo Seinos: I remember at the January meeting approaching one individual who gave a very passionate public comment. And I asked him that we were going to print – I mean a Federal Register notice if he was interested to look up for it on the (unintelligible).

So I done it once to that one specific person but, you know, the process has to be open and free.

(Elisa): Sure.

Gustavo Seinos: And I am calling out to the community, to you guys if you know also individuals once the Federal Register notice comes out encourage them to apply. But applying does not guarantee the person will be remembered. We don't select them. The secretary does.

Faith Newton: Don.

Don Wright: So I just want to clarify again. Under the clinician heading the charter says that three shall be individuals with expertise in healthcare delivery, private healthcare services or insurers or voluntary organizations concerned with the problems of individuals with ME/CFS.

So I just want to make sure that that's clear. They do not have to be actual clinicians. They just have to fit within that category.

Faith Newton: Thank you Don.

Gustavo Seinos: With the vacant position you have you remember is (unintelligible) living whose term expired in November. Any other questions?

We skipped a part of the agenda. My apologies. We need to approve the minutes from the last meeting. This is a new procedure. As you know, the minutes are posted on the Web site within 90 days after the meeting. Those minutes are approved by myself and the chair.

But we want to have the whole committee approve them and if there is any change in them we will revise the minutes from the last meeting and post it on the Web site. But I will send you the link with the minutes. I hope you guys read them. And we can discuss any changes now.

Faith Newton: Any changes to the minutes from the last meeting? Do I need to take a roll call Gustavo? Or can we just do it as one?

Gustavo Seinos: Let's do a roll call of all the members.

Faith Newton: Of all the members.

Gustavo Seinos: Don no comments on the minutes?

Don Wright: I just want to say I make a motion that we adopt the minutes as provided.

Faith Newton: Is there a second? Any of the members can say second.

Woman: Second.

Faith Newton: Any discussion? I will do an individual roll call. (Elisa).

(Elisa): Approved.

Faith Newton: Donna Pearson

Donna Pearson: Approved.

Faith Newton: Lucinda Bateman.

Lucinda Bateman: I will pass.

Faith Newton: Amrit Shahzad.

Amrit Shahzad: Approved.

Faith Newton: The non-voting liaison. (Unintelligible) right okay. All right all in favor. Obviously approved. I also approved. So minutes have been approved.

Gustavo Seinos: And they are final because they already on the Web site.

Faith Newton: Thank you.

Gustavo Seinos: Now we will move to presentations. Dr. (unintelligible) you are up.

Man: Thank you.

Gustavo Seinos: You can stand up here or have the clicker or you can…

Man: (Unintelligible).

((Crosstalk))

Man: Sorry I can't see my slides from the podium. No I can do it from here. Probably not be able to see it. But I am (unintelligible) the CDC ex officio in the CFSAC. And as you are probably aware there are a lot of ME/CFS activities happening at CDC over the years.

The major one that happened recently, the MCAM study as most of you know. But my update today will focus on the activities and accomplishments that happened since the last CFSAC meeting just to save time.

Now I will start describing about the CDC Web site. You are probably aware that the Web site – we are working on the Web site in three different sections. There was a section for the general public and there is a pediatrics section with different fact sheets. And a section for healthcare professionals.

The section for the general public was revised and posted on our Web site in June of this year. And most of you may have already seen that.

The section for pediatrics which incorporates fact sheets for education professionals and the fact sheet for healthcare professionals and parents and guardians. These are downloadable fact sheets was posted on our Web site in October.

In the section for healthcare professionals we are still working on that. We hope to complete the draft by probably around early January for at least having it cleared through CDC. CDC has its own clearance system for anything that will be posted on the Web site.

So within the ME/CFS program the drafting would be finalized around January and prepare the content for CDC clearance. And it will be posted as soon as that clearance is obtained within the agency.

Faith Newton: Leah Williams do you have any kind of community review of your materials before you post them?

Man: If you recall we had a roundtable that we organized that remind me over a year ago where we gathered input from patient communities and ME/CFS experts. And so our drafting of the Web site incorporates those comments that we have received.

Now for the healthcare professionals we tried to stick out input from clinicians and researchers before finalizing and putting it on the Web site.

Faith Newton: I just wondered if you had any input from the people who were actually affected by these materials being available for healthcare professionals? Namely the patients.

Man: Again there would be – the drafting is based on the input we have already received okay? We have already received comments and gathered updates or reviews that were given at the roundtable discussion that we had about a year ago.

Faith Newton: I understand that. But that doesn't necessarily mean that everything that gets into the final materials is consistent with the comments that were made in the beginning of the process.

Man: What would appear in the final material would be CDC cleared version. Once it is cleared by CDC we cannot change it. We would have to (unintelligible) another clearance process to shorten the process. Beth is there anything you wanted to add to that?

Beth Collins Sharp: We are definitely aware of the areas of concern. I think that is perfectly clear. And the materials that were prepared for the general public reflect the basic understanding.

The main difference for the healthcare section is that it will include a little bit more details. But it is basically the same material expanded somewhat. Plus we include background information on the various case definitions to help clarify for them.

And so our process has been fulfilling what we have to do at CDC and we are gathering – we talk to people in a very informal way and get individual opinions for this. So I look forward to a successful completion of this work.

Faith Newton: This is Faith Newton. I want to comment on the fact sheet for education professionals and the fact sheet for parents and guardians. I reviewed them and I thought they were exceptionally well done.

So for our parents out there that are looking for information for children there are resources that are up there on the CDC We site on the pediatrics pages are very, very well done. If you are looking for resources about schools and how to educate your children that have ME/CFS. It is exceptionally well done.

Man: Thank you (unintelligible).

Faith Newton: You're welcome. Go ahead. Can you identify yourself please?

Terri Wilder: Terri Wilder. I just had a question about the Web page. So while the CDC removed exercise as a treatment on your Web site. We know that exercise or exertion can be harmful to some patients.

So it feels like that statement needs to be put in it particularly in the probably health providers section but definitely in the other section that the general public would be looking at.

I mean I am thinking about kind of the work that is done in New York State with the health commissioner sending out his letter to over 85,000 physicians. That specifically said, you know, this can be harmful. You know so please be aware of that when you have a patient that presents that you might be diagnosing with this disease.

I think we need to be teaching people about kind of energy envelopes and what can happen. You know kind of pointing to symptom management. I mean I think it really needs to be like not only removing that sentence that was on it but also replacing it with a statement that says this can be harmful.

Because if you are reading this for the first time and you are unfamiliar with our disease you may not know that this is harmful. You removed that but people don't know that it is harmful – could be harmful to patients unless it is clearly stated.

Man: Thank you for the comments.

Faith Newton: I will go back and reread the general public to be sure. But it is very clear in what we are developing. Because this has been the biggest point of confusion and we want to make sure that exercise is a concern and can be harmful.

At the same time, give people that have – provide the information about maintaining exercise and activity through the activity management approach.

Terri Wilder: I think – I just want to be clear that if it is not stated in there, that exercise or exertion can be harmful and it is not clear.

Faith Newton: It is stated.

Terri Wilder: We are getting feedback that it is not clear.

Faith Newton: Well I will look at the general public but for sure it is in the – we have statements like that.

Man: In the clinician version that would be clearer in January.

Terri Wilder: I mean we will look when it is published but this is just the feedback we are getting from folks.

Man: Thank you. The other activity that we had was we had the stakeholder engagement communication call which we used to call (unintelligible) in the past. This is the 10th call and we had it on November 2nd.

And the invited speaker participants included Dr. Ellen Clayton who was the Chairman to the Use of Medicine Committee for ME/CFS and Dr. Lucinda Bateman who was just sworn in. And Dr. Peter Rowe presented during the communication call.

And the topic of their presentation was take home messages from the 2015 (unintelligible) medicine report on ME/CFS. And that was very well received.

There was about 120 code lines that were available during this communication call, individual lines. But, you know, multiple people may be participating on one line. So it is a big reach out to the community.

In the audio files and the transcript is posted on our Web site. So people can go back and listen to the presentation again. The transcript for the previous call, the 9th stakeholder engagement communication call is also on our Web site.

Now the other event that we had is a live continuing education event that we hosted in Atlanta and that was focused on the award winning documentary (Ann West). We secured (unintelligible) Theater for screening the movie, their documentary which also included at the end of the discussion right after the film was screened.

The (Ann West) documentary was a wonderful documentary which I very strongly recommend for people to watch if you have not watched it. It was produced by (Jenn Bria) who was the actor and also the producer.

She chronicles her life, high functioning PhD Harvard student until she became a victim of ME/CFS. It is very well done and the kind of tool that we need to raise awareness for ME/CFS. So I strongly recommend for people to watch it.

And I hear from (unintelligible) that may be in the running in the short list for the Oscars. Top 15 for the Oscars for this year. So another reason to watch the Oscars.

Now the event that we hosted we obtained a CE continuing education program for it for various professions including that listed over there for physicians, nurses, pharmacists, veterinarians, health education specialists, public health professionals to encourage them to come to the event.

So any one of them who fall under the categories could potentially obtain a CE if they attended the event. And we screen the PBS edited version of the documentary which is a little bit longer than one hour.

It was very well received. Over 100 people participated. Came to the event. Panel discussion was provided by Dr. Unger, Dr. Nancy Klimas and (Jenn Bria) herself was at the event.

Now there were various presentations that our staff participated in since the last meeting. They are listed on this slide. The Immunogenomics 2017 conference in October that Dr. Unger presented at. In (unintelligible) ME/CFS initiative think that took place in Tyson's Corner here in Virginia.

In the 2017 annual meeting of APHA. APHA is as you know the largest gathering of public health professionals. Giving us the opportunity to raise awareness about ME/CFS. This year the APHA conference was held in Atlanta which was very convenient.

And our staff participated in the conference in various capacities. Dr. Lily Chu for example had a special symposium organized on ME/CFS (unintelligible) approaches to capturing and (unintelligible) ME/CFS and our staff participated in that. Along with the oral and posted presentations at the conference.

The other activities we had participated in. We had our annual MCAM meeting. So recipients of our funds from the seven different multi-clinic sites actually came to Atlanta on December 8th and we had a meeting. And fortunately it happened on the same day as snow was dumping on Atlanta.

That somehow affected our meeting. We despite the snow we were able to complete the meeting and we had to cut it short. Didn't go through all the whole date but we got what we wanted to get out of that meeting.

I was focusing on gathering information or enrolling information on young patients with ME/CFS in control and comparison groups for those patients going forward.

Now we are planning to have a continuing education module in collaboration with WebMD and Medscape with a target launch of May 2018. And we want that to be a CE activity, continuing education activity.

We would like to have it moderated, a panel discussion between healthcare providers and focused on the diagnostic criteria that is developed by the IOM committee.

We also are planning to have the roundtable process of stakeholder engagement the way we did it in the past. And some of you in this room participated in that. And we are planning to have another one and we have contracted with (unintelligible) Associates that actually hosted or helped us host the first stakeholder engagement meeting.

And it will help us to host another one. I don't think we have decided on a date yet but as soon as we do we will announce it and invite people to participate.

Terri Wilder: Sorry this is Terri. Can I just ask a question? So for the next roundtable when you say announce it. Is that people can let you know that they are interested in participating? Or is that kind of an invitation only situation?

Man: We can't possibly invite everybody. So we would like to have as many patient representatives as possible from the different communities. Different patient communities.

Last time (unintelligible) people participated. Probably around 30 or 40 and we are limited by the venue. We are limited by funds. We are limited by several things. But we would like to accommodate as many patient community representatives as possible.

Beth Collins Sharp: Right. Although this time our focus is a little bit different and we are going to be trying to encourage more of the healthcare professionals. We will have patient input for sure but it is going to be weighted a little bit more to the healthcare professionals.

Because we are really focusing on their educational needs and how to get their communities engaged and understanding. And the patient support will be there because you need clearly a patient understanding. But this roundtable focus is slightly different this year.

Terri Wilder: So if there was a patient that works in clinical education…

Beth Collins Sharp: Yes, yes absolutely. We appreciate your expertise and appreciate all the contributions you have already made.

Terri Wilder: So but I guess I am trying to understand the process. Do you apply to be on it?

Beth Collins Sharp: This isn't something that we have asked for applications. It has always helpful to know that people are interested. We usually reach out and ask for people's responses and sometimes people say they can do it or they can't do it and refer it to other people.

And so yes feel free to reach out to us. Because we always are looking for people. And if it doesn't work out for this project there will be other projects. But it wasn't going to be an official open up. We do have your name. A lot of people.

Woman: Beth would this be appropriate for school nurses?

Beth Collins Sharp: That is a good question. We had been focusing again on healthcare professionals for the most part but school nurses would be part of that. So we are very early on in the process. Just had our first meeting. We just wanted to announce that we are going in that direction.

And part of the process is, you know, you have an idea of what you are going to do. Focusing actually to be very clear about what the objectives are at the end. And so we are early on in that.

In our prior roundtable we did have nursing representatives but not school nurses per se.

Woman: Thank you.

Man: So clearly it would help us tailor our educational material that we will be producing to the needs of the clinical community. And focusing on the IOM and spreading the word about the IOM diagnostic criteria to the clinician community.

Now we have been collaborating with other HHS agencies and different activities including participation in the various CFSAC working groups. The pediatric education working group. The medical education working group and the (unintelligible) working groups will be presented during this CFSAC meeting.

We have been working with NIH. We have cofunded the common data element project was NIH. There have been some activities which I am sure Dr. Vicky Whittemore will be presenting during her update tomorrow.

And Dr. Beth Unger have been actively engaged in different domains about it. They have been identified for the common data element project. And we also participated in the FDA with the FDA development qualification program. We provided some of the data that we have gathered, collected as part of the MCAM study for use in that qualification program.

Now focusing on the CFSAC recommendations from the past. And Dr. Faith Newton touched upon some of these. The two recommendations that we thought relevant to CDC included the recommendation that was given by the CFSAC in the past to work with Center for Parent Information Resources.

This center works with the Department of Education. They actually specifically received funding from the Department of Education to reach out to parents and provide resources.

And we have been working with them to try to identify – I mean develop ME/CFS Web sites tailored specific to the education needs of young ME/CFS patients. Parents could potentially use those resources. They work with the school system to try and get maximum education for their children.

And those resources are being developed and the Center for Parents information Web site will include information on their Web site regarding the educational needs.

Now the other recommendation had to do with development treatment guidelines for ME/CFS. By no means this is specific to CDC because CDC alone cannot do it. But we wanted to take the initiative to develop a plan on how to address this issue and how to develop the guidelines.

And we have initiated the process with a target date of early 2018. We would like to present the options for different ways of developing those guidelines. And present it to the different ex officios within HHS and take it forward.

And we haven't finalized any plan at all at this point. But we are thinking through different options and Dr. Unger who probably was heavily involved in developing this plan and may expand on this.

But, you know, as I said by early 2018 we would like to have a plan developed that we could present to others for input on how to develop this guideline going forward.

Beth anything you would like to add?

Beth Collins Sharp: Yes I guess. We have been actively working on this. It is a big question. And right after the meeting we were fortunate that CDC's office for association – Office of the Associate Director for Science, OADS developed an informational program about guideline development. Because it is not just our group, a lot of groups at CDC need or consider developing guidelines.

And the process for this is ever evolving. And so they had a presentation that was available to go and talk to different groups. So we invited them to our group and they gave us a really good overview of the entire process.

And we followed up with them and we have gotten the initial preliminary things like completing a form that walks you step by step sort of decision trees. Should we develop guidelines, are they needed and those kinds of things. We have got that far.

We have met with the Management of Analysis and Services Office, MASO for some of the decisions. As you know, guidelines need to be based on evidence and in most situations this is on published peer review scientific articles.

And we feel that for ME/CFS that will be insufficient as much of the knowledge is at the level of expert opinion. And so we spent a lot of – we are still asking a lot of questions about what will be the best way to accommodate this kind of information so that it is not lost. And all of the rules for getting expert opinion into the federal government are very complex.

So we realize that there again we will be on a cycle of finessing and refining specifically the questions and what the charge to the working groups that will be approaching this will be.

The charge being exactly how many questions we are asking. Who are we developing answers for. In other words, what sort of clinicians and under what clinical situation? So it is a multi, multi-step process.

We have also been giving guidance to not expect it to be happening fast. And we believe that it is worth the time that it will take to invest to get the first of these guidelines in place.

And once the guidelines are in place it is clear that there is sort of by mandate. They can't stand for more than three years without being reviewed and reverified. So once they are in place there will be a process for continual updating.

And that is where we are at. Other than to reemphasize this can't be CDC's project alone. We will be relying on contributions and work of the ex officios and the community at large.

Faith Newton: Questions for Dr. Balay or Dr. Unger?

Courtney Miller: Hi Dr. Balay and Dr. Unger.

Faith Newton: Tell who is speaking.

Courtney Miller: Sorry, Courtney Miller.

Faith Newton: Thank you.

Courtney Miller: With Simmaron Research. I want to recognize both of you and your teams' work both to integrate stakeholder patient experts' opinions and experience in the revamping of the Web site. Particularly excited that you were able to use Unrest as a continuing education prompt in the community.

I want to ask something that you didn't report on. It was an extensive report and I am glad to share all of the work that you are doing. On the MCAM study, the multi-site study, you know, I think you guys has – the CDC has the most comprehensive, well-constructed largest set of data on patients with this disease and matched controls.

And we are very eager to see more of it published. I know you have that on your set of lists. But if the question is resources, you know, how can we figure out a way to get staff time or analysis time or, you know, some expert input? Either within the government in different agencies. You know how do we move that forward?

I appreciate the sharing of it with I think both the NIH (unintelligible) study and you alluded to the FDA outcome measures. But there is a wealth of knowledge in what you have. And so help us figure out how to help you get it out and get it published.

Beth Collins Sharp: Thank you I appreciate that and we are very aware that the clock is ticking and that we have this great data and we need to get it out. We are working with our group and I think your suggestion to reach out and find other expertise as needed is wise. And we will do that.

The next manuscript that is in preparation is again descriptive of the heterogeneity of the patients. Because I think that that's one area that even researchers when they come into the field just don't realize. And so that is in preparation and hopefully it will go fast.

And then I think some of the other ones we are waiting for complete data. Like one of the most – well everything is important. But we are looking forward to contributing data on the NK cell function testing but then we have to finish the testing.

Similarly for the exercise we need to complete a set. And for our – the morning cortisol data again we are waiting until we have a complete set. And so there are some things where, you know, we have got a lot of data but it is not ready to put out.

Now, you know, even interim analyses can be really helpful and raise interest about the project and the field. And I did want to just add one little additional comment to the immunogenomics meeting that I presented at.

This was very, very preliminary data. These were scientists interested in really high tech approaches to immunology and they were very fascinated about the problem of ME/CFS.

I have never had a group of people be so interested. So it is encouraging that when you go and you present a start of some information other scientists are going to start to respond.

So all of those efforts are important and we are moving forward.

Courtney Miller: Thank you.

Faith Newton: I would like to thank Dr. Unger and Dr. Balay for the work that they have done the last couple of months since the last CDC meeting. I think you have made an incredible amount of progress and I think the community is very pleased with what is going on.

Man: Thank you.

Faith Newton: Any other questions? Let's move onto the FDA.

Man: So we have (Keith Hurt) who used to be the alternate to (unintelligible) – to (Janet) it appears have moved to another position and now we have (Keith) representing the FDA.

(Keith Hurt): Thank you. I appreciate the opportunity to share the FDA's activities since our last meeting.

((Crosstalk))

(Keith Hurt): Since last June the agency has met with two sponsors regarding drug development. Programs for the treatment of ME/CFS of which one has led to a new treatment IND. I can't reveal any more of what we met with but that is promising that we have had one new IND.

The second update is regarding the clinical outcome assessment qualification program which Dr. Balay had mentioned. This program – let me get my glasses on – facilitates the collaborative setting where the FDA works with stakeholders in guiding clinical outcome assessment development so that they can develop new outcomes for clinical trials.

There are multiple interested parties often work together in working groups to develop a clinical outcome assessment for qualification. And this allows for sharing of resources and helps facilitates new outcomes which the FDA will try to have sponsors use.

So last year the PROMIS Network Center of the American Institutes of Research made an initial package for review regarding a plan to conduct qualitative research using the PROMIS fatigue item bank in patients with ME/CFS.

And while we were reviewing submission we had discussed the then recently collected data from the CDC and reached out to them for collaboration between the groups.

And as Dr. Balay had mentioned that the summer of the CDC and the PROMIS investigators agreed to collaborate to further examine the data from the CDC's patient study that may help to identify gaps in any existing evidence and to allow for a plan qualitative research to address the gaps.

So hopefully what I will do is come up with some new patient poured outcome using the PROMIS Fatigue scale that will again just provide another endpoint that can be used in a clinical trial for any interested parties trying to develop drugs.

And that we have had a couple of in-services as well for new reviewers who have entered our division who are reviewing for chronic fatigue. Any questions?

Terri Wilder: Hi this is Terri Wilder. Can you – is the (unintelligible) working with any other institutions besides the CDC?

(Keith Hurt): Not directly. I think there is some facilitation between NIH if they come to us and need input on what they would need for a trial. But that is primarily the other agencies. Right now it is CDC and I think occasionally NIH.

Courtney Miller: So this is Courtney Miller. I am, you know, I think Dr. Maynard knows more of my and my husband's background and this disease and the FDA. You know I have sort of a couple of questions and a couple of points.

One is if there is the essential need to work the existing clinicians, expert clinicians in whatever outcome measure, package, process you are working on.

I guarantee you if it is some outside organization developing some measure on its own we are going to miss the mark. We have missed the mark for 30 years. We can't afford to do that this time.

So I hope this process is substantial and is built around stakeholders including patients. You know our experience with the only drug that has been in clinical trials for 25 years has been disastrous with respect to a licensing process.

We in the field, the patients need a first drug approved by the FDA. It is a precondition to getting, you know, pharmaceutical investment in this disease to see that the FDA is actually willing to approve a medication for this disease.

So and our experience is very personal. You know my husband can't leave the house because Ampligen is all but gone after the denial that FDA made five years ago, five years ago this month.

And so the progress needs to be much more substantial and I appreciate the report. I am glad there is a project you are working on at FDA but we need to move this forward and it doesn't happen overnight. I understand that.

So I guess one of the things I wanted to raise from the context of this committee meeting for the committee is, you know, how do we put together a working group that addresses what we need to do across agencies to bring clinical trials, treatment trials to patients?

We are not going to learn what works until we start trying it. And it is not happening by nature of the free market. That is not working.

So particularly feedback to the FDA I really hope that as the six month meetings progress here we can hear a more full and detailed plan of how you can stretch your agency and move this for our disease. Move any number of things.

Attract pharmaceutical industry, reach out to them. Figure out what outcome measures are critically important but figure out how we integrate our community and our experts mostly into that.

And then for the committee I would really like to put forward now or later in the agenda how we put a working group together that plans big and small. Whatever it is we can do to have the federal agencies talking to pharmaceutical companies. Laying out, asking what do we need to create clinical trials in this disease?

You know we are (unintelligible) field is not tilled. It is not even, you know, it is not fertilized. It is not – except that it is wide open and we have patients willing to do clinical trials. Willing to move to do clinical trials. I mean it is a desperate need.

So I don't know when for the committee's sake we want to talk about, you know, I will do the work. You know I would like the agencies especially NIH, FDA and CDC to be part of a discussion of what can we do across the federal agencies to attract, create the momentum for treatment trials.

Faith Newton: This is Faith. We have on the schedule for tomorrow afternoon for 4 o'clock for next steps and that is typically the time we discuss working groups after we hear the presentations today, tomorrow and where we are headed.

(Keith) do you want to respond to Courtney's (unintelligible)?

(Keith Hurt): I do. And so I just want to clarify. So this PROMIS Fatigue Qualification Program is just it is a very small part. It is something that somebody that these investigators (unintelligible) program.

The FDA has actually met with sponsors and told them for a clinical outcome all they need to do is come up with something that shows that the patient feels better. It could be a questionnaire.

It can be – it doesn't matter what it is. Just show us that there is some measure that you can do in a (unintelligible) controlled study that the patient feels better. It can be getting out of better. I feel better. I can play with my children. It doesn't have to be anything validated. It doesn't have to be anything qualified. We really want to move the process forward.

Unfortunately, the FDA can't go out and solicit pharmaceutical companies to try to make the drug do it. That is definitely something that is better brought by the patient advocacy groups. There is enough patients to make it financially viable for them.

But we have met with sponsors and told them the seriousness of the disease. We are going to accept a large amount of risk for the risk benefit profile. And the benefit does not have to be anything. It is not high hurdle. Show that over a period of time, 12 weeks that patients feel better.

With that said we have had one new company come in or one new investigator come in to try to perform a clinical trial in patients. There are plenty of patients we have told (unintelligible) companies. The problem tends to be what we have seen research is getting the pharmaceutical companies to get motivated to go because there is generally a monetary profit (unintelligible).

And we can't go out and tell each company to try to do it. NIH might be able to help with that to get a trial going from an investigator's standpoint. But I can't say from our standpoint when we have met with sponsors the – I want to say lower the bar but you do not need a lot of clinical outcome.

The primary endpoint is just showing that a patient feels better. And they can come up with almost any questionnaire as long as it at least has some face validity we would be accepting it.

So we are really trying to facilitate anyone coming in for a drug (unintelligible). And that goes from the highest levels all the way down to our division. Everybody at the FDA is hoping that something will come through.

Faith Newton: Terri.

Terri Wilder: Hi, Terri Wilder. I realize we are going to talk about this later but I support what Courtney said and that we need a working group. But I just have a quick question about outcome measures. Are you guys working on any outcome measures beyond PROMIS?

(Keith Hurt): So we don't necessarily work on the outcome measure per se. But let's say a company came in and proposed a questionnaire which said, you know, what is your energy level in the morning? What are my daily activities?

You know you can get out of bed or you, you know, can leave the house and it is a visual analog scale, et cetera.

We will accept whatever a sponsor is going to propose. I mean we may recommend alterations but we want just a patient report outcome to show that a patient is feeling better. It doesn't have to be validated. It just has to be some type of outcome measure for that trial.

So from a study design it doesn't get much easier than that for a company. That they can propose almost anything and we will accept it.

Faith Newton: Leah.

Leah Williams: Leah Williams. This is a different topic. But I am wondering if you have a comment about the current crisis and availability of saline and medications due to the hurricane in Puerto Rico and how the FDA is responding to that?

(Keith Hurt): I (unintelligible) actually the case.

Leah Williams: This is anecdotal but a number of patients are having a very hard time getting medications and also saline for home use.

(Keith Hurt): I do not know about that but I will try to look into it and if you send an email to Gustavo I will try to get back to you on that.

Leah Williams: Thank you.

Terri Wilder: I just want to thank you for bringing that up. This is Terri Wilder. It is a concern for sure because many of us depend on IV saline. A lot of us use kind of Myers' Cocktails and there is a little bit of a panic in the community about it because of what happened in Puerto Rico. Because they are a large manufacturer of saline.

They also manufacture another drug that people with ME use. So we definitely would like to hear how that is going to be resolved. I think there is a higher level of intervention that needs to happen from our President.

But I think it is something that is very concerning to people. Just I mean I get weekly IVs of saline.

(Keith Hurt): So I am not sure if that is for the same (unintelligible). I know there is a problem with supply of a drug that we will often declare an emergency and then we can get it from other vendors. We can get it from Europe or other places that we normally wouldn't get medication. So I will see if I can look into that.

Terri Wilder: My question would be then how will they get the response if you look into it? Where does that information come back to them?

(Keith Hurt): That I don't know. But if Gustavo would email me I can email him and he can disseminate it.

Faith Newton: Okay that works. Go ahead Courtney.

Courtney Miller: Just want to follow up and not leave unsaid the fact that there is a drug and there is a sponsor that you guys need to be working with to figure out how something that works. Whether it is a subset of people or not with this disease doesn't disappear and it is disappearing.

So I would ask you to go back and figure out how does the agency make something happen on Ampligen.

Faith Newton: Any other comments, questions or concerns? All right let's move onto to the next presentation. Thank you again.

Social Security Administration. (Michelle)? Or I am sorry – yes (Michelle).

(Melissa): (Melissa).

Faith Newton: It is on my agenda wrong. My apologies (Melissa).

(Melissa): So I am going to just talk a little bit about the Social Security Disability Program this morning and good morning to all of you. And just to kind of tell you what I am going to tell you. This is going to be a little bit of a refresher. If you know about the disability program and if you don't then I am going to just walk through some things for you.

Kind of the definition of disability from the Social Security Administration's perspective. What it takes? What the process is? What it takes in terms of evidence that we need when we are trying to establish whether or not an individual is disabled.

And then we are going to walk you through a little bit of data from 2017 and from prior years.

All right so trying to look over the slide here. We have two disability programs that we administer. One is the social security disability insurance program more frequently known as Title 2 or worker's disability. So this is based on what you pay in as a worker for your social security earnings.

The second is supplemental security income which is a needs based program. And you still have the medical criteria for both programs.

Let me just see. So disability is defined in the Act. It is the inability to engage in any substantial gainful activity. And substantial gainful activity we have determined is a monetary amount and the monetary amount changes every year.

And so this is based on wages, gross wages that you would earn that would be it has declined right now. It is $1170 per month. And again that number changes every year.

Okay the disability has to be due to a severe medically determinable physical or mental impairment that has lasted or is expected to last for at least one year or result in death.

Gustavo Seinos: (Melissa) I hate to interrupt. This presentation is not in your binder so we will email it to everybody and post it on the Web site once it becomes available.

(Melissa): Thank you. Okay the process for determining disability. So it is – when I started off in the disability program in the early 80s this was a process that was in place then. It is still the process now.

And it was drilled into me until I can truly say it in my sleep what we have to do. So it is, as the person currently working at SGA. So if you are an applicant and you are earning $1170 a month regardless of what your medical, your physical or your mental condition are your claim would be denied. Because it is disability plus income.

So if someone is not working at SGA then they move to the next step. And that is, is there a severe impairment? And severe impairment is kind of a term that we use specifically with an SFA. The term severe means is there more than a minimal limitation on your ability to do basic work related tasks?

And those would be standing, carrying, lifting, walking, pushing, pulling, things like that. Just basic daily work activities that you have to perform. And it is a pretty low threshold.

At this point we are also looking at not only what is the objective medical evidence but what are the symptoms that a person has as a result of their medical condition?

So we will weigh all that when we are deciding whether or not someone's condition is more than non-severe. Step Three: So just the impairment or combination of impairments meet one of our medical criteria. So, we have the blue book - I don't know if any of you are familiar with that. It's on our Web site. It's a document that lists all the medical findings -- mostly objective some functional -- for many different body systems, including muscular skeletal, special senses, respiratory, cardiac, et cetera.

And it lists a variety of objective medical findings that in and of themselves are serious enough that we say, if you have these findings, then we will decide all evidence - everything else being consistent -- that we will make a finding that you are disabled under Social Security's rules for disability.

If you're - if you don't have findings that are as serious as in our listings, we move to the last two steps. And this is where we start to bring in information about well, what is it that a person can do despite the medical impairments that they have? So, here we look at something we call the residual functional capacity. What can a person do regularly and continuously during the workday and the work week.

And what we look at is whether or not - if a person has work history, does that functional capacity that they have, can they go back and do the kind of work that they did before, either as they did it or either as it's generally performed by others doing similar work in the national economy.

Okay, so if we say that a person can't do the job they did before or anything that's close to that, then we, SSA, has the responsibility for deciding whether or not there's any other work that exists in the national economy that a person can do.

So, if I say that an applicant has the ability to do light work, that means they can stand six out of eight hours in a day, lift 20 pounds, and ten pounds and do other things, I'm going to look for jobs that fit that criteria. If there are jobs that fit that criteria, then the decision is denied and if there are not, then the decision is an allowance.

So, that's a very simplistic way to look at it, but that's the basics of how the program operates.

So, how do we do this? How do we get evidence and what kind of evidence do we need to make a decision on a claim. So, obviously, we're going to contact the medical providers that the claimant identifies as providing either treatment now or anytime in the history of when they said they were disabled.

So, generally we're going to go back to the point in time the person said they were disabled. We may go back a little bit further based - to get evidence based on the nature of a person's -- excuse me -- medical condition. Chronic fatigue is one of those conditions where we realize that the course might be variable and we're going to want as rich as a medical history as we can get to understand exactly what the course of impairment has been.

Okay, but we're going to be looking for diagnoses, test results, things like that. If we can't get medical evidence from the claimant's own treating sources that's sufficient to adjudicate the claim, we might have to purchase a consultative examination. That's not our preference. We would prefer to get the evidence that we need to make a decision from the patient's treating sources.

But, we do have - it depends on the areas of the country on how responsive medical providers are. And I can't quite remember what the typical consultative exam rate is.

Okay, so once we have information that says yes, a person has this medical impairment, we bring a lot of other evidence into play that is critical in helping us understand how an impairment impacts a person's ability to work.

We're going to get activities of daily living - finding out what this person is able to do. Not just today, but day in and day out. You know, what is their daily routine look like? Do they have more good days than bad days? What makes the difference for this individual?

We may get information from third parties -- friends, family members, employers, others in the community -- that are well-versed in this applicant. There are times one might actually contact an employer. But, we do that in partnership with the applicant, who says, "Yes, this is the person that I think can give you information about my medical condition."

Okay, so, I've already talked about that, pretty much. We've spent a lot of the past three years updating our medical criteria for disability. If you're ever watching at all what we publish, in terms of our medical guidelines, we've published new medical criteria for several of our medical listings last year.

We've published new mental listings - the first time they've been published since 1985. We've published new neurological listings, respiratory listings, new listings regarding HIV. We are working on the last set of medical listings that have not been revised comprehensively, and that is our muscular skeletal listing. We are hopeful that they will go during this fiscal year.

Terri Wilder: Can I just ask a question?

(Melissa): Sure.

Terri Wilder: Can you - sorry, this is Terri Wilder, can you talk about kind of what kind of efforts have been made to update information about (unintelligible) chronic fatigue syndrome? As you mentioned HIV and other illnesses that - what's specifically have been updated? I guess the reason why I'm asking this is because there's some concerns about people being denied because people don't really understand our disease.

That can be a disease of disability. So, you know, has the documents been updated related to our disease and are there efforts to educate, you know, claims reps, staff, the judges, you know, about our disease. Because you know, sometimes our disease - like our lab values, “look normal.”

You know, and I guess when you were talking about that, you know, light work could be standing for six hours or lifting weights for 20 pounds, you know, there are people who may - who cannot, you know, do that. And it’s beyond kind of the functional capacity to do something like that, you know. Even people who work kind of in an office environment, can’t stand. You know, so…

(Melissa): That’s an excellent question. And I - my answer…

Terri Wilder: I’m sorry that it was jumbled (unintelligible).

(Melissa): That’s okay. I think you want to make sure that we have our eye on the ball. That we are continually scanning the environment to understand what’s happening with evaluation, treatment, and care of ME and chronic fatigue. Yes, we are doing that. We have staff whose lead responsibility is to continually evaluate the research that’s available.

We are producing - in addition to updating all of our medical criteria, we are revising - we are looking at all of our training products - all of our online disability case studies, where we take real cases and we provide training material for our staff. That is available for disability examiners in the states, as well as the administrative law judges.

We’re working closely with our partners in the Office of Hearing Operations that they’ve changed their name to - Hearing Operations, it used to be Disability Adjudication and Review - that was the judges. So, we’re working with them on their training scripts.

We are doing continue - we have been an accredited provider now for continuing medical education for all of the doctors that adjudicate claims for Social Security disability benefits. So, the doctors that work for us and for the state disability agencies.

So - and I cannot recall specifically if they’re doing anything in regards to CFS. So, I don’t know more specifics than that, but I can get it and I can provide it to this (unintelligible).

Terri Wilder: Okay, great. That would be helpful.

(Melissa): Yes.

Terri Wilder: I mean, it would just - it would be helpful to hear like…

(Melissa): Right.

Terri Wilder: …what research are you using to drive the decisions because there's bad research out there about our bodies and we would want to make sure that Social Security doesn't think that that is legitimate research to drive their decisions?

(Melissa): So, one more thing before I move off that is, regardless of what lab values there are or physical exam findings there are or are not, once an individual has a medically determinable impairment of CFS or ME, then really what we are looking at is what is the person say they can and cannot do as a result of their medical condition. And that guidance is the same for CFS patients as it is for any other medical impairment that we have.

We have revised our policy this past year for how we address symptoms. That's Social Security ruling 163P, I think. I could be wrong on that. We've also published a regulation on how we consider medical evidence and who can provide medical evidence for impairments, to include physician assistants, audiologists and advanced registered nurse practitioners.

We've also - that part of the regulation revised how we consider opinions that we get from medical sources. So those are applied to all claims. And those are all things that I think are very important to CFS/ME patients because a lot of it is opinion symptoms - "Tell me what you can and cannot do. Let me look through the evidence and establish based on what you're telling me."

Yes, ma'am.

Donna Pearson: Hi, Donna Pearson. At the last meeting, the notes say that you said that the continuing medical education program on ME/CFS has been rolled out and doctors of SSI are receiving the training. And when you were asked if specific members may see the content - to see if it reflects (unintelligible) criteria, you said that it was based on the SSA ruling and that you would have to find out on whether we could see it on that? Or could you tell us any more about that?

(Melissa): No, I sure don't, but I will get that for you. I did not - I was not aware of that, but I'll talk with our staff person who attends and get that information.

Woman: (Unintelligible), I'm going to ask (Gustavo) to send that out.

(Melissa): Okay.

Woman: Actually, (Melissa) can send that directly to (Gustavo).

(Melissa): Yes.

Woman: (Gustavo) can send that out to the committee.

Donna Pearson: Just a little point I want - this might be a good time to mention it - I love the fact that you're doing your follow up, which is fantastic. And another suggestion would be to pour over the minutes and see who said what they would do to find out - to get an update. Because all kinds of people are saying they'll do all kinds of things, and we lose track of that.

Woman: Correct. I agree with you. What we're trying to do is as we go through and do that is to literally to write down, you know, what's being said and what can be done.

(Melissa): Right.

Woman: Okay.

(Melissa): And I know one of our staff is sitting in the back and so she's going to help me - keep me honest and answer questions that you've asked because it's important what you ask.

All right, so now's the data part of the presentation and I truly cannot see any of these, so I have to be looking down at kind of my talking points here.

Man: (Unintelligible).

(Melissa): I can't no - I can't see it well enough to do it, so - and I have notes, so I'm supposed to be reading. That's fine.

So, this slide talks about initial claims. So, as you know, there's an initial application process or reconsideration, which is the first level of appeal and then an administrative law judge hearing process. (Unintelligible) each level. And this information goes back from fiscal years 2001 to 2017, so it's a pretty rich set of information, in terms of cases filed, cases decided, and cases allowed.

So, I think what you're going to see consistently across the slide, which matches pretty much everything else that's been happening in the disability program, is you see a spike in the 2008-2009 range, which was coincided with economic downturn. We had a large increase in applications for all impairments during that period of time, chronic fatigue was no exception.

So, right now, what I can tell you is that there are nearly 13,000 individuals who are currently receiving Title 2 - the worker's disability and/or SSI. A person can be getting one or both. And that's where chronic fatigue was identified as the primary and secondary impairment.

Okay, again, determinations of disability are driven by filing ranks. The more people that apply, I think what we generally see is then the allowance rates start to fall. Because sometimes people who were able to be employed when the economy was good, may lose their jobs in a bad economy and yet may not

necessarily meet the disability requirements. That's generally what we found for all impairments - across all impairments.

Okay, so the number of impairments - so the peak in 2008 was 2100 claims that were adjudicated for chronic fatigue. Between 2008 and 2017, all determinations - so all decisions that we made - our initial claims decreased by 6% because were not filing with as much frequency.

So, the number of cases that had a primary diagnosis - primary impairment of chronic fatigue, decreased more than 6%. So that fall off was not as consistent with the 6% decrease, just like it was for all impairments. And I'm not exactly sure why.

Okay, the initial allowance rates for all claims between 2008 and 2017, declined about two percentage points, from about 37% down to about 35%. So, for chronic fatigue cases, in 2008, the allowance rate was about 14.6% and 15% in 2007. So, the allowance rate has stayed consistent. Okay.

Recons - again, this is the first level of appeal. There are reconsideration claims in all but 10 states. So, for 10 states, they have something called the prototype process. It's a testing regulation where there is no reconsideration to claim those directly from the initial level directly to the administrative law judge hearing. Okay.

So, the data is similar there. I know that the average allowance rates for all reconsideration claims is about 11%. It's been as high as about 13%. For chronic fatigue cases, it range from a high of 9% down to 7.6%. So again, it's had that consistent variability just like every other impairment groups have had.

Terri Wilder: Can I ask a question, I'm sorry.

(Melissa): Yes.

Terri Wilder: This is Terri Wilder. For the ten states that don't do reconsiderations…

(Melissa): Yes.

Terri Wilder: …can you name those ten states?

(Melissa): This is a test. I can name part of them. Let me see - Pennsylvania, New Hampshire, New York, Alabama, Louisiana, Michigan, part of California, Oregon - how many have I named? Let me get you the ten.

So what happens with those cases, again is the claimant is noticed. When they get their notice that they're allowed or denied and they have appealed rights, they're advised that their appeal is directly to the administrative law judge.

Terri Wilder: It's directed to - sorry, say that again?

(Melissa): When -so when a claimant gets their denial letter, they're directed as to what their appeal rights are. So, for a non-prototype state, they're directed to file the reconsideration level of appeal. For a prototype state, they're directed that their appeal right is directly for a hearing with an administrative hearing law judge.

Terri Wilder: Okay.

(Melissa): Okay. This has been going on since 1999.

Terri Wilder: (Unintelligible) since 1999.

(Melissa): Okay, so the recon data again is similar and for the administrative law judge. So the allowance rate for chronic fatigue cases at the administrative law judge level in 2008 was 77% and in 2017 it was 67%. Now you might say well why is it so high at the ALJ level and not as high as the DDS level.

So cases that get to the administrative law judge level have a couple of things happening: Generally, they are the more complex cases. They've also changed the (unintelligible) since they were last seen and decided by the DDS.

Right now the wait time for a hearing is over a year - substantially over a year. So, persons' conditions may have changed. They may have moved into a different age category because we consider age differently for every individual when they get to another chunk of age.

But the administrative law judge allowance rate has gone down in the past five years from about 66% for all claims down to about 45% for all claims, across the board. So that's where administrative law judge action is happening right now.

Okay, I have just a couple of things. So, sometimes when someone applies for benefits based on chronic fatigue, they may also have more than one medical impairment that they say causes them to be disabled. Up on the screen it lists some other impairments that are some that we see at times associated with chronic fatigue claims.

Affective and mid disorders, none is the second category - I'm not sure that's an impairment. Other that's not specified. Back impairments, osteoarthritis, fibromyalgia. So there's a lot of impairments that may be specified with it.

One of the things that was an interesting factoid is chronic fatigue syndrome has been allowed most often when there is no secondary impairment. Not sure why, but just reading through in my prep for today, that was interesting to me. And that's something that I'd to know more about.

Okay, I think that is the end of data and refresher. Any more questions? I see some hands. Leah.

Leah Williams: Leah Williams. I have two questions. The first is that there is a very conservative estimate of 1 million people with ME/CFS in this country and an estimated 25% of them are home-bound or bed-bound. And you're saying there's only 13,000 that have qualified for disability, which means there's another 237,000 people out there who can't get out of their house. Is there going to be any attempt to help those people?

(Melissa): So, a lot of it depends on who chooses to apply for benefits. We can't award benefits or evaluate a claim if nobody ever apply for benefits. Right now, there's about 2000 claims a year for - that's based on chronic fatigue syndrome.

Leah Williams: Okay, my - I would say that your chart of applications and decisions is extremely discouraging to people who might be in the position to need disability. So, for example, that your first chart that you showed and you said there was a spike in 2007-2008, I look at that and I see a plateau up until about 2007 and then an - a very sharp drop off over the next couple of years.

And that's not because people aren't sick. And it's not because they all found jobs. So, I would guess that something changed in the process to really - strongly discourage people from applying.

(Melissa): We have done nothing to discourage any individual from applying for benefits. Now, I would tell you that the administrative law judge backlog has started to increase, probably since about that time. And what we have heard is that some people may not be applying because it's a process takes a very long time. So, that's one thing. And also the administrative law judge allowance rate has markedly decreased by 20%. Sixty-six percent down to 45%. That's been a significant difference.

Leah Williams: Thank you.

(Cindy Bennon): I'd just like to make a couple of comments from the trenches. One is that I think patients are often discouraged at the point of application - at Social Security. For example, I have patients who - I've had several patients tell me that if they haven't worked and put into Social Security that they were told they weren't eligible, which doesn't jive with what you were telling us about those two categories.

(Melissa): So, you're not eligible for Social Security disability insurance for Title 2, if you haven't worked and payed into Social Security. If you don't have earnings that means you're insured, just like, you know, you'd have medical insurance, if you're - if you don't pay your insurance, you're not insured. So, the same thing for Title 2.

SSI is a needs-based program and if a family or - I personally get very confused if I have to think about the income and resources means test for SSI. They talk about are you living with other family members, how is their income counted against your eligibility resources. I am not the expert on that and I don't understand most of that.

But it is - it is if someone hasn't work, they cannot be eligible. They can only be eligible up through the date that they're ensured and for SSI, the means test is very precise.

(Cindy Bennon): Okay, but the other comment I wanted to make is that generally the disability attorneys that I've worked with -- and it's a significant number -- feel like their case doesn't have a chance unless they link to other illnesses, particularly depression. And it's troubling that it appears to me - maybe you could help me with this -- but that the allowance or the determination, you know, the allowance is even lower if the case is linked to depression than if it's used -

And I think this is an important education piece to pass down the pike to attorneys, but it's a hard argument to make because there it - they want to win and they use all their old techniques…

(Melissa): Right.

(Cindy Bennon): …to see what they can do and I'm - sometimes it trashes the case.

(Melissa): We have conversations regularly with representative groups: NASCRA, the National Organization of Social Security Claimant Representatives and other groups. And they've talked to us about changes in the adjudicative climate, things like that.

I know that our hearings and appeals group have done a lot of training for staff, a lot of quality reviews on judges' work. A lot of other educational opportunities as a result of remands from the courts. And errors that they find in the quality review process. So there's that.

Just one factoid that's not up on the screen. Overall, over every single person who's on the rolls for disability benefits -- for Title 2 or for SSI -- over 70% of them have been awarded at the initial or reconsideration level. So, not having to wait until they go before the administrative law judge. Seventy percent of every person who's on the rolls.

(Cindy Bennon): I just - my last comment is I've never had that happen with one of my patients.

(Melissa): Okay.

(Melissa): Leah.

Leah Williams: It looks like that rate is much, much lower for any CFS patients, right? You're quoting 15% (unintelligible).

(Melissa): I'm just talking about every person who's on the disability rolls for every impairment that is addressed (unintelligible).

Leah Williams: (Unintelligible) suggest that the rate is much higher for other impairments?

(Melissa): Well, I would say probably cancers are very high near the, you know, 80-90%, things like that.

Yes ma'am. You just had your hand up.

Terri Wilder: Hi, Terri Wilder again. I have to - want to go - I'm a little obsessed with this ten-state thing.

(Melissa): No problem.

Terri Wilder: So bear with me. So, I'm just wondering do you happen to know where can you find out what states have the highest number of ME claim applicants. I mean, the reason why I'm asking is for a couple of reasons. You know, we don't have a ton of expert clinicians. Like, you know, we have maybe 10-12 in the country.

It just happens to be that, you know, probably California has more than the other states. So, I'm just kind of curious like if you know what state has the most ME claim applicants. You know, the other thing that's kind of plodding in my head is that, you know, there are people out there that are very, very sick - that are disabled and they may live in, you know, Senatobia, Mississippi where don't have access to an ME expert.

So, they may actually never get diagnosed officially with this disease and - but then try to apply for Social Security and then, you know, it just doesn't line up because they've never gotten an official diagnosis, which shows, you know, a problem with our clinical care system here.

(Melissa): There are claims where we will never know the diagnosis unless or until a person passes away and there's an autopsy done. Disability does not - is not determined solely based on a fixed, firm diagnosis.

Terri Wilder: Okay.

(Melissa): There is objective but medical evidence of, I know something - I know there's something that's wrong with this person. I know that they have an impairment. I may not know the name of it, but there are findings that are available. That should not stop a person being able to apply for disability benefits.

And, I'll do a plug while I'm here. A person can file for benefits online. So, a person with chronic fatigue who has difficulty - I mean, I've heard you talk about leaving the house. You can file your application online.

Somebody - you know, you might have to pass a few documents back and forth, but if you establish a My Social Security account and you're applying for Title 2 benefits, you can file your disability claim, including all your medical providers, everything else online.

Terri Wilder: But just back to my question, can you tell us if you know which state has the (unintelligible).

(Melissa): I do not know.

Terri Wilder: Could you find out for us?

(Melissa): I do not know. I do know - I'm not sure - yes. We'll find out about that and I'll give back whether or not you'd need to ask specifically for that. But, yes.

Terri Wilder: Okay, thanks.

(Melissa): Any other questions? Thank you.

Oh, I'm sorry, (Courtney)?

(Courtney): I don't know if this is a question for you, but this drop off it is, you know, significant from the early 2000s to the later 2000s. And, you know, if you take 2008 or '09 or the years of the Great Recession out of it, it's still a significant drop off. And I'm wondering whether the ICD codes changed. Whether, like, you know, something else is happening here because people are getting - if anything, they're getting diagnosed more with this disease. But I don't know, something is…

(Melissa): Let me see what I can find out.

(Courtney): I mean, I don't know if it's on your end or if it's just for us to work into diagnosis and -and then, it is a complex disease. The rate for approval under administrative law judges, you know, looks much better than…

(Melissa): I understand that was only 200 cases.

(Courtney): That went on to an administrative law judge?

(Melissa): Yes.

(Courtney): In those years?

(Melissa): Yes.

(Courtney): Or is it…

(Melissa): That was…

(Courtney): Is that all the ones that went on?

(Melissa): So, each year, the administrative judge adjudicated probably - in the past, say since 2014, no more than - so they allowed 200 cases in 2014. They only adjudicated less than 400 cases with chronic fatigue. So, the scales are different in each graph because the proportions are different. But it's a small number of claims - very small number.

Woman: (Theodore), question.

(Melissa): Okay.

(Ted Ganeisinom): Just Leah and (Terry) were saying made me think, if you need objective findings in order to get the claims (unintelligible), then you need to have a clinician making those findings. It's impossible to do it without having the objectives, is that right?

So, if you have uneducated clinicians or patients unable to find an educated clinician, you won't be able to get the objective findings. And so even though there might be a million people, if they're not getting the objective findings, that is one of the log jams. It may be problems with Social Security Administration, but it's certainly a problem out in the real world getting you the right information. I just want to make sure I'm hearing that correctly.

(Melissa): I would agree with your statement that what Social Security does and what the medical community does are related, but separate. I mean, I'm saying it another way. It relies on a provider that is educated, correct.

Terri Wilder: I swear this is my last question. It's Terri Wilder, again. So given the update to SSR-163P, will there be any updates to SSR-141P, which was the ruling for CFS.

(Melissa): So (Susan), I'm looking at you and I see you shaking your head. I think we're looking at the SSR.

(Susan): We are… right now…

Terri Wilder: Can she come to the mic so other people can hear?

(Melissa): Sure, (Susan). Come on up. (Susan Luther) is one of our staff experts on CFS as well as other medical impairments. Come on up.

(Susan Luther): I'm not sure (unintelligible), (Melissa). To answer your question, we are looking at that right now. I can't give you a firm date on which the update will be published. Unfortunately, I've actually just recently started working on this, so this part of my education, thank you. This is very useful.

But, we are looking at that, especially in light of the Iowaian report that came out a couple years ago and obviously the (unintelligible) research.

Woman: Can I also add a comment? I want to make sure that we're looking at it because a couple times, we're just referring to it as chronic fatigue. That we make sure that we're looking at it as MECFS or chronic fatigue syndrome and that we're not mixing it up with other diseases or other illnesses.

And can we get that information by state because I agree, I'm quite surprised that the numbers have decreased, given the increase in the number of patients - both adolescent and adult. So, I'm - would be very interested in that data, as well.

(Melissa): So, I know that we do not have an impairment code that we use for ME, so everything will be categorized under CFS, the impairment code for that.

Woman: Okay.

(Melissa): Systems being what they are and changing systems being what that is. Okay, thank you.

Woman: Thank you.

Terri Wilder: Thanks, again.

Faith Newton: We have presentations from the liaison organizations. We're going to start with (Courtney Miller) from Simmaron.

(Courtney Miller): (Unintelligible).

Faith Newton: Whatever is more comfortable for you.

Man: We can give you the clicker.

Faith Newton: We can give you the clicker.

(Courtney Miller): Do I point it up there or down here? How do I…so, I'm (Courtney Miller), I'm representing Simmeron Research. I wanted to just, very quickly, remind folks that our primary goals are to redefine ME/CFS through science, identify diagnostic markers, characterize subsets of ME/CFS patients.

I think that's probably one of the most critical things we need to do in science. Pursue research that can lead to potential treatments and do it through the eyes and the experience of - primarily of (Dr. Petersen) collaborating with lots of research institutions and other clinicians.

But that's the viewpoint through which we're doing this research. And I'm, you know, going to talk a little bit about the accomplishments that our researchers have had. We really have focused on and spent the last five or six years driving a focus on immunological studies. We've published 15 peer-reviewed manuscripts in collaboration with many other researchers in the field.

We had a specific focus on spinal fluid studies because we've access to a very rich repository of those and the ones that we've published so far have reinforced the immunological findings that are happening in the - in other studies. And we've collaborated on finding subsets. So, over the course of the six years of our existence, we've published differences - along with other researchers and collaborators - differences in…

Man: (Courtney), I hate to interrupt. We're having some problems with the live stream - HHS studio. So they have to disconnect the slides and then try to reconnect it again, so if you can wait 30 seconds.

(Courtney Miller): Sure.

Man: Are we good, sir? All right. Thank you.

(Courtney Miller): Okay, so a number of our publications and collaborations have characterized differences in patient subsets. So, short duration versus long duration look different in the immunological profiles. Classical versus atypical cases in spinal fluid in particular look different. And recent publications related to the microbiome demonstrate different microflora in any patients who have irritable bowel syndrome and those who don't.

But turning to the most recent and the most exciting news - really want to take a moment to praise NIH and the patient community and expert community for the announcements that have happened in the last few months. This is the largest infusion of NIH finding for our disease in our collective memory and our collective memory is pretty long.

I specifically want to praise patients and experts for making the effort over a number of years to bring change to NIH. But I also want to praise NIH for doing the hard work that it takes to change an institutional approach and to rework its program. And of course we encourage more of it and we are particularly - Simmeron and (Dr. Petersen's) clinical site are proud of the collaborate in - primarily in the Lipton grant that as awarded.

The Center for Solutions for ME/CFS it is - deepens the six-year partnership that we have had in providing clinical insight and samples to Columbia University's research and the goals of that grant are to really assess and identify an end-functioning metabolics (sic), microbiome, the effects of exercise and develop some sort of app for patients to track the disease.

We will also be collaborating and providing samples to (Dr. Hansen's) grant team at Cornell.

As for our research work ongoing, we expect in the New Year to be publishing additional results from the spinal fluids studies - Phase II of those studies. We're -- as I said earlier -- looking forward to additional publications from the CDC's multi-site study and really want to emphasize that we believe that results need to be published to change the field. Whether they're positive or negative results. I mean, whether we find things or not.

And I'll underscore what I've started the morning talking about, but treatment is our most pressing, unmet need and we have to broaden the responsibility to everybody to build the field of evidence-face treatments. To do it collaboratively, to create treatment trials, and to study responders.

So, the complicated nature - the, you know, the notion that we have such a diverse population in the patient base, we have to use that to inform the treatments because treatments are not working across that broad spectrum. And so we're not getting an approval for antigens. We have to study the responders to immune-related - at least from the experience of our clinical site, the immune-related treatments do have responders.

And we need to study it. We need help, we need infusion of expertise and of researchers to take data. We have, you know, an immense amount of data in that clinical practice for all of those - for (ampligens), for (sidophavere), for other forms of anti-virials, for IVIG, for Gamma.

We don't have data on (unintelligible), but there is data now for a study that had a small subset of responders and finding a way to have FDA help review that data or the agencies themselves - NIH, CDC - I think those are - there's an amount of knowledge out there that we could formalize that we don't have yet to lead us to treatment trials and better options for patients.

So we are doing our part on that, but I really want to encourage ideas and an input - how do we do that in a way that actually moves us toward treatments. And I think that's the end.

Faith Newton: Questions, Keith?

(Keith Hurt): (Unintelligible) on the updates, so I want to applaud you for, you know, your organization's trying to find a immunologic changes that could help with the (unintelligible), et cetera.

I want to point out that for the - you know, for FDA trials, again you can use patients based on clinical criteria. It doesn't have to be immunologic. And outcomes are just feeling better so that that shouldn't hinder a clinical trial at this point, also. And so, it's important to find a subset of patients. If you can, that would be more responsive and you can enrich a patient population for a clinical trial.

So, hopefully the research that you're doing can find out patient population that would be more responsive to a drug therapy and then you enroll that type of patient into the study to get a drug approved.

(Courtney Miller): Yes, I would answer that, you know, we had - I know that (amplegen) had data showing a ten-point Karnofsky Scale improvement and it was deemed not sufficient. For patients who are going from 20 to 30 or 30 to 40, or whatever that scale is - I'm not expert on the scale, it is improvement but there are some who do much better than that and there's some who don't respond at all.

We should be helping ourselves with the expertise on trying to identify who and why, right. We now have treatments that do produce in some people responses. So, how do we use that to work backwards in a science to figure out what's actually wrong with them, as well as try to identify a way to get medications approved.

Faith Newton: Any other questions? Donna.

Donna Pearson: Hi, Donna Pearson. Keith, so are you basically saying - it sounds to me like you're say the FDA has really relaxed, basically, their standards for drug approval for this disease based on the knowledge that you've gain in the last five years. Is that true?

(Keith Hurt): Relaxed sounds kind of (unintelligible).

Donna Pearson: I know.

(Keith Hurt): But we've opened up to try to get a drug approved - so, for instance, if someone had rheumatoid arthritis and the end point was just that you feel better, it probably wouldn't float. But for chronic fatigue, since we don't know - you know, we don't know the underline ideology, we don't know necessarily good outcome that we have allowed - well, pretty much allowed almost any outcome measure that would capture that a patient feels better, to some extent.

Donna Pearson: And did I hear you say something about only 12 weeks of trial time? So for chronic indications, currently we like to see a change in 12 weeks for a chronic drug. However, there may be some cases -- for instance in lupus -- where we may want longer trial because the disease lacks and weans. But if you can show an improvement in 12 weeks, that would be ideal.

Donna Pearson: So if - the (amplegen) patients who already have presented - and (Dan Petersen) really knows who is a responder and who is not. And I think he has all kinds of information about the sub-types. I would assume that they would apply to you for - they would have to apply to you for a new study, but they could still use these same patients over a 12-week period. These who have declined significantly since they've been off it. I mean, I know it's between the drug manufacturer and that FDA, but I just want to have a better understanding here.

(Keith Hurt): So, yes, we obviously - I obviously can't get into a lot of specifics, but what we ask from any sponsor is that there's a well-defined patient population, things are pre-specified prior to going in, the study is well-controlled, so there's usually a placebo arm -and by placebo, we don't necessarily mean absolutely nothing, we mean standard of care, for instance.

And that there is some (unintelligible) and double-blinded and that there is some clinically meaningful outcome. And we've determined that for chronic fatigue, a clinically meaningful outcome is a patient reported outcome that makes - that we could somehow capture that the patient feels better. That answer…yes.

Faith Newton: Thank you.

The next liaison presentation is Leah Williams from the Massachusetts CFIDS ME/CFS Group.

Leah Williams: Can I get the clicker

Faith Newton: She needs the clicker.

Leah Williams: Hi, it's really a pleasure to be here. In-person meetings are so much better than online meetings. So, I'll just give you also a quick reminder we are the oldest and the most active state-level patient organization in the country. We were founded in 1985 and our mission is to improve the lives of all people affected by ME/CFS and FM, advancing awareness, care, treatment and research. We do patient services, we do education and awareness activities, and we do advocacy.

So, I'm going to give you a little update on the things we've been doing since the June meeting. We've had a very active fall. So, in patient services, we have provided physician referrals to 68 people and we've responded to about 50 other requests for services and information.

So, the physician referral is one of the most important things that we do. It's also one of the hardest because there are so few doctors who are knowledgeable and expert. And many of the ones that we have in our database are retiring and they're not being replaced by younger doctors.

We have been making an effort to increase the number of doctors that we can refer to. We're also trying to do a better job of following up with people who we give referrals to and find out what their experience was with that doctor should that doctor continue to be in our database.

We sponsored three in-person support groups. And those had been going on for quite a while. In the education and awareness category, we have updated our Web site - particularly the pediatric pages to reflect the new information that's been posted at the CDC.

And I agree with the former comment that the new materials are excellent. The CDC did a really good job improving those materials. And so we're very happy now to link them on our site. Before there was a little hesitation, but now we are very happy for people to go to the CDC and copy - you know, take those materials to educate people.

And we have also posted the new fact sheets that the pediatric education working group here came up with it. (Faith Newton) is the author of.

We have also established a relationship with (Dr. Ennitmaz) at Jackson Laboratory in Farmington, Connecticut. He was one of the recipients of the NIH - an NIH collaborative research center funding. And eight people from Mass CFIDS went down and met with his group. I wasn't one of them, but it was a very positive meeting.

He was really excited to know that we were close by and interested. And in fact, he's going to give the lecture at our next annual event, which will be next November. So, we're really excited to be helping with that.

We had our annual event in November. We had (Linda Tennenbaum), who's the CEO of Open Medicine Foundation Common give a presentation about current research at Stanford and also at other places. We had a - between 80 and 100 people attend that talk. And these in-person events that we have, we only do one a year because they take a lot of time and energy to organize.

But they're extremely important for the patient population -- the ones who can get there, at least -- to meet other people who are in a similar situation and to just have some social support.

We also for this one for the first time, has a meeting for local researchers beforehand. This was very informal, it was just over lunch. We unfortunately didn't advertise it enough, so we had four or five people come, but the people who came said, "I had no idea there were other people in Boston doing this research."

And so, this, I think, will be a very important thing going forward to try to get all these people in a room and talking to each other. And so we will continue to do that before our annual event and hopefully a lot more people will come next time.

We've been invited to make a presentation at the annual meeting of the Massachusetts Academy of Family Physicians - that's in March of 2018. And this will be just an overview of ME/CFS and how it, particularly affects pediatric patients. (Allen Gerwick), who is our medical advisor will make most of the presentation and I will also contribute part of it on the pediatric aspects of it.

We've had a number of things going on with the Massachusetts Department of Public Health. We met with Commissioner (Barrel) and her staff in June and we are - we have an effort to get a letter out to all physicians in Massachusetts.

Our medical advisory committee has come up with a letter and that seemed maybe not so practical, and so now we're focused more on trying to get that letter out to all nurse practitioners and physician assistants in the state and maybe aim for the physicians a little bit later.

We are also working with the Massachusetts Department of Public Health on making contact with the school nurses in the state. We have made presentations at school-nurse continuing education conferences in the past, but this would be a broader effort to really contact all school nurses and let them know that if you have a kid who is having trouble, this is a trouble getting to school, this is a possibility that this is what's causing it.

On the advocacy front, we have been working with the Massachusetts state legislature to try to get two pieces of legislation through. One is on tone medicine, and I know that's a topic later in this meeting. So, trying to get health insurance to cover tone medicine for the people who really can't get out of their house to a doctor's office and then there's also a right-to-try initiative. So there are right-to-try medications for off-label uses in many states, but not in Massachusetts. And so, we're trying to get that piece of legislation introduced.

We had developed a relationship with the Senate president, which was great until he got swept up in the current sexual harassment scandals. So, we will have to start rebuilding a relationship there.

One of our big efforts this fall was a screening of "Unrest" at a local theater. This was co-organized with (Riska Solomon), who is a fantastic organizer. I also did a lot on that and (Susan Buckley), another volunteer. This is the largest community-based screening "Unrest" in the world. We had - that's a typo - we had 360 attendees. We almost filled this theater, which was fantastic. The energy was incredible.

We had donors who gave us funding to cover free tickets for healthcare professionals and researchers. We has 150 people sign up for free tickets, but only about 75 actually showed up, which is fine. That was 75 more doctors who have now seen “Unrest,” which is an incredibly powerful messenger for patients and our community.

I - this is just a little side story, but I invited all my neighbors and several of them actually came. And then a couple nights ago, one of them came over and said, “Can you come over and have a cup of tea with us. We have some questions.” They just wanted to talk about the film and that they had learned so much and that they had friends that they thought might have this and they didn’t know. You know, it was just really a great thing.

For that event - so this was something (Riska) did - was she got 19 co-sponsors, including the Massachusetts Department of Health, the - different hospitals, disability law center, universities, ME Action, Hadassah Northeast, various film festivals and this turned out to be actually be really positive because they all promoted the film for us.

So, for example, MGH sent out a note of about it to 27,000 people on their email list. And we had a number of things like that, which helped promote the film, which was really great. And in fact, this event was so successful that ME Action has developed an online guide for future screenings based on this event.

And I know we weren’t supposed to include photographs, but I wanted to include two from the screening. So, the one on the left is (Riska) introducing the film and introducing a statement from the entire Massachusetts Federal Congressional Delegation. So, two senators and nine representatives all signed this statement of support for ME/CFS patients.

And that was really exciting and we’re using that as a basis for working with them further and asking them, for example, to maybe write a letter to NIH to ask for more research funding. But we’ve now got the attention of all 11 delegates.

And then we also had a post-film discussion that was moderated by (Debra Becker), who’s a senior correspondent at WBUR, which is one of Boston’s NPR stations. And this panel included a researcher, an ME advocate, who is sitting right back there; a patient and a healthcare advisor.

And the panel was very well run. Anybody at NPR knows how to handle a microphone. We had a volunteer videographer who filmed it and then edited the video, and that has now been posted online. If anybody wants to see it, there’s a link on our Web site and we are also trying to get that shown on local cable TV stations. So we have a number of volunteers who are working on getting that out.

I think that’s my last slide. Yes. So, if anybody has any questions?

Gustavo Seinos: Leah, Gustavo Seinos, here. A number of times I get emails on (unintelligible) in box, supporting, asking for, you know, some new patient who have been diagnosed or things she or he has and it's looking for a referral. I assume that I can refer them to your Web site so you can refer them to…

Leah Williams: You can absolutely refer anybody to our Web site. Our physician referral database is really New England base, so we have doctors in Massachusetts, Connecticut, Rhode Island mostly. We really can't help people from other parts of the country. It's quite a big effort to maintain this database and understand who the doctors are and who we can refer people to.

I don't think there's a good physician referral service anywhere else in the country that I know of.

Terri Wilder: This is (Terry), (Gustavo). I'll be talking about that in my presentation.

Gustavo Seinos: Oh, okay.

Faith Newton: Any other questions for Leah? Thank you. And (Courtney), nice job, as well and Leah, as well.

(Terry Wilder), ME Action. Oh, did I miss something? Clicker's coming.

Terri Wilder: Hi, I'm Terri Wilder. So, I'll be representing ME Action today and giving our update, and just like the other presenters, just to give you kind of an overview of who we are, just in case you're unfamiliar. ME Action is an international group of people living with ME and their allies.

Our vision is a world that understands, supports and cures people with ME. And our mission is to grow and mobilize a community of people living with ME and allies to be strong and effective advocates for people with ME and related conditions.

Since June, we've been very, very busy. So, I'm going to divide this up into several different kind of sub-topics and the first thing that I'd like to talk about is the role of training in the work that we've done. So a lot of what we've been doing since June is really focusing on virtual teach-ins and the development of how-to guides.

Just to kind of give you a little history of kind of the language "teach-in," that's from my Act Up background. So, Act Up has kind of historically been known - which is the group that has long-term AIDS activists have done what's called "teach-ins," where they teach their own members information, do skills building so that they have the tools in which to advocate.

So what we started in 2017 was these virtual teach-ins. In - one of the ones that we did in July was kind of really inspired by kind of the work that we're all doing at local levels.

While we put a lot of effort in kind of federal advocacy, you know, people with ME live in states and neighborhoods, in specific areas - that's where they're sick, that's where they feel good on the days that they feel good, that's where they see medical providers, that they have medical providers.

So really having a teach-in that really kind of thinks globally, but acts locally was really the purpose of our July teach-in. In August, we decided to have a virtual teach-in really on, essentially social media activist messaging. Since a lot of us are homebound or bedbound, we can't get out and yell and scream at a protest and have signs, but there are opportunities to advocate through social media and the press.

So we convened a teach-in called "Speak Up, Tweet Back, Write a Meme: Activist Messaging 101 in the Social Media Age." And we had a guest expert in public relations and press convene that teach-in for us.

In September and in November, we were able to develop some how-to guides. So in September, we had a how-to guide on how to talk with the press - that can be found on our Web site. And in November, we produced a how-to guide on how to host community screenings. And there is a list of our contributors that either helped with virtual teach-ins or the how-to guides.

Some of the folks are living with ME, other folks are experts in a particular topic area. And these've been really well received. Particularly because people can access them on the Web or through kind of blue jean technology, which is like Skype. So it allows for access for people kind of around literally the world who otherwise wouldn't be able to kind of show up to a space physically and get this information.

I also want to talk about a lot of the outreach that we've done. To no surprise, because the film director and kind of lead person in "Unrest" is our co-founder of our organization. So ME Action, of course, is an official partner of the "Time for Unrest" campaign.

Some of the highlights from this campaign is that we had a Washington, DC screening of "Unrest" and a virtual reality event, which I don't know if folks know what virtual reality is. You kind of put these little kind of funky-looking masks on and then you kind of like are literally experiencing something. And so in this case, you're kind of experiencing what it might be like for a person with ME. In this screening, NBR - and then it was sponsored by Senator Booker.

Another piece of this ad campaign was helping to write the petition that went out. So this is a petition to fund ME research equally and fairly. It's a - basically a petition asking for the NIH to fund ME research equally and fairly.

We also helped "Unrest" screening hosts - with people literally around the world with community outreach and post-screening organizing. And we helped "Unrest," - the "Unrest" team - the impact team (unintelligible) virtual screening discussions for homebound audiences.

And one of the things that we realize after the virtual screenings discussions is that we really need more support resources so that folks who are homebound really have access to seeing this. And I think things are just kind of naturally become available, particularly in the United States when “Unrest” is shown on January 8 through PBS.

So, if folks couldn’t make it to the theaters or at a community event - if they have access to PBS, they’ll get to see it.

So, in terms of “Unrest” screenings, again, I know we weren’t supposed to have pictures, but you know, it’s so tempting to kind of show people exactly kind of what happened. So, here is a picture of us in New York. That was our theatrical premiere in New York and kind of after the premiere happened on a Friday in October, we had multiple screenings - I think seven to ten days out.

The picture that you see there is from a Sunday afternoon matinee at the IFC Theater in the West Village in New York City. That’s myself along with New York State Senator (Brad Whilmen), who’s really become quite a champion for us. He’s just a lovely man and really kind of just started hearing us and wanting to be supportive. So we invited him to be on a Talk Back. That, of course is (Dr. Susan Levin), who’s also my physician. And then (Ted Kerr) was invited. He is a long-time AIDS/LGBT activist and a professional moderator. So he was invited to be part of that.

You’ll also see the - I think the names somehow got switch. But the second picture is actually Atlanta. In Atlanta, there was a good crowd that showed up. I was pleased. My brother showed up. I’m from Georgia and basically threatened him with his life and told him I wouldn’t get him a Christmas present this year if he did not show up, so he graciously showed up.

But something that you should know about that is that we had a sociologist from the Georgia State University moderate. She was one of my professors in my PhD program. We actually had a famous rapper who’s living with ME that was on the panel. And then of course (Wilhelmina Jenkins), who’s also a person living with ME.

The third picture is from Tucson, Arizona and after that particular screening, they launched a statewide meeting afterwards. Again, we cannot over emphasize how important these screenings have been to connect people to one another and build a sense of community and also connect one another to advocacy and really thinking about your individual state and what your individual state can be doing to put ME on the radar of your elected officials, your public health folks and medical community.

So, I’d like to talk a little bit about advocacy and - because, you know, we have a limited number of time, we decided just focus on kind of what has been happening in New York. So, a lot of advocacy has been happening in New York in the last year-and-a-half. And of course a lot of this was really kind of built with much excitement after the premiere of “Unrest.”

We have a solid kind of coalition now for the New York state ME Action chapter. And just to highlight some of the things that we've been working on at the state level is that we have been having meetings with many, many New York state senators and assembly members to talk about the need for funding in our state.

The lime disease community last year was able to get a budget item into the state budget for $400,000. I think we deserve as much, if not more. It's also an opportunity to raise awareness. We've met with our local kind of state assembly people who represent us and just recently met with the New York state Senate health chair of the Health Committee and the chair of the Assembly who is the chair of the Health Committee.

We've also met with New York City council about funding awareness and introducing a resolution. We met with New York City council member Corey Johnson, who is the health chair. He has offered to do a resolution for us.

And one of the things that I would say that I'm really, really excited about is that we have worked - just have a beautiful relationship with the New York State Department of Health, which I'm eternally grateful for. We are almost at the end part of developing a Web page on the New York State Department of Health specifically on ME.

It not only has a section for medical providers, but the general public. And I'm very gracious to all of the work that they've done. (Mary Demmick) has been part of this group and we are really excited because when I was diagnosed in March of 2016, I went immediately to the New York State Department of Health and found nothing.

And so we brought that to their attention and they immediately responded. And we literally have had weekly phone calls for several months. So, I'm very excited about that.

We are working with the New York State Department of Health in selecting a date for an "Unrest" screening in 2018. It will be targeting public health and medical providers. My dream is that the Health Commissioner will be there because he was so amazing in being so responsive when we had the letter go out to over 85,000 physicians.

We've also met with the New York City Department of Health and Mental Hygiene. And I should mention that this is really significant because they are the largest city department of health in the country. So, we've had meetings with them. We are selecting dates right now for an "Unrest" screening, again targeting medical providers and public health folks to come.

We've talked with them a lot about clinical education. One of the things that is about to be released in the city is they have a primary care project. And their staff will be distributing an article and a primary care project newsletter that will go out to medical providers in New York City.

Additionally, Erie County Department of Health, which is in the western, upstate part of New York, is in conversations with us to have an "Unrest" screening in 2018. Again, targeting public health folks and medical providers. I'm very grateful to the Erie County health commissioner who did not even hesitate when I approached here. I should also mention that she is a pediatrician by training. So she of course got the pediatric primer that was released.

We've also been working with medical societies and associations to get them educated about our disease. We are right now submitting a (sic) article to be placed and published in the 2018 spring journal for families - New York State family physicians. We're also in the process of submitting a journal article for the New York State Journal of the Nurse Practitioner. We'll continue our work with school health nurses. We need to follow up with them in 2018.

Faith Newton: Before you move on to your next section, I just wanted - you glossed over it, but the fact that you sent out a letter to all 85,000 physicians in New York State is extremely impressive and I think we need to look to see whether we can duplicate that project in other states.

Terri Wilder: Sure. Yes, I appreciate you bringing that up. I didn't include it because it came out in - officially came out in May. I can certainly talk a little bit about that briefly if you want me to.

We did have a letter that was sent out to over 85,000 physicians. Our health commission who is Dr. (Howard Zucker), graciously - I mean, it was - I was pretty shocked how open his office was to this. But they worked with us to put information in his - he has a monthly physician's letter. If he - he picks two topics a month. And out disease was picked as the second topic.

And worked with us to put the information in there. To encourage medical providers to take this seriously when their patients present with symptoms to please put it on their differential diagnosis to not recommend exercise because it could be harmful to their patients.

He put links to (Jed Breya's) TedTalk, which we know people watched because the health commissioner's office emailed me and said, "We have this physician in upstate New York who has a question about (Jed Breya's) TedTalk.

I had to call an emergency phone call for the next business day after the letter came out because my email was exploding and my social media was exploding and the health commissioner said their office was ringing and emails were exploding. Not only from people from New York State, but literally from around the world.

Because as we know in this room, it often feels like nobody cares about us. So when a health commissioner does something like that, it really excites the community. And people are like, “How do I do that? How do I get a copy? We want to replicate that.”

Faith Newton: Thank you.

Terri Wilder: So, just moving on, the support that we’ve provided to people living with ME - we’ve set up 14 Facebook groups that were created to provide support and connection for subsets of the community, you know, by location, demographic, and interest. We started a Living with ME support group, which has just been an incredible resource to people. It has grown my 220% between July and November.

And so these are regular support group meetings that are virtual or kind of weekly telephone calls, monthly topical video calls. You know, this is really helping people have access to peer support. Just to give you an idea, kind of some of the monthly topical video calls, you know, coming out to your family and friends when you have ME. It can scary to actually say the words, “I have ME,” and then have to explain what it means.

There was a topic on depression, suicide, and mental health. There was a topic on ME and work and there was also a topic on avoiding push-crash cycle.

The topic of this slide is for you. So, we also launched a new ME Action directory. It’s basically, you know, who’s around me? It’s pretty basic. You know, it’s still a work in progress, but the core function here is, you know, where is support groups, organizations, and medical providers?

We launched it about two months ago and, you know, we really want it to be kind of the go-to platform to get information about resources around the country.

And so, I’m now going to end by talking about something that I think really needs to be recognized. Our community is still experiencing deaths. And I just want to frame this in kind of a quote from a philosopher who said that “those who do not remember the past are doomed to repeat it.”

In November of this year, (Laura Dawn Henderson) died. This a self-portrait of her. She is an artist and it was when she was 16 years old, before she was diagnosed with ME. I never met (Laura Dawn Henderson), but I remember her. I remember seeing her on social media. I remember seeing her at the New York City theatrical premiere. I don't know why caught my eye. I was walking into the theater. Jenn Brea was outside greeting people as they were coming in the theater. And, I happened to notice this woman that was kind of squatted down talking to Jenn, and I just -- I don't know -- there was something

about her that just drew me to her. And, then I kind of went in and I later found out that that, in fact, was (Laura Dawn Henderson). She had travelled from Tennessee to New York City because she wanted to be there for the theatrical premier. And, now she's not with us anymore.

I also want to talk about Ann Barry. Ann Barry died recently. She was from a suburb in Chicago. She desperately wanted to see Unrest. She died before a screening was done in her town and they dedicated that screening to her. This was something that Ann Barry said, "You know, I'm missing faith in the Health and Human Services, NIH and CDC". This is her message and her voice to people in power -- that this disease needs to be a priority. People are dying.

These are only two examples that I'm showing today -- but we know people are dying all around us on a regular basis. And, every day that this isn't addressed -- systems and people are complicit at our deaths. People are struggling. They want change. They want to live. So, if you're not thinking about ME every day and doing everything possible to end this -- then you are part of the problem that is creating harm, despair and death to us.

You are actually inching us closer to death versus inching us closing to health. So, we every day we don't have a biomarker -- every day we don't have an FDA approved drug -- we are inching closer to death.

I just want to say that ME is not only a public health crisis, it is a political crisis. And, when we are consistently being sent messages that we don't matter -- this is what happens. People die. Thank you.

Syreeta Evans: Thank you, Terri. Questions, comments? (Venters)?

Courtney Miller: Courtney. So, two very mundane, kind of turn back in part of your presentation - the letter that you got from the Commissioner of Health, I think, is something that we ought to shoot for getting the Surgeon General to write.

So, one, like, the mundane part is you had a ton of materials you talked about -- that you've worked up and down the State of New York -- can you make that accessible? Can you put them on any action to make them, you know, we could replicate all of that in 50 states if we don't have to write it at all, again? But for this body, I think, you know, whether it's drafted, you know, collaboratively, or I don't know who works in HHS with the Surgeon General but that would change recognition of this disease in that that letter will in New York.

At least, go a long way, so, I sort of wanted to put forward, you know, how do we do that on a national level? And, that's not all that you reported on but that one thing could probably have the most impact.

(Cindy Bennon): (Cindy), I would just like to give a little historical content -- more than a decade ago when I was on this committee, that was one of our recommendations that the Surgeon General letter write a letter to physicians and when it came full circle, they said we needed a state of the Knowledge Workshop, which got done. So, I think, maybe it is timely to close that circle again or ask that question again.

Terri Wilder: This is Terri Wilder again. I just want to respond to Courtney. So, the actual letter by the New York State Health Commissioner is actually on the ME Action website. We, of course, praised him and tweeted and, you know, made sure that he knew we appreciated it. So, there's a little article about it. We actually put it in a Google doc so that people can access it.

And, I would second that recommendation for the Surgeon General. I realize that it is not the same thing but, you know, in the early years of the aids epidemic, C. Everett Coop sent out, actually, a letter -- it's called Understanding Aids -- to every single household in the United States about HIV. I realize, it was a different time. It's a different disease but I remember opening that mailbox and reading about this disease that would then later define my professional life. I don't think it's too much to ask for the Surgeon General to send out a letter. And, we have an example of a public health official who did that for us and I'm sure that Dr. Howard Zucker would graciously let him copy the text.

Syreeta Evans: (Donna).

Male 1: So, I'm thinking that we probably need to -- on the fly -- maybe, for tomorrow afternoon create a recommendation that CFSAC and make about that unless someone else has a better idea.

Syreeta Evans: Obviously this was set tomorrow afternoon. Any other questions, comments? Dr. Kaplan's working group - medical education work group. Somebody want to pass him the clicker? You are up. Welcome.

Gustavo Seinos: You can do it from there, Dr. Kaplan, if you want.

And, I have to publicly thank Gary Kaplan for continuing to share this working group -- even after his membership on the committee expired back in November -- and for gracefully coming in on this cold day, giving up his clinic for a few hours to make this presentation and the work group that he led.

Gary Kaplan: Gustavo, thank you. I've had the privilege of serving on this committee for the last four years and serving this community for the last four years and getting to know a number of you. And, I'm truly grateful for the opportunity and congratulate the new members who have just joined this task force. There's a lot that needs to be accomplished but the good news is -- there's also been a lot that has been accomplished in the last four years, specifically with P2P and IOM. Things have moved forward and, I think, that we're -- especially the work that's been done at Stanford -- we are on the verge of getting some decent biomarkers.

Okay. This is truly the result of full participation of everybody on this committee. And, who needs to be added to this list is (Nua Noire) (sic), my research assistant, who has worked tirelessly transcribing the minutes of each meeting, as well as helping organize this material that you are going to see today. So, a big shout and thank you to (Noire) (sic).

Where are we? So, just as quick background, we all know that the Pathways to Prevention Conference in 2014 as well as the IOM Report in 2015 really significantly moved the field ahead -- acknowledging the existence of ME/CSF -- astonishing that it needed to be acknowledged -- but, nevertheless, finally, the official imprimatur was given to the disease and acknowledged it as a distinct medical condition.

Research since IOM and P2P has further elucidated potential biologic markers -- by the work being done at Columbia and Stanford, in particular. With better insights into the biology of the disease, new treatment strategies are being proposed and studies are ongoing with regards to appropriate treatment protocols.

So, despite these advances, there are very significant problems -- ignorance being first, second and third. And the ignorance is both in terms of knowledge of how to diagnose and treat this disease and ignorance in terms of an attitude on the part of the profession toward this disease that people who suffer with this are somehow malingering -- that they do not deserve the attention from the medical profession. And this is truly a tragic occurrence and needs to be overcome. And, it's one of the big challenges that we saw as part of the education committee that we needed to address.

The IOM reported that there were fewer than 1/3 of medical school curricula, less than 1/2 of medical school textbooks had information about it -- ME/CSF. And, certainly, as we have seen and heard from the community whose testified before us over the years and what the IOM acknowledges that patients are frequently subjected to truly hostile attitudes from their health care providers. And, I can't tell you -- as a physician -- how many patients that I've seen who actually have PTSD as a result of the care they received -- or lack of care or inappropriate care they received from their various providers. So, as a consequence of this lack of knowledge and the medical stigma of the ME/CSF community is severely underserved by the medical community. So, at the end person meeting at the beginning of this year the chronic fatigue CFSAC created the Medical Education Working Group and we were charged with formulating a series of recommendations to the Secretary of Health on how to improve education for health care providers on ME/CFS. I will warn you that we have 14 of them -- 13 of them - I'm sorry, that you are going to need to be looking at and considering for your votes.

We provided a wide array -- so our mission became provide a wide array of extensive and easily accessible education material, resources and tools to health care providers. And, we included past physicians, the natural pathic physicians, nurse practitioners, PAs, social workers, psychologists, nurses

and psychiatrists. The reason for this is that frequently these are the first line people seeing individuals struggling with ME/CSF, so, it's important that they be educated to recognize the disease and recognize the treatment for it --so, disseminate clinical guidelines and best practices.

One of the major challenges we found was what was the information we were going to disseminate because there is not actually solidified understanding and agreement in terms of what it is should be done to treat these individuals. There is a great deal of information about diagnosing them at this point in time but treatment remains highly controversial.

So, we had to figure out what it is we were going to make available to the clinician. And, at this time -- given the controversies in the field -- that the best source of treatment guidelines for ME/CSF is expert opinion of clinicians with long experience in treating patients struggling with this disease.

That didn't work. How do I go back? There we go. So, we've got 13 recommendations to address these challenges and we grouped them into essentially four large categories -- content of educational materials, dissemination strategies, facilitation of educational efforts with HHS and further recommendations. Gustavo, as a point of order, do you want me to just go through all of the recommendations and then you can come back and vote on them or do you discussion on them as we go along?

Gustavo Seinos: We just want your presentation because after lunch, then we are going to come back and go over each of the recommendations, remembering these are not -- these are work group recommendations to the committee. The committee eventually will vote on them after lunch.

Gary Kaplan: Perfect. So, you should have in your packets of all of this information and you should have references to everything within the packet as well.

So, the first thing was regarding content of medical materials. CFSAC recognizes that treatment of patients with ME/CSF needs to be personalized and that ME/CSF treatment is an evolution. Given the urgency of the unmet healthcare needs of patients with ME/CSF CFSAC recommends dissemination by the HHS of the treatment recommendations in the 2014 International Association for CFF/ME Adult Primer and in the 2017 ME/CSF Pediatric Primer by the same organization.

CFSAC also recommends that CDC continue to move forward with the June 2017 CFSAC recommendations to create a plan for developing a clinical practice guideline for use by primary care clinicians. These treatment guidelines need to fulfill evidence based standards such as grade, as applicable and/or IOM standards for developing trustworthy clinical practice guidelines and need to be developed in a collaborative and transparent manner. And collaborative I would suggest also needs to include the community.

Dissemination strategies -- with regard to dissemination of educational materials to clinicians and the general public, we propose that CFSAC adopt the following recommendations:

CFSAC recommends that all educational material disseminated by HHS, the VA, Department of Defense, or healthcare providers and for the general public be informed by the findings of the IOM and the International Association CFF/ME 2014 Adult Primer and Pediatric Primer - and the 2017 Pediatric Primer.

Since it is crucial that terminology, diagnosis and treatment recommendations for ME/CSF be consistent across all federal agencies CFSAC recommends that all outdated federal websites or outdated materials provided by federal agencies be removed or updated as quickly as possible, and by no later than the end of 2018. One example of this was the content provided by the CDC. The med ed portal needs to be updated to align with these standards.

CFSAC further recommends that the materials provided by HHS, VA and DOD are to be regularly reviewed and updated as warranted by the research and consensus expert opinion. Given the shortage of qualified healthcare providers with expertise in the treatment of ME/CSF CFSAC recommends that the agencies within HHS:

first, provide funding for ME/CSF Project Echo program

second, provide funding for CME/CE training conference programs on any CFS led by experts for physicians, nurse practitioners, physician assistants, nurses, social workers, psychologists and psychiatrists.

Continued school health and pediatric ME/CFS educational initiatives as recommended in the January 2017 In Person CFSAC meeting.

Continue outreach to professional medical societies, internet medical provider information websites, such as UpToDate and internet public medical websites, such as Mayo Clinic and Healthwise, to inform them of the new information on the CDC and other federal agency websites.

With regards to facilitation of educational efforts within HHS, CFSAC recommends that all materials published or distributed by HHS take special care to address negative provider attitudes and disease stigma -- such as by using a standard description of the biological multi-system nature of the disease, relying on the IOM report, IA CSF/ME Adult Primer and Pediatric Primers -- stating explicitly that individuals with ME/CSF are neither malingering nor seeking secondary gain but suffering with a chronic disabling biological disease.

CFSAC recommends that AHRQ work with the authors -- this is worded poorly but let me fix it for you. So CFSAC recommends that AHRQ work with the authors of the 2016 Addendum to the 2014 ME/CSF AHRQ Evidence Review to get notice of the Addendum published in the Annals of Internal Medicine. Put a period there. Scrap the rest of the sentence and then it makes sense.

CFSAC endorses the IAF CFS/ME's proposals for changes to the ICD9-10 CM coding for ME/CSF. Again, that's referenced for you, so you can see what's all - what all that represents.

CFSAC recommends that federal agencies' coordination be enhanced by creating an overall inter-agency plan to act on these recommendations.

Two, convening monthly inter-agency conference call to report and discuss progress on the plan.

Three, providing targeted agency updates on activities related to the plan of CFSAC meetings for at least the next two years.

Further, it was the recommendation of our committee that CFSAC create a standing committee to maintain a list of all ideas relating to medical education, including the recommendations of federal agencies above, but also ideas for private state level activities and review this list and action item at each CFSAC meeting for at least the next two years.

There was an incredible grid of information that I believe (Sharmane) and (Beth) and (Robin) put together that is included as part of the references here that is the beginnings of that outline of the recommendations that people have made. It's about institutional memory and keeping track of what recommendations have been made -- what has been fulfilled.

What we attempted to address here is that we have a Tower of Babel within the medical community at this point in time with regards to ME/CSF. We do not have standardization. We are beginning to have standardization of terminology but even that's somewhat debatable. We don't have standardization of diagnostic codes. We do not have any legitimate agreement on how to go about treating this disease. Okay. And, so, and we've got information. We've got PACE trial. We've got all this information all over the place, which is highly controversial and, in many ways, has been really derogatory toward individuals struggling with ME/CSF.

And, so what we attempted to address was the beginnings of realigning all of the information that at least the government is putting out to try and having us all be on one page -- all signing the same note -- so we are getting out a consistent piece of information to every single healthcare provider in this country -- and, so that begin to bring some sanity to the field as a whole. This was - we went perhaps a bit beyond our scope with regards to the education committee but it's also a big problem that needs to be addressed.

And, so, we are hoping that you'll find these recommendations useful and we're hoping that you will pass them.

Syretta Evans: Questions? (Cindy).

(Cindy Bennon): These are excellent recommendations. I thank the committee. This is a crisis in our country and in the field. You may see a map that has a few centers -- but by and large even in Utah where I've been practicing for all these decades -- the stereotypes and the biases and attitudes persist and we really - really need to come together to change this and I think this report is a very good start. I just wanted to say that the appendices here - I don't have the appendices in my binder and in talking about ICD9 codes really...

Gustavo Seinos: They were sent to you. We received them. By the time of printing, we received them after the fact so they were emailed to all the members.

(Cindy Bennon): All right. I'll check on that.

Gustavo Seinos: But we received the most important thing from Dr. Kaplan which is the actual presentation with the recommendations. And, remember these are recommendations from the Work Group. You guys have to vote on them. After lunch, we'll discuss them. And, we already have them in a Word document so I learned how you guys worked. We have it in a Word document that we can make changes and addition or anything you want to do.

Syreeta Evans: Let's discuss the process for a little bit. Typically, what we do it after lunch we will literally put the recommendations up there -- one by one -- and then we will Wordsmith them and then we will vote on them, okay, and have discussion about them. So, during lunch if you have the time -- take some time and look at these recommendations and think about how they are worded and if they're doable and we can go from there. We have about an hour to do that and that's a pretty tall order to go through all of Gary's recommendations.

Gary Kaplan: The committee's recommendations.

Syreeta Evans: Questions?

Gustavo Seinos: So, we can start earlier.

Syreeta Evans: Yes. We're going to break early for lunch.

Gustavo Seinos: Yes. It's 12:20. Let's start at 1:20.

Syreeta Evans: Let's start at 1:20 because I want to make sure we get this done by 2:30 before public comments. Thank you.

Gustavo Seinos: And, you are welcome to have lunch in the cafeteria which is down the hall to the right or we have the Office on Women's Health Conference Room downstairs if you want to go down there and have lunch or you can have lunch here.

Coordinator: ...will have music in your main conference until your conference resumes. Thank you.

Gustavo Seinos: I'm going to go over there and change them. We are going to take turns. Hello. Can you please take your seats? One second.

So, we typed the recommendations beforehand. They are up on the screen. Syreeta and I are going to take turns sitting this computer editing them. So, you guys go ahead and start discussion.

Syreeta Evans: Gary, you all set?

Gary Kaplan: (Unintelligible)/

Syreeta Evans: Can you see them now?

Gary Kaplan: Okay.

(Beth): It just seems to me B and C are really part of the same thought. I think they need to go together rather than be separate.

Syreeta Evans: Can you scroll down so we can see C and D.

(Beth): B and C.

Syreeta Evans: Oh, B and C.

(Beth): Yes.

Gary Kaplan: I'm editing this inappropriately here.

Syreeta Evans: Got you. Okay. So, are we going to go one at a time? Okay.

So, Letter A: CFSAC recognizes that treatment of patients with ME/CFS needs to be personalized and that any CFS treatment is in evolution. Given the urgency of the unmet healthcare needs of patients with ME/CFS CFSAC recommends the dissemination by the HHS of the treatment recommendations in the 2014 IA CFS/ME Adult Primer and in the 2017 ME/CFS Pediatric Primer. All right. Discussion on this recommendation.

Well, that's easy. Everybody good? Everybody's good. Want to vote on them one at a time? See, I think so too. Let's vote on them one at a time. Do I need to take a role call Gustavo or can we just do all? All the members are here. Right, so it would be five.

Okay, all in favor of Recommendation Number One, say aye.

Group: Aye.

Syreeta Evans: I need any opposed. Motion passes. So Recommendation One A is approved.

Recommendation One B. And, I'm going to give them time to type in the changes. Okay. One B CFSAC also recommends that the CDC continue to move forward with the June 2017 CFSAC recommendation to create a plan for developing clinical practice guidelines for use by primary care clinicians. Discussion. Donna.

Donna Pearson: Donna Pearson. I would agree with (Beth) that B and C could probably be combined into one paragraph.

Syreeta Evans: Let me read C and then let's figure out how we are going to do that. Or, Gary, comment?

Gary Kaplan: So (Ted) actually had brought something very early on in our conversations and reminded me of them and then it got dropped. But one of the things he wanted to put in was guidelines should be at two levels -- one for the standard care of patients with ME/CSF and one for more advanced care for those who fail to respond to standard care. So, he's talking about creating levels of CME for the primary care doc people who recognize it and may treat it basically and then for specialty care.

Syreeta Evans: Okay. How do you want to change the recommendation for B and C.

Gary Kaplan: I'm working on that.

Syreeta Evans: (Cindy)?

(Cindy Bennon): Can we just add and specialty providers?

Syreeta Evans: What do you want to add that to?

(Cindy Bennon): After primary care clinicians, so -- developing clinical practice guidelines for use by primary care clinicians and specialty providers.

Syreeta Evans: (Beth)?

(Beth): I think, given the scope of work we are going to be hard pressed to get to the primary care physicians. I'm just saying, practically speaking, the scope of what is available to be considered, I don't know that we'll get there. I mean you can recommend it, but I think we would be better focused on where, what the original recommendation was and how we're moving forward.

Syreeta Evans: (Cindy Bennon):

(Cindy Bennon): I think that the process that will be needed to develop clinical guidelines is going to be, support with the evidence base and that ends up being the arena of specialty physicians. So, in my experience -- the last about 18 months -- I've had many opportunities to present CME and talk to specialists and they are very - very open to these guidelines and to the science so I just, I think, if, you know, limiting it to primary care physicians may not serve the purpose we want and so, CMEs are kind of different than official treatment guidelines to get through all the whole process, and I'm just telling you what I feel where we're at. We'll come back with what we can propose that we think we can do but we've been focusing on basic, you know, primary physicians.

Syreeta Evans: Other input? Other discussion? Gary, go ahead. I'm sorry.

Drew Helmer: This is Drew Helmer. You know, we have an analogous situation in the VA where we're finding that we really need to raise awareness among all providers, and primary care providers in particular -- but that sometimes there is a need for specialized interventions. So, I guess I would support the idea of the guideline trying to meet both of those needs because they really are part of the same evidence base and just because one type of provider is doing one portion of that and another type is doing another portion -- I understand the concerns about, you know, the workload and the complexity of it -- but, I think, it can probably be incorporated.

Syreeta Evans: Gary?

Gary Kaplan: So, in honoring (Ted)'s recommendation, I, so in Two B of creating and developing clinical practice guidelines for use by primary care physicians and specialists. I think if - I hear (Beth)'s concern but I don't want to dilute out what we are recommending. At the same, I think there needs to be an acknowledgement of levels of CME development and that we need to be able to address, not just those who are needing to recognize the disease when they see it, but those who are going to be treating it for extended periods of time and those who are actually specialists in it. And having the HHS support, excuse me, support different levels of CME, I think, would be a useful thing to put into our recommendation and it can be done again simply by saying for use by primary care clinicians and specialists in the field.

Syreeta Evans: (Beth):

(Beth): Okay. You keep saying CME which is continuing medical education which is different that treatment guidelines which what this is about. And, yes, I believe continuing medical education could be developed by experts that deal with ME/CFS patients on a regular basis and could be specialized -- directed toward specialists. I just think the treatment guidelines -- given the body of evidence and the literature that's there -- it's going to be very challenging. Certainly.

Syreeta Evans: It seems like CMEs is a different recommendation.

Gary Kaplan: It is a different recommendation

Syreeta Evans: Okay. That's what I thought.

Gary Kaplan: Yes.

Syreeta Evans: So, CMEs is a different recommendation. I'm also concerned if (Beth) is stating that there is considerable work to be done with primary care clinicians and that has to be done first, and then adding, you want to add specialists to it, as well. What?

Gary Kaplan: Yes.

Syreeta Evans: Okay. Is that doable? Is that a doable recommendation? That is my concern. (Beth) or Ermias?

Ermias Belay: A primary care clinician is not just for giving medication and treatment. It starts with recognizing the condition, overall management of the patient. Based on the IOM recommendation, how do they go about identifying the condition in the patient and how do they manage the patients as a follow up? So, it's again, and it continues from the IOM recommendation of how primary care clinicians or physicians would work up the patient and identify the condition and how do they manage it would be addressed in the treatment guideline.

Syreeta Evans: (Cindy Bennon):

(Cindy Bennon): What about a compromise and just take the word primary care out so that we have a little bit more of an open slate there for use by clinicians? Because, honestly, it's kind of an artificial distinction to divide primary care from specialists and, I think, we need to be forward thinking because by the time we have these recommendations, you know, if they are watered down and simple, they're not going to be very useful. And, if we leave the door open to include whatever we can during the process, I think we will end up with a better product at the end.

Syreeta Evans: Does that work:

Ermias Belay: That may be a good compromise.

Syreeta Evans: Okay. So the compromise is going to be take out primary care?

Terri Wilder: I keep raising my hand.

Syreeta Evans: Oh, I'm sorry. Go ahead Terri.

Terri Wilder: This is Terri Wilder. So, I work in the field of clinical education and distributing practice guidelines and the world is concerned about primary care clinicians because the whole model of healthcare is moving toward, like, primary care clinicians should be handling lots of things, not just cold. And, I just, I think the reason why there, it is in there is because of what this gentleman just said -- is that, you know, probably more times than not, we all presented to our primary care clinician who then couldn't figure out what the heck was going on with us. And, then it took forever and ever, -- sometimes years -- to find any specialists and then if there's only, you know, a dozen of them in the country, you know, you're lucky if you happen to live in a state with someone. So, I think the idea is that, you know, we are also building capacity for clinicians here and if people are going to be presenting to primary care clinicians, we want these practice guidelines to be distributed to them and used by them and spoken in their language -- that, like, you can recognize these symptoms. You can put this on your differential. You can know what to do with people that have these symptoms. So, I mean, I am, I would be very -very disappointed if we took out primary care.

Syreeta Evans: Alisa..

Alisa Koch: So, as a physician, I disagree because, for instance, many people where I live too in New York -- they don't have a primary care physician. They go see, I know, and exactly, but many people will go see an internist, for instance. Wouldn't you want them -- in other words, I think is inclusive, rather than exclusionary. In other words, will the primary care doctors not see this because we get rid of the words primary care?

Terri Wilder: I'm just telling you that it's been my experience that this is, keep peace -- and I live in New York state and that is the model in New York state is that we're trying to get primary care clinicians to understand practice guidelines and have them directed to them in their language.

Alisa Koch: And can hospitalists? A lot of people present and go to the hospital. They wouldn't see these, you know, if we make it too specific.

Terri Wilder: But, we just said we would add specialists.

Syreeta Evans: No. They're, the compromise is to get rid of primary care and just put for use by clinicians because they thought it was too narrow. (Cindy)?

(Cindy Bennon): I have another compromise. What if we said for use by clinicians with a focus on primary care.

Terri Wilder: I would be comfortable with that. Thank you.

Syreeta Evans: Yes. (Gary)?

Gary Kaplan: (Unintelligible).

Syreeta Evans: (Cindy)?

(Cindy Bennon): (Unintelligible).

Syreeta Evans: (Beth)?

(Beth): (Unintelligible).

Syreeta Evans: And Ermias?

Ermias Belay: Yes.

Syreeta Evans: Alisa?

Alisa Koch: I would like to first compromise better because I still think that excludes people. I think people will skip over it if they don't have a focus on primary care and I would rather more people know about this than less people.

Syreeta Evans: Let's take a vote. (Cindy) What was the last recommendation so he can?

(Cindy Bennon): My first recommendation was as it's written up there and my second compromise was to use, like, clinicians with a focus on primary care providers or an emphasis on.

Syreeta Evans: Gustavo?

Syreeta Evans: ..... with an emphasis on primary care?

(Cindy Bennon): Primary care providers.

Syreeta Evans: Don't worry. We are not going to worry your spelling Gustavo.

Gustavo Seinos: Can you clarify that statement?

Syreeta Evans: So, for use by clinicians with an emphasis on primary care.

Gustavo Seinos: Do the clinicians - is it for clinicians who are specialists in primary care or are we saying the guidelines will be written for all clinicians, however, we will emphasize some aspects of the guidelines for primary care clinicians? That's two different possibilities.

Syreeta Evans: They are two different things. So, what are you thinking? What is the group thinking?

(Cindy Bennon): Welcome Wordsmithing.

Syreeta Evans: Go for it.

(Cindy Bennon): What did I mean? I just mean that we, I think what I'm hearing from (Beth) is that the target audience is primarily going to be primary care providers and so, I would like to figure out a way to say it that the primary recipients of these guidelines are primary care providers but I, we need to do something to keep it more open for all of the above reasons and.

Syreeta Evans: So, if Gustavo puts at the end of that primary care providers for use by clinicians with an emphasis on primary or for primary care providers.

(Cindy Bennon): How about an initial emphasis on primary care practice?

Syreeta Evans: So we word it that.

(Beth Collins-Sharp):I'm sorry, (Debbie). This is Beth Collins-Sharp from AHRQ. I was just thinking about AHRQ. I used to be there. I'm from HHS. What I was thinking is that CDC will require a lot of time to develop these initial guidelines and so that if there could be an initial focus on primary care, that doesn't preclude somebody else from taking it and then focusing it on somewhere else and that's what I was thinking -- starting with -- initiated with whatever.

Syreeta Evans: (Keith)?

(Keith): I don't really want to weigh in on whether or not primary care should be there but do a lot a patients with CFS who go and see a patient and get referred to a rheumatologist, a neurologist and they may limit neurology, rheumatology, infectious disease from getting the guidelines or at least paying attention to them if you limit it to just primary care.

Syreeta Evans: Gary?

Gary Kaplan: We add on guidelines should be at two levels:

One for the standard of care -- patients with ME/CSF and one for more advanced care for those who fail to respond to standard care.

So, in C you will put it in -- first we leave the CDC along with the primary care physicians and in the second part, we're suggesting a little bit expansion of the that in addition to the primary care physician.

So, the whole point of (Ted)'s comments are to understand that we need some form of graded guidelines so that people, you know, there's a limit that the primary care docs can manage and then there's treatment guideline for the people who are going to specialize in this. And, being able to disseminate is really kind of two different pieces of information that go out. If we leave B alone and put - add this to C I think it -- C looks a bit more toward the future anyway.

Syreeta Evans: Okay. So, go back to B and B would then state what it did before, -- clinical guidelines for use by primary care clinicians -- which is what it originally stated. And then at the end of C you want to put what?

Gary Kaplan: Guidelines should be at two levels -- one for standard of care of patients with ME/CSF and one for more advanced care for those who fail to respond to standard card.

Syreeta Evans: Okay. Does that help (Beth)?

(Beth): It doesn't help me because I don't know what standard care is and I don't know what failure to respond -- what advanced methods are out there. I mean, I don't know of any advanced methods. I mean, I've talked to lot of clinicians that try a lot of things. It's very individualized. I don't know that there is a standard, so I understand that, you know, we don't know enough. I think these are, if we achieve these recommendations as they are -- it would be momentous. And there's always going to be a need for more and they need to be refined and I think as the people that will be making this -- and by the way CDC is making the plan. We can't -- it can't be just our plan. I just had to say that. But as the experts are convened through a very transparent and open dialogue, the issues of what kinds of levels of care, I think, will naturally come up. And, I do think there is increasingly a recognition that patients that are at one level of functioning -- you can't - one size does not fit all. You can't recommend the same thing for people that are completely bed-bound, as you do for somebody who can move a little bit. So, that should come out in these guidelines.

Syreeta Evans: So, B right now says: clinical practice guidelines for use by clinicians with an emphasis on primary care. I would add the word providers. The only other - which -- let's take a vote and see what the vote is. Leah?

Leah Williams: My only comment is that with an emphasis on primary care providers is a dangling modifier so it's not clear if that's about the clinicians.

Syreeta Evans: Yes. My English. Yes. Okay. Leah, so, put it in correct grammar for us please.

Leah Williams: I don't have a vote, but I personally would go back to the original primary care clinicians because I feel like it's most important to educate them.

Syreeta Evans: Should we take a vote? We have how many recommendations, Gary?

Gary Kaplan: I can add.

Syreeta Evans: Right. And, it's quarter to two, so I want to move forward and see where we are at with this. So. Do you want me to leave it the way it is?

(Donna): This is (Donna). I will make one other suggestion.

Syreeta Evans: Go ahead (Donna).

(Donna): For use by clinicians with an emphasis on guidelines to be used by primary care providers.

Syreeta Evans: Say that again.

(Donna): For use by clinicians with an emphasis on specific guidelines to be used by primary care providers or something like that. If it doesn't help, forget it.

Syreeta Evans: (Ted).

(Ted): I'm taking off my AHRQ hat and putting on my American Academy of Family Physicians hat. And the Academy has brought up -- and I think rightfully so -- that guidelines should be what guidelines -- not who guidelines. So, are you saying that a guideline written for primary care doesn't apply to a rheumatologist whose taking care of the same patient? That doesn't make sense. So, if we are going down this path, it might be better to just say recommendation to create a plan for development clinical practice guidelines for ME/CSF.

Syreeta Evans: Period.

(Ted): And, that then allows for the complexity that (Beth) was just talking about. It all comes out and we're micro-managing what CDC is trying to do. It might be better to just drop the last part of the sentence.

Syreeta Evans: Can everyone live with that? Okay, so.

(Cindy Bennon): Or can we put something in there about with, I mean, I know, this is not dissemination. We have another section about that but, like, can there be something that talks about, like, with a specific dissemination plan?

Syreeta Evans: When we get to dissemination, let's go there.

(Cindy Bennon): Okay. But it's part of this recommendation, so.

Syreeta Evans: (Beth).

(Beth): Well, I mean, the recommendation is that CDC moves forward with a plan and the plan will have to include -- and I've been advised by this -- not only, you know, refining how the guidelines are written and the primary target audience for the guidelines. If you pull up, like, the opiod guideline, MMWR, it's really lines out in detail so that we will, and we'll come back to agencies and, I think, there will be time to be sure that we're framing the questions correctly.

But, then secondarily, guidelines, CDC does not move forward with guidelines -- I've been also advised -- without coming up with a dissemination plan and a communication plan as part of it, to be on it. So, I think that will be covered and there'll be time for CFSAC and everybody to comment on it. So, if this is the charge that CDC moves forward with a plan and I think, those elements are part of that plan and that's what we've been told that the CDC guideline process involves.

(Cindy Bennon): I'm just concerned that if we, you know, a year from now, try to remember what we said, and we didn't say we want the dissemination plan to include targeting -- specifically primary care providers -- and it's not written, we may all have memory lapse.

Syreeta Evans: Let's come back to that when we get to two. So, Letter B -- Recommendation to Complete a Plan for Developing Clinical Practice Guidelines for ME/CFS period. I'm going to do a roll call. Any further discussion?

(Cindy Bennon): You don't want to move C up into that?

Syreeta Evans: Oh, yes. Move C up into that. I'm sorry. ME/CFS period. Delete the rest of the sentence. Then take C. Yes. For use in ME/CFS. No. Wait, wait. For ME/CFS -- not use in. It's Practice Guidelines for ME/CFS. There we go. Then take C -- these treatment guidelines need to fulfill and just put it up there. It's not going to be separate. There we go. Perfect. Okay.

Okay. Voting - -yes or no. Alisa?

Alisa Koch: (Unintelligible).

Syreeta Evans: (Donna)?

(Donna): Yes.

Syreeta Evans: (Cindy Bennon):

(Cindy Bennon): (Unintelligible)

Syreeta Evans: Ermias?

Ermias Belay: (Unintelligible).

Syreeta Evans: A safe yes. All approved. Motion carries.

Dissemination Strategies Two A -- can you move that up please a little bit. I forgot the screen.

CFSAC recommends that all educational materials disseminated by the HHS, VA and DOD for healthcare providers and for the public be informed by the findings of the IOM, IA CFS/ME 2014 Adult Primer and the 2017 ME/CFS Pediatric Primer. Any discussion? (Cindy).

(Cindy Bennon): I would like to bring up that the literature review for the IOM report ended in the middle of 2014. So, most of what was presented at the Stanford ICFS conference had not reached publication status. Neurologic studies and most of the current studies on metabolomics and some of the other progress that's been made in the last few years, so I think, I would love to find everywhere that it's most applicable to add a statement that kind of implies that the high quality of literature since the IOM should be included and you would find that very consistent with the wishes of IOM report. That basically said it was preliminary and shouldn't be considered a gold standard as new research became evident.

Syreeta Evans: Comment, Gary?

Gary Kaplan: So, we recognize that there is ongoing development in the field and we needed a place to start. We've got our crisis going on. We needed some place to get information out quickly and so these were the sources that we identified as being able to in agreement with the community that's best practices at this time and we wanted to be able to say, "Okay. Here's our start point". If you read down, we're also calling that there be constant updating of this material and that it be done in a consensus and transparent manner. So, this is just the start. I don't want to dilute -- this one I actually want to fight for -- because I don't want to dilute this one down. Because this allows us -- out the starting gate tomorrow -- because we've already got stuff done and then we'll add on as we need to.

Syreeta Evans: Any other comments? All in favor, say aye.

Gustavo Seinos: I have a comment.

Syreeta Evans: Go ahead Gustavo.

Gustavo Seinos: The comment is that we -- HHS and us -- dictate either the VA and Drew Helmer in here, or let alone, DOD to do something outside, within our realm. We can share and encourage but at the moment we don't even have an official from the VA. I'm talking to some people and trying to bring.

Drew Helmer: Yes, you do.

Gustavo Seinos: I'm sorry - from DOD and trying to bring somebody -- hopefully by the next meeting in the Summer -- but at the moment, so the challenge is (unintelligible) and we have to recognize that. Remember when we discussed in June that we were not going to send forward recommendations that were not.

Syreeta Evans: Correct.

Gustavo Seinos: Hard to achieve.

Syreeta Evans: (Ted).

(Ted): We discussed this and this CFSAC can't even tell HHS what to do, you know. And we recognize.

Gustavo Seinos: I think you made the same comment before (Ted).

(Ted): Right. So, we, I said explicitly which is why it's a recommendation that it be disseminated and it's telling the VA and the DOD -- here is a recommendation and this is the rationale which are easily defensible. They can do what they want to do but for us to not take this opportunity, we think would be a lost opportunity.

Donna Pearson: I'm Donna Pearson. I'd just like to add although agreed that we would prefer to put forward things that are definitely possible, we don't want to preclude that from putting forward recommendations that we feel strongly about, that we think should be considered.

Syreeta Evans: Okay. Let's try it and let's see what happens. Okay? (Beth)? Right. We can make the recommendations that we want but we do need to be mindful that we make recommendations that are attainable because in the past history of this committee is that we've made recommendations that just simply can't be accomplished. So, let's see what we can do, and you have a good point (Ted) that it is a recommendation. Gary.

Gary Kaplan: It's a recommendation. We were hoping that HHS will take it to heart, but I think this also begins to address the problem of the Tower of Babel. We've got so much different information being put out by so many different agencies. We are saying guys, we need to come together. We need to get on the same page. We need to be unified. But that's the recommendation. It's certainly not a commandment. We can't do those. But it's a recommendation strongly to HHS which we do respond to but also saying we need to pull in all the branches of the government who are putting out information on this and have it as a unified piece of information.

Syreeta Evans: The recommendation stands as written. All in favor, say aye.

Group: Aye.

Syreeta Evans: Any opposed? The recommendation for Two A is approved.

Two B - Since it is crucial that the terminology, diagnosis and treatment recommendations for ME/CFS be consistent across all federal agencies, CFSAC recommends that all outdated federal websites or outdated material provided by federal agencies be removed or updated as quickly as possible and by no later than the end of 2018.

One example -- content provided by the CDC for the med ed portal needs to be updated to align with these standards. Comments? Discussion. (Beth).

(Beth): I just need to explain that the one CDC article on med ed portal is published and it's a published article. It's not something we can take down or modify. It was updated. It may not -- we are reviewing it, but we can't undo a publication which it essentially is.

Syreeta Evans: Thank you.

Ermias Belay: It's not on CDC's website.

Donna Pearson: I didn't understand that. What does that mean?

Ermias Belay: It's published on med ed portal.

Donna Pearson: Oh, it's published on med ed portal. Okay.

(Donnick): This is (Donnick) with a question from our CDC experts. So, if something becomes obsolete and I don't think this is completely obsolete but if something did, there must be a way to let that be known so that it's not continuing to circulate out there across the globe. So, what can be done so that we don't have old information out there because people are still using this old information, as I'm sure you know.

(Beth): Right. And, I, you know, we are looking at it but it's nothing that we can -- we may be able to publish new things. In fact, we do have some other things planned for the med ed portal. And, it was in preparation right at the time when IOM was coming out and it does reflect the IOM definition. So, we have, like, for example, it was pointed out that the CDC's tool kit was no longer on the website, but you could find it and we managed to track down how that happened, and it's now removed. So, things that CDC has, we can sometimes remove. We are usually advised to archive it or mark it out of date rather than remove it but we felt in this case, it was easier just to take it down since it wasn't a definitive publication. But there are lots of articles that are published that, you know, then are superseded by a new article and it's not -- it's just as new information comes. It's not that we go back and retract every single article that's been updated, so.

(Donnick): But if this is being used for medical education, it's like using a 20 year old text book or something.

(Beth): I don't. Right.

(Donnick): It's not effective.

(Beth): I believe that the current information in there is about communicating with patients. It's a combination. What's published is the second half of that and in combination, it uses the opportunity of communication and with patients and learning to listen with the - how to recognize ME/CFS. Okay. It does reflect the IOM and we are going to look at it again with any detailed -- if there's anything that's incorrect but we have looked at it through one time and, so, anyway, you can leave that in there but we can't take it down.

Gary Kaplan: Quick question. If we simply remove the example.

Syreeta Evans: That's what I was going to recommend.

Gary Kaplan: Yes. I don't believe it...

Syreeta Evans: I agree with you.

Gary Kaplan: recommendation at all and solves potential conflict.

Syreeta Evans: Yes. I would like to remove the example because that's. Okay. So, we know it can't be removed.

Gary Kaplan: The request was for it to be updated, so.

Syreeta Evans: Yes. By federal agencies be updated as quickly as possible. Can we change the recommendation? So, we take the example out, Gary, and we say by federal agencies to be updated as quickly as possible?

Gary Kaplan: Yes. You don't want by no later than, you don't want to give them a timeline?

Syreeta Evans: Yes. No. I want to leave the rest of it in there. I just wanted to take the word "removed" because (Beth) and Ermias said it can't be removed but can we put updated?

Gary Kaplan: Oh. I see what you're saying.

Group: ((Crosstalk))

Syreeta Evans: Oh. Okay. All right. Got you. Oh, it can be. All right. So, leave everything in there, except for the example?

Gary Kaplan: Yes.

Syreeta Evans: Okay. Everybody's good? Any other discussion? Gustavo?

Gustavo Seinos: (Unintelligible).

(Ted): Not one specifically for every CFS.

Drew Helmer: Right. We don't have anything that's specifically ME/CFS.

Syreeta Evans: So, do you want to?

(Cindy Bennon): Can I just, sorry, I don't think people can hear Gustavo.

Syreeta Evans: Gustavo what are you - yes - I either need to repeat what you are saying, or we need to put a mike over there for you.

Gustavo Seinos: What I'm saying is -- is that the only two agencies that I can think of that have a website addressing ME/CFS is the CDC and NIH. DOD and the VA does not, and the recommendation calls for all federal agencies.

Drew Helmer : Well, I will just say that if somebody found a website that specifically relates to ME/CFS and they pointed it out to us, we could try to comply with this recommendation, but I think this a recommendation to the Secretary of HHS and so, I -- in the spirit of inter-agency cooperation -- I think it's important that the VA be consistent. And, we could try to do that but I'm not aware of any ME/CFS website in the VA right now.

Syreeta Evans: (Mary).

(Mary): I could be wrong, but my understanding is that the VA

Syreeta Evans: Say (Mary Gibbons). Say your name.

(Mary): I could be wrong, but my understanding is the VA does have a website for chronic multi-symptom illness.

Drew Helmer: Yes.

(Mary): And ME/CFS is considered part of that disease and so those guidelines for how it's diagnosed and how it's treated are not consistent with what is on the CDC website, the IOM criteria or the field at this point.

Syreeta Evans: Thank you. So Gustavo, what do you want to do with that -- all federal agencies? Just leave it the way. (Cindy).

(Cindy Bennon): I would say that just leaving it the way it is leaves it open.

Gustavo Seinos: I agree.

(Cindy Bennon): In case they ever do get one.

Gustavo: In case they ever do get one.

Syreeta Evans: Okay. Any further discussion? All in favor, say aye.

Group: Aye.

Syreeta Evans: Any opposed? Two B is approved.

Two C -- CFSAC recommends that the materials provided by HHS, the VA and the DOD are to be regularly reviewed and updated as warranted by the research and consensus expert opinion. Did we already say this or no? No. That's not covered. Okay. (Gary), you want to comment?

Gary Kaplan: No. I think it's just talking about looking into the future and making sure there's updated. I think it's a pretty benign recommendation myself.

Syreeta Evans: Okay. Discussion? All in favor, say aye.

Group: Aye.

Syreeta Evans: Any opposed? The motion so passes. Recommendation C is approved.

Recommendation D -- Given the shortage of qualified healthcare professors - providers with expertise in the treatment of ME/CFS CFSAC recommends that the agencies within HHS, oh, here we go, okay. Scrolling down -- provide sufficient funding for ME/CFS Project Echo Extension for Community Health Outcomes programs. Okay. Good.

The second part of it is provide funding for CME - CE training conferences, programs on ME/CFS by experts from MD, DO,NP, PA, nurses, social workers, psychologists and psychiatrists. continue schoolhouse and pediatric ME/CFS educational initiatives as recommended in the January 12-13, 2017 in person staff CFSAC meeting, continue outreach to professional medical societies, internet medical

provider information websites. UpToDate is an example. And, internet provider medical websites, MayoClinic, Healthwise, to inform them of new information on the CDC and other federal agency websites. Discussion?

All in favor, say aye.

Group: Aye.

Syreeta Evans: Any opposed? Recommendation Two E is approved. Actually, it's Two D.

Recommendation Three -- Facilitation of Educational Efforts within HHS. CFSAC recommends that all materials published or distributed by HHS take special care to address negative provider attitudes and disease stigma, such as by using a standard description of the biological, multi-system nature of the disease relying on the IOM report 2015, the II CFS and the Adult Primer 2014 -- and we have a typo there -- and the ME/CFS Pediatric Primer 2017 and by stating explicitly that individuals with ME/CFS are neither malingering nor seeking secondary gain but suffering with a chronic disabling biological illness. Discussion. Leah.

Leah Williams: On that last statement, should we reverse it so that we say the positive first which is that they are suffering from a chronic disabling biological illness and then put the negative second? And they are not malingering nor seeking secondary gain?

Syreeta Evans: Yes. I would agree. Switch the order. So Gustavo will put stating explicitly that individuals with ME/CFS are suffering with a chronic disabling biological illness. Okay. Somebody add a word in there. Wordsmith it for me.

Leah Williams: And are not.

Syreeta Evans: And are not.

Leah Williams: Malingering.

Syreeta Evans: Nor seeking secondary gain. Thank you. Are not malingering. Delete the neither. You're doing a good job. Very good. Thank you. Seeking second gain period, and you can delete the but for the recommendation. Any discussion? All in favor, say aye. Oh, I'm sorry. Donna go ahead.

Donna Pearson: It's just a grammar thing. I think the nor should be an or.

Syreeta Evans: Is it a double negative?

Donna Pearson: Neither, nor and not or.

Syreeta Evans: Where are you? Are not malingering or seeking secondary gain. Okay. Right.

Leah Williams: As long as the not carries over. Right? You could say and are neither malingering nor seeking secondary gain. I just want to make sure that the negative stays with the seeking secondary gain. Right.

Gary Kaplan: The original had neither nor.

Leah Williams: I think we just go back to neither nor.

Syreeta Evans: Yes. You want to go back to neither nor?

Leah Williams: Neither malingering nor seeking secondary gain.

Syreeta Evans: Say that again, Leah.

Leah Williams: And are neither malingering nor seeking secondary gain. Change not to neither.

Syreeta Evans: Okay change not to neither

Leah Williams: I think it's neither.

Syreeta Evans: Here we go. We're good. Neither malingering nor seeking secondary gain. That's good. All in favor, say aye.

Group: Aye.

Syreeta Evans: Any opposed? The motion so passes. Three ayes approved.

Okay, the next one is now going to be Three B. Below. CFSAC recommends that's -- I don't know if they were numbered incorrectly or if I just missed it. Sorry.

Gary Kaplan: Gustavo you need to insert the number four and then the heading Further Recommendations right there.

Syreeta Evans: All right. Are we good now?

Okay. Four -- CFSAC recommends that AHRQ work with the authors of the 2016 Addendum to the 2014 ME/CFS AHRQ Evidence Review to get notice of the Addendum published in the Annals of Internal Medicine in June 2015 which contains the original article. It's Four A. Gary.

Gary Kaplan: My recommendation is to put a period after Annals of Internal Medicine and drop the rest of the sentence because otherwise it looks like we are trying to change the past.

Syreeta Evans: Okay. So, put a period after.

Gary Kaplan: Annals of Internal Medicine period.

Syreeta Evans: Okay. And, then delete the rest of it.

Gary Kaplan: Bag the rest of it. I don't think it contributes.

Syreeta Evans: Okay. (Ted).

(Ted): My AAFP hat is off. My AHRQ hat is back on. You can do what you want today but it's part of my report for tomorrow that this is a contract that no longer exists and AHRQ's ability to tell authors that they have no control over what do is somewhat limited. It was - it occurred to me this morning as I was thinking about it again. Again, this all pre-dates me, but there is another person we might be able to get involved and that is Cindy Mulrow who is - who was on the IOM panel. She cares about this. She's an editor at the Annals of Internal Medicine and perhaps I can call her up and say what can be done. But, I mean, so you could put this down. You can make that recommendation, but the recommendation has been made before. I've talked to the people who can make it happen -- who tried to make it happen and they've told me if the contract is over, we have limited ability to tell people what to do. And, so, you know, I hate to eliminate because we don't want to lose track of it, but I hate to have a recommendation that we can't do and I'm going to try when I get home tonight to email Cindy and see what she says about other options. So, that's sort of half my report from tomorrow but I don't know how that impacts how you want to deal with this recommendation today.

Syreeta Evans Gary.

Gary Kaplan: Okay. This is a new piece of information for me. So, it sounds like you can't work with the authors because you don't have any relationship with the authors, so the recommendation doesn't make any sense. Can we re-Wordsmith and recommend that AHRQ

Man: How about reach out to the authors?

Gary Kaplan: I'm sorry.

(Ted): You can't work with the authors.

Man: That AHRQ reach out to the authors or contact the authors?

(Ted): You really want, what you want is an addendum published in Annals of Internal Medicine. So, you can suggest that AHRQ - can you work with Annals?

Faith Newton: To seek publication?

(Ted): Yes, it would make sense to me -- and again -- I'm sort of a messenger but now I'm - I have the power. But the people who've tried this before have informed me that they've gone to the authors and it was unsuccessful.

So, to have the recommendation be the same thing that has failed in the past, doesn't make sense.

Gary Kaplan: Right.

(Ted): To recommend that Arc work to get the Notice…

Gary Kaplan: Okay.

(Ted): …we might succeed or fail but it allows me to think of other ways than going through the author. And I can work with (Cindy) and see what can be done.

Faith Newton: All right, so (Ted) re-word that so it works for you.

((Crosstalk))

(Ted): (Unintelligible) recommends that Arc work - and then just delete - with the authors of the 2016 Addendum -- let's see -- work to get the notice of the Addendum published in the Annals and the Addendum of the 2014 ME/CFS Arc Evidence Review. How's that?

I can…

Faith Newton: Slow down a little bit.

(Ted): Yes.

Faith Newton: …because (Gustavo's) got to get that.

(Ted): Take out - move 2014 ME/CFS Arc Evidence Review and then move that down to after Addendum.

Faith Newton: The Second Addendum, right? The Addendum published?

(Ted): Yes.

Faith Newton: Which Addendum?

(Ted): Oh my gosh - the Second Addendum.

Faith Newton: That's what I thought. Right there.

(Ted): And see - so, if you do that - so it recommends that Arc work with - and then get rid of the - with the authors of…

And so then - it's the Arc work to get the notice of the Addendum to the 2014 ME/CFS Arc Evidence Review published in the Annals of Internal Medicine. Does that - I think that's right.

Faith Newton: All right, wait a minute - look - to work to get the notice of the 2016 - what is it?

(Ted): Yes.

Gustavo Seinos: I just…

(Ted): To get the - well, there's two things I guess that's what - do we want -- in the Annals -- the 2016 Addendum published? Or, do we want in the Annals a notification that there is an Addendum?

Faith Newton: Gary?

(Ted): And the end refer - we'll reference to a web page where their Addendum is.

Gary Kaplan: Validate.

(Ted): Pardon me?

Gary Kaplan: Validate. (Unintelligible).

(Ted): So, work to get the - get rid of notice of… Yes, so - recommends that Arc work to get the 2016 Addendum…

Faith Newton: All right. So, let's get that part in first. To get the 2016 Addendum… All right.

(Ted): …of the 2014…

Faith Newton: Okay, so we start delete after that probably down to…

(Ted): Yes.

Gustavo Seinos: Delete.

Faith Newton: Okay. You have to delete all the way down to…

(Ted): Everything.

Faith Newton: …2014.

(Ted): Right.

Faith Newton: There now. Okay.

(Ted): So…

Faith Newton: Now is it okay?

Gustavo Seinos: Yes.

Faith Newton: (Ted)?

(Ted): Well, I will be very glad to take that as a recommendation -- obviously -- I will work to make that happen and see what I can do. I'll work with the editors.

Faith Newton: Any further discussion? Leah?

Leah Williams: It seems -- (Leah Williams) -- it seems to me you'll need the authors to participate if you want something published. No?

(Ted): I don't know. I mean they're a contractor of the government and so I don't know. I'm too new. I don't know if they work under contract - does it belong to them or does it belong to us?

((Crosstalk))

(Ted): I - that's part of what my recommendation is - is to find out and reports to you in triplicate tomorrow morning.

(Cindy Bennon): I could tell you now that it belongs to Arc…

Leah Williams: Okay.

(Cindy Bennon): …and so you can work towards having it published there. And another option is to have it indexed in (PubMed) - so that it can be found in searches as a second opportunity.

Gary Kaplan: Annals. I'll just be first off…

Faith Newton: All right. Any further discussion? All approved say aye. Any opposed? The motion is approved - 4A. Yes -- I know -- we're getting there - 4B. (SESAC) endorses the IACFS ME proposal for changes to the ICD 10CM coding for ME/CFS.

(SESAC) recommends that the federal agency coordination be enhanced. Okay - a System 1. That's another record. That's 4-something. That's 4C, right? Okay.

So, we're just going to do 4B. So, Gustavo I'm just doing 4B. The next little bullet is actually 4C. Any discussion on 4B? (Cindy)?

(Cindy Bennon): This is what we got later - it wasn't originally in our packets and everybody should have a copy of it. I've had a chance to breeze through it and think it's carefully thought out and much needed. So, it would be my input to accept it - to (leave) this in.

Faith Newton: Yes. Any other discussion? All in favor say aye. Aye. Any opposed? The motion is approved - 4B.

4C (SESAC) recommends that the federal agency coordination be enhanced by - first creating an overall interagency plan to act on these recommendations. B convening monthly interagency conference calls to report and discuss progress on the plan.

Third part of it is providing targeted agency updates on activities related to the plan at (SESAC) meetings for at least the next two years.

Yes, I would to hear from the ex-officios and unfortunately (Vicki's) not here. Is this even doable? (Beth)?

(Beth): Yes. I - It might be better to wait until (Vicki's) here to discuss it if we could possibly delay it until then.

Faith Newton: Yes.

(Beth): You won't have time tomorrow?

Faith Newton: We will.

(Beth): Yes.

Faith Newton: Yes. Is everybody okay with waiting until (Vicki's) here tomorrow - because she's obviously going to play a role in this she's with (MENS) and IH?

Okay, so let's table this recommendation until tomorrow when (Vicki) is here. And we can discuss this after her presentation? At 4?

Gustavo Seinos: Four.

Faith Newton: Okay. We'll discuss it - are you here? Okay, we'll have to have a conversation to make sure everybody's here as to when we're going to discuss this. I'll work that out later because I want everybody on this conversation.

The next one. Is it D? Thank you. Wait, the one that we're discussing tomorrow is D or is that C? Okay. So, the next one is D - 4D it is recommended? Okay.

So Gustavo your one below that is 4D. Let's see. Does that one have to - is that the last one? It's the last one.

Gustavo Seinos: The last one and they're unrelated, so…

Faith Newton: They are re…

Gustavo Seinos: They're unrelated.

Faith Newton: They're unrelated. So, 4D let's read this. It is the recommendation of the Medical Education Working Group that (SESAC) create a standing committee to maintain a list of all ideas related to medical education including the recommendations for federal agencies above - but also ideas for private or state level activities and review the list and action items on each (SESAC) meeting for at least two years.

So, this would-be part of the Medical Education Working Group. Part of… (Barry)?

(Barry): Well we - not necessarily the standard Medical Education -- although it could be called that - whatever -- but it's about maintaining institutional memory. It's about keeping track of what these recommendations are -- and making sure they're updated -- and seeing which ones are being implemented and which ones are not being implemented.

And too often what happens is a lot of things get discussed at the meetings and disappear. This is a way of keeping institutional memory going by having a standing unit that will report -- on a regular basis -- as to any changes.

Faith Newton: Okay. You will…

Gustavo Seinos: Who will report? A working group - to the committee?

(Barry): A working group to the…

Gustavo Seinos: Okay.

(Barry): This is - and this is within (SESAC) - this is not outside of (SESAC).

Faith Newton: Okay let me address this. You weren't here at the beginning of the meeting. What I did this morning is that I took the recommendations from January and from June and I did an update on all the recommendations.

So, that's going to be standard procedure from now on. So, we will take the recommendations from this meeting -- the December meeting -- as well as what's left over from June and we will have what the recommendation was and then what the update is.

I think that's something that we need to continue to do -- specifically for what you're saying -- because we do need that institutional memory.

Okay. And that should be part of standard practice. Does that satisfy everybody and didn't - and is what I did this morning do that?

(Ted): So, I think the question is -- to the working group members -- do you think Faith can possibly keep up with everything that - I heard all the conversations of the working group members and it was quite intensive.

Faith Newton: So, you want the working group to keep up with it - not the…?

(Ted): I guess my question is - how much work can you do Faith?

Faith Newton: It's not that - it's that those are the recommendations that have been made on (SESAC). Okay? So - and it's really isn't -- quite frankly -- my role or whosever in this role, but that - those recommendations do need to be updated at every (SESAC) meeting at the start.

And that should be standard procedure. (Charmian)? I don't know. I can't even see that. Somebody passed this spreadsheet out and I have glasses that…

((Crosstalk))

(Charmian Proskauer): This is a little bit different from what you're saying Faith. I agree that what you did this morning was great and we should do that. This is beyond that.

Faith Newton: So, what are you saying?

(Charmian Proskauer): Because this list -- that we have - which is on the spreadsheet -- is a very comprehensive list and it's a work-in-progress so things can be added over time as good ideas come up for what could be done to improve medical education on ME/CFS.

Those could be added to the list -- as long as someone is maintaining it and reviewing it -- it wouldn't necessarily only include things that the federal agencies do - that's not the intention.

But it's -- for example -- the kind of thing that Terri talked about this morning with a letter on ME/CFS being distributed by the Department of Health in New York.

That sort of thing would be included on the list and if we're reviewing it -- periodically at every meeting -- it gives us a chance to bring those ideas forward - discuss them - and make sure that everybody knows about them and hopefully we can replicate things like that.

((Crosstalk))

(Charmian Proskauer): So, it's a much more comprehensive approach.

Faith Newton: Thank you. Comments or discussions from folks at the table? Okay. Any further discussion on this recommendation? All in - again? (Beth)? Oh, sorry. (Charmian)? Last name? Pronounce it correctly for me please.

(Charmian Proskauer): (Proskauer) P R O S K A U E R.

Faith Newton: Thank you. And the first name is spelled C H A R M I A N.

Donna Pearson: Faith?

Faith Newton: Donna?

Donna Pearson: Donna Pearson, I just want to make sure that we clarify -- for whomever signs up to serve on this Committee -- what a working group can do and what a working group cannot do.

Because some of the things on the list - reach out to me - push in major newspapers or some other different ideas - which individual people might want to do - cannot be done on behalf of the (SESAC).

So, it'll be important for you all to review the list -- with the working group -- and make sure that they're doing things that they can do - bringing them to the right places and then doing other things as individuals or as organizations.

Faith Newton: Well, one of the things we're having this afternoon is an ethics training this afternoon for all members and I think that'll clarify some of the things that we can and can't do. (Unintelligible). Donna?

Donna Pearson: This list was not that the work groups would do it but just as a way to not lose good ideas and to trigger other people to think about it -- so again -- not to - make sure that we're capitalizing on each other's progress.

Faith Newton: All right. All in favor…

((Crosstalk))

Faith Newton: All in favor say aye. Aye. Any opposed? This recommendation is approved. Let me apologize. I should have probably taken this recommendation -- delayed it -- because we're behind now and we were supposed to have public comments starting now.

And we also have not had a break. So, let me ask Gustavo what he would like to do.

Gustavo Seinos: No. We have to go on this public comments because these people are - waiting to speak. So, I'm not sure - how do we bring the Operator on?

Coordinator: (Unintelligible) this is the Operator.

Gustavo Seinos: Hi. We're ready to do public comments and we can start with (Denise Lopez Mahana).

Coordinator: Okay. One moment. (Unintelligible) Miss (Mahana) your line is now open for public comment.

(Denise Lopez Mahana): Good afternoon. Welcome to the new (SESAC) members. Both of my children (unintelligible) got so sick - so young. They were 12 and 13 years old. They are house bound, partially bedbound because of ME.

They are so disabled by ME that they cannot cook, clean, et cetera. They are so disabled by ME that they have not been able to finish school - learn to drive - have a job.

They are so disabled by ME that they do not have the capacity -- or skills needed -- to live independently. Recently, I couldn't leave the house for four consecutive days because of the severity of their symptoms. I am their sole 24/7 caregiver.

I do so willingly because I love my sons but at their age my sons should be living their own lives - instead -- because of ME -- I have been their full-time caregiver for nearly 13 years.

In that time, I have seen very, very little progress regarding this disease. There is no sense of urgency to help my sons and all patients who cannot live independently.

Who will care for my sons when I can no longer do so? Who will advocate on their behalf - arrange and take them to appointments? Detail what's transpired since the last one?

Take notes - follow up on changes - sort meds - be alert to side-effects - care for them during day and the night episodes that happen without warning? Check bills for accuracy and pay them? Insur - do comparative research for large purchases -- like a mattress -- insure sufficiently stimulating interesting environments?

Arrange for home maintenance during their functional hours? Deal with insurance companies - compare insurance policies for best affordable coverage? Deal with utility companies? Keep them in touch with the world?

Who will cook - clean - sort - do - put away laundry - change sheets - rotate mattresses - load, unload the dishwasher? Who will do all this and more as I do now?

I ask because given the lack of urgency for patients' lives - these things will have to continue to be done even after I die. The medical community and social services agencies are woefully uninformed about ME and its horrifying impact.

This leaves patients very vulnerable and unsupported. That's not good enough for my sons or any other patient with ME. CDC has done nothing to eradicate the stigma patients and caregivers face on a daily basis.

The number of clinicians qualified to appropriately diagnose and manage this disease is appallingly low. Health care professionals are not provided accurate information about this disease.

The number of researchers studying ME is miniscule. Research funding for this disease has been horribly inadequate for decades. Research criteria for this disease is also embarrassingly inadequate.

(NIH) -- and others -- have said for years that a research case definition needs the consensus of ME specialists. When we ask why the same level of scrutiny the (NIH) clinical study is employing - they characterize the patients (via) the (CCC) plus adjudication of patients by ME specialists.

Why that same level of scrutiny isn't required for all studies - we're told there isn't enough known about the disease for a research case definition. None of this is good enough for my sons or any patients with ME.

What does good enough look like? Full and ongoing involvement of every applicable government agency and ME stakeholders in all projects - appropriate social services support for patients and caregivers - a wide spread well-funded sustained program to eradicate stigma and misinformation surrounding this disease.

Intensive - widespread - appropriately funded work to ensure that all healthcare providers are knowledgeable about this disease. Concerted ongoing fully funded efforts to bring researchers to this field.

Sustained research and center funding commensurate with the burden of this horrible disease. Promptly convening a fully funded project that brings together international specialists to reach consensus on any research criteria and their proper operationalization.

Starting right now let's make things good enough for my sons and all patients with ME. Thank you.

Faith Newton: Thank you (Denise) for your comments.

Gustavo Seinos: All right the next speaker will be (Christina Ohsolvac). Operator can you open her line?

Coordinator: Miss (Ohsolvac) your line is now open.

(Christina Ohsolvac): Yes. Hello. Can you hear me?

Gustavo Seinos: Yes, we can.

(Christina Ohsolvac): Okay. Thank you. Good afternoon. I'm a person also with ME/CFS and I also am representing the Chronic Fatigue Syndrome and the Support Group of Southeastern Michigan and I'm also actively involved with ME Action Network.

My own story is like that of many people with ME/CFS. I got sick after a severe infection and have never recovered and I can no longer work. I'm here to battle insurance companies to get treatment - the entire hospital system have refused to treat me - and doctors who don't believe in this disease treat me -- and others -- like a nuisance and a pariah.

I've yet to wage an expensive legal battle and go to court to try to obtain short and long-term disability insurance from the likes of Sedgewick and MetLife. Many of these large disability insurance companies use hired gun physicians like (Dr. John Brush) who has not only said that ME/CFS does not exist despite the 2015 IOM Report.

But also seems to have a documented history of stating that all ME/CFS Fibro and Lyme patients have undiagnosed depression or personality disorders. Despite the objective evidence that refutes those claims and clearly shows there is a psycho - physiological basis for the disease.

I have been fortunate enough to be treated by two ME expert clinicians who know better. It is grossly unjust that independent physicians -- hired by long-term disability insurance companies -- (costly) speak to uninformed judges that people with ME suffer from undiagnosed psychiatric disorders and that ME/CFS does not exist.

These false assertions provide millions of people with ME from receiving the adequate medical care and the disability benefits that they so desperately need and deserve. Why is this continuing to happen?

It is abundantly clear that ME/CFS patients are not good for insurance companies bottom line. The insurance industry continually asserts that millions of people with objective (whatever ports) functional test results and other markers are all making this up.

Health insurance won't cover us either. A majority of US physicians cannot -- and will not -- diagnose or treat people with ME. In fact, many people with ME get coded under our (coal) morbid conditions and if we're lucky ME/CFS is an afterthought.

Physicians cannot properly treat us if insurance companies dictate that our disease does not exist. The ICD timecode listed as payable as long as the patient record does not prove that another more definitive -- and possibly non-covered -- diagnosis exists.

It is imperative that people working in our government agencies stop the longstanding malfeasance in this matter. We had - need to come together and stop patient blaming - stop hindering research progress by underfunded grants -- and the inadequate RFA's -- and give this disease credence so that people with ME can be diagnosed - treated - and receive disability insurance benefits.

The insurance industry dictates patient care and with the continued slow pace of progress -- and lack of support for people with ME -- we will continue to have the insurance industry further marginalizing a patient population with (the sick) subjected to decades of suffering.

The insurance industry is getting away with this because they are saying - find the cause of ME or we're not paying. And this litigious society in which we exist -- lawyers, insurance companies and mega corporations -- have pushed physicians and entire hospitals to protect themselves so ferociously that insurance companies have snuck in the back door and stolen the floor plan.

How many more patients must needlessly suffer? How many must more die or commit suicide because we're told - sorry, you're on your own?

Thank you for your time and consideration.

Faith Newton: Thank you very much for your comments.

(Christina Ohsolvac): Thank you.

Gustavo Seinos: And the next speaker is (Bobbie Soville). Operator? Her line please.

(Bobbie Soville): Hello?

Gustavo Seinos: Yes, ma'am. Go ahead.

(Bobbie Soville): Hello. You can hear me? Hi, I am the mother of a daughter who has been ill for 27 years. And I just hear all these other parents -- the previous - (Denise) speaking and the previous woman -- and I'm just so moved.

Okay. What I wanted to bring up is I want to recommend that you have a Medicare representative on (SESAC). In addition, that you recommend to the Medicare -- or state facilities -- that there be (Telehealth).

My daughter lives in a rural area and she cannot go out easily -- to a doctor -- without great help. Having a (Teleconference) would be a great advantage to people like herself.

Also, that Social Security pay for care visits for those who are bedbound. And I don't know how you can make that recommendation to the right parties - but if you could make that recommendation to the right parties - just even sending them a letter that this is what's needed.

ME (their) patients are ill and they need an interaction with the healthcare provider. Another thing - if you could recommend -- to the newly funded Research Centers of Excellence -- that they have to engage stakeholders.

They have to really engage them - not give lip service - not just have a web meeting. The research center should have a community advisory board that meets regularly and the Centers should really engage the community because the community -- as you know -- are the people who know what this disease is about.

This community of ME patients and parents have good ideas. They can help the Centers with recruitment ideas. And if I have any extra time - please give it to any needed next speaker.

Thank you.

Faith Newton: Thank you (Bonnie). (Mary Dimick)? And (Mary) is here with us today.

(Mary Dimick): Thank you for the chance to talk to you. (Timbre) -- as so mentioned earlier -- (Unrest) does an excellent job of highlighting the terrible debility of ME. The abuse and disbelief of the medical community. The neglect by the government and research community and even the distain of the public at large.

For many patients this reality is made even worse by the finance - resultant financial devastation and societal abandonment as expressed from this passage from a patient.

"While (Unrest) is a fantastic spot start I must speak up for all the people with ME who are struggling to get food, water, warmth, housing and rest needs met. There are thousands of us without homes who are living in tents in the desert - nursing homes - hospitals - cargo trailers - and cars who are often freezing, isolated, and desperate.

There are thousands of us who can't swallow food - keep it down - or even get (Prentrollment) nutrition. There are thousands of us who are alone -- without family or friends. There are thousands of us who are not getting our emotional needs met or who are being abused.

There are thousands of us who rely on caregivers that don't show up to help us eat - or pee - or change our stinky pee sheets from the time the previous caregiver also failed to show up.

There are thousands of us who don't know where next month's rent will come from or either where the money for food will come from - let alone the money for heating - cooling - care or assisted devices.

There are thousands who do not have access to basic necessary medication like thyroid pills." That's the end of that patient's passage.

I truly appreciate what is being done and I know that science takes time and medicine needs evidence. But, I also know that the speed of scientific and medical change is dependent on the political world to drive it.

So, let's be real. Compared to the tremendous burden of ME and the magnitude of the problems we face - our national response amounts to little more than a bucket of water on a raging inferno.

People with ME live so close to the edge that some have chosen suicide as Terri talked about.

Any other national response suggests that it's not that bad - that everything is okay because we will eventually get more research money - do drug trials - change the wrong-headed views of doctors - fix the crisis and access to clinical care and fix the myriad other elements that are broken from 30 years of neglect and distain.

But at this rate, it could be a decade -- or more -- before we produce an outcome that really makes a difference in the lives of patients. People with ME have had to sacrifice their fragile health to expose the neglect and mistreatment.

Now it's up to all of us who are healthy. I call on each of us -- especially those with the leadership position -- to demand an aggressive plan with vastly greater urgency - a commensurate financial commitment - the serious attention of both the research and medical communities - and zero tolerance to the bad science and false narratives that have held ME hostage for the last 30 years.

We must not wait -- for eventually -- to make a difference for these patients and we have no reason to wait for eventually. There's things we can do today. Thank you.

Faith Newton: Thank you (Mary) for your comments.

Gustavo Seinos: The next speaker is (Davey Estevan). Operator can you open his line?

Coordinator: We were unable to reach Mr. (Estevan).

Gustavo Seinos: We'll move on then to the next speaker (Laura Phillips).

Coordinator: One moment please.

Gustavo Seinos: Sure.

Coordinator: We do not have a phone number for Miss (Phillips).

Gustavo Seinos: (Colleen Steckel)?

Coordinator: Miss (Steckel) your line is now open.

(Colleen Steckel): Thank you very much. My name is (Colleen Steckel). I was diagnosed at age 29 with (C-FIBS) and I've been sick for 28 years.

I'm an advocate, a support group leader, and have experienced and witnessed indescribable suffering that has led to at least 38 untimely deaths in just the last two years.

You've heard for decades how severely debilitating ME is for those of us who fit the ICC. Research funding levels -- and lack of doctor education -- show a lack of understanding about the breadth of this epidemic.

Know that our doctors are coding us as CFS, ME, (Fibro-pots) et cetera. So, the disease prevalence is buried. Here's a perfect example of the rampant lack of understanding we face every day.

As of last week, Mayo Clinic states that - treatment for CFS is -- and I quote -- "Gradually increasing the intensity of your exercise over time may help reduce your hypersensitivity to exercise - just like allergy shots gradually reduce a person's hypersensitivity to a particular allergen."

According to this, ME is not what they're calling CFS. We need accurate information disseminated for ME as per the ITC.

The horror stories in this treatment -- coming from patients who go to the top clinics - like Mayo and Cleveland Clinic -- make it clear the CDC has not shared our expert's knowledge about the complex nature of ME's broken oxygen exchange system - impaired energy production and immune and autonomic abnormalities.

This leads to unnecessary suffering and early deaths. With the loss of (Dr. Learner) -- and now (Dr. Lap) retiring -- the fear rippling through the community because there are too few knowledgeable doctors is overwhelming.

Every day that proper information does not reach our doctor it means at least a million US citizens suffer without medical care another day. Patients who are more disabled -- than someone with congestive heart failure -- suffers every day.

In an effort to bring to light the breadth of the suffering, I will close with information gleaned from an online group -- with thousands of members sick with ME -- where hundreds of people responded to the following question: What age did you get sick and how long have you been ill?

The age of onset ranges from age 9 to 55. When I added the numbers of years -- of the first 278 people that posted -- this equaled 5,195 years of suffering. Take a moment to let that sink in.

Five thousand one hundred and ninety-five years of suffering for just 278 people. That's an average of 18.7 years -- per person -- waiting for doctors to have the information they need to alleviate our suffering.

That sampling of just a small percentage of our community should shake everyone here to their core. This neglect -- by our healthcare system -- is incomprehensible - a disgrace - unfathomable - unconscionable - and criminal.

Thank you for listening.

Faith Newton: Thank you for your comments.

Gustavo Seinos: The next person is (Janelle Wiley). Operator?

Coordinator: Miss (Wiley) your line is now open.

(Janelle Wiley): Hello, good day. I wanted to talk about something so it can be done -- or planned -- right away. There's been a long gap of getting little done - which is partly improved of late - very slightly.

This is an important disease that attracts a lot of people and time should be considered of the essence. So, I want to talk about planning to make a real difference.

An (NIH) Institute needs to take responsibility for the disease. (Vicki Whitmore) has been doing good things - but she doesn't seem to have significant funding.

We need to be actually in some particular institute. There are several existing institutes that would make sense - or it might even be possible to create an institute of (sodule metabolism and signaling).

(CFSAC) should develop a strategic plan for the disease - including checkpoints and benchmarks. There should be an effort to build on the diagnostic process we have made -- and are making -- and create a standardized diagnostic process.

Recognizing that it will be complex - like an autoimmune disease whether or not this is one of those. NIH should issue RSA's at the very next announcement and increase the frequency and amount until reaching a level that fairly represents the debility - prevalence - and the fact that we are lagging behind.

Such as $250 million dollars a year. Example RSA's would be - an RSA for developing a guidance document for when to prescribe assisted devices or technology and organize home help and provide home medical care.

RSA's for the type of physiology of the disease -- for a pilot drug trials -- for drug trials in invitro samples. RSA's for assessing the utility and validity of outcome measures currently being used and for new patient reported outcomes.

RSA for developing cognitive testing that would demonstrate brain fog and the (quest genetic) could be used in the office. RSA's for validating possible tests for diagnosis and assessment - the various aspects of the disease.

In making tests like MKC's (too) clinically useful. There needs to be recognition of the full scope of the severity of the disease. Right now, the official documentation has the upper half. Let's get everybody recognized.

I can already hear you reply that funding is very hard and the situation is particularly bad this year. The thing is -- whether times are good or bad -- we always get the short stick. Always. And in real terms our funding has decreased even in good years.

The story is - it's the government's actual job to do science - (unintelligible) the patients and make people's lives better. Let's do that - together. We're counting on HHS to pull together and do their part to make things happen quickly.

Thank you.

Faith Newton: Thank you for your comments.

Gustavo Seinos: The next speaker is (Marci Butler Meyers).

Coordinator: We do not have a contact number for Miss (Meyers).

Gustavo Seinos: (Matina Nicholson)?

Coordinator: And we are showing Miss (Nicholson) has disconnected from the line.

Faith Newton: Can we try her again and go to the next speaker and come back to her? And the same thing with the other one we couldn't get a hold of?

Gustavo Seinos: Yes. We're being told (Matina) was - she - her line drop is - we can move on to the next speaker (Charlene Hardy) and then call (Matina) back, Operator?

Coordinator: Yes. Miss (Hardy) your line is now open.

(Charlene Hardy): Thank you. Should I start?

Gustavo Seinos: Yes. Go ahead please.

(Charlene Hardy): Okay. I am an ME/CFS patient and currently (boarded) in the cold dark quiet (unintelligible) all day and all night. These are my points. I have documented a lot of things because I think I'm about one medication away from a coma which is the end stage of this disease.

I have suggested that educating doctors and specialists - using a simple little book -- that was written by a doctor with this disease -- might be the best way to go.

It's called - ME and me. And it's written by Dr. (Hng) H N G. I find doctors and the legal (SFDI) people cannot watch long documentaries -- or movies -- (that will tolerate) many documents.

So, a simple book they can read in 15 minutes might do the trick. (SFDI) needs to know that the disease is like late stage cancer or AIDS. And we cannot play games with lawyers and judges.

Obviously, they don't know what the disease is so they also need to be mailed this book. All (SFDI) officers - lawyers - judges. We offer a doctor - offered to give bulk discounts so (HHS) can do this tomorrow. Her email is rcolormusic@hotmail.com.

Doctors do not do house visits so they never see how disabling this disease is. It's - I have offered my doctors -- many times -- to come to my house even as a (gesture) -- from the doctor -- and see how I'm bedridden all the time. And (don't even) make it to the bathroom.

I have been going to doctors for four years and I keep getting the excuse that they did not study viruses at medical school and they do not know that anti-virus can be (used).

In my case I am off the charts at (unintelligible) virus (which I still do). Which means 24 inflammation keeping temperatures at 60 degrees even in winter. If I had antiviral (unintelligible) I might have never been tested for (unintelligible).

The doctors are not taught about it at medical school and won't touch it. The other thing they tend to do is give us antidepressants which causes nausea and loss of appetite.

In May this year I nearly died from violent (projectile) vomiting - diarrhea where all these excessive meds -- that are wrong -- for this disease. (Weird) spells and they added them back.

Their answer to the problem was to add all these wrong medications back. Which has made me sicker. The only place that seems to have any hope for us is Open Medicine Foundation in Stanford.

And they are doing genetic research. I have suggested that HHS could fund willing patients to do the (DNA) test that shows the common mutation we all seem to have - which is triggered by different viruses - Lyme's disease - parasite - who knows.

But it seems to be a genetic based disease and all the medicines in the world that are (handily) being thrown at us by Big Pharma make us sicker. So, first do no harm is the strongest thing that I can say in wrapping this up.

And in hoped that HHS will indeed send this little book to all the doctors - the specialists - the lawyers - the judges - nationwide. Politicians - if they have time -- they seem so distracted -- it's 15 minutes of their lives and it could make the difference between someone living and dying.

Thank you.

Faith Newton: Thank you for your comments.

Gustavo Seinos: Operator can we go back to Miss (Nicholson) now?

Coordinator: Yes. Miss (Nicholson) your line is now open.

(Matina Nicholson): Hello? My name is (Matina). I have had ME and I've been suffering for over ten plus years. I try not to keep count as it's too painful to think about the time that I've lost -- such as my great career -- and my favorite city - NYC.

I had to move home to live with my Mom and near my Dad so they could help take care of me while I should be caring them because they're in their mid-eighties.

Excuse me I have a bad cold. And the more time I (live) is based on the treatment I need for ME. I'm at the point where I need treatment such as (Ampertin) - or some type of immunotherapy (unintelligible).

As with many of us I have - the complexity our disease I have (podge) fiber - EDS - (hyper-vicdoty). On top of that I detect two more (comorbidities). I was just diagnosed with CFID and inflammatory arthritis.

So, I'm coming to a major obstacle for many of us that has come to. In getting diagnosed with inflammatory arthritis I had major obstacles.

I've delayed treatment now for over a year and a half because the first rheumatologist saw that I had ME/CFS and told me that - twisting my arm and my ankle and told me I was fine - I'm getting older - get used to it.

I was livid. I was in Pharma this is how you not - you do not diagnose a patient like that. This is - you need to change the stigma of ME/CFS and educate your doctors.

Now I have to deal with the consequences of living with damaged joints which I caught a year earlier. And this is all one case of my story.

This happens all the time and patients have to live -- or people with ME -- have to live not only suffering with ME for long the severity in years but with the (comorbidity) might get missed because it's all just (messed up).

So, to end this - we have a major problem - we are dying out here from misdiagnosis - misunderstanding - and uneducated doctors. Our patient population needs doctors. Our experts desperately need help.

ME/CFS faced a crisis in clinical care and is adversely impacted by poor medical education. But I was great - it was great to hear the talk by (Dr. Gary Tapen) today. Thank you and I hope this presentation and its replication is a high priority.

We need funding and we need it now. Let me go back to what (Dr. Ellen Patten) said at the last CDC teleconference - it is striking the amount of resistance there is to taking care to providing care for these patients.

And I don't know what it's going to take to fix it. I hope it get fixed soon but it's quite striking. For me, I do have a great expert. Many do not. They're on waiting lists and trying to find a doctor.

It took me ten years to find two local cardiologists to take care of me for ME and (POTS). I've lost two primary care doctors and now looking for another one.

Now let me turn to the great achievements as you've heard from (UNREST) the great advocacy. With all these efforts and great awareness our doctors prepare to diagnose and treat. Now, this is a major problem.

Before I end I want to acknowledge the great work from everyone here - but we need to step it up. People with ME/CFS have no quality of life measurements than any other disease tested.

People are dying and continuing to commit suicide. This is unacceptable in today's world - that a disease be neglected for this long and it's one of the lowest (unintelligible) funding levels.

Thank you and please make a priority.

Faith Newton: Thank you (Matina).

Gustavo Seinos: Operator can we have Miss (Butler Meyers) back on the line?

Coordinator: One moment please. We do not have a phone number for Miss (Meyers). Miss (Meyers) if you did dial in if you can press Star 1 so that we can open your line.

Syreeta Evans: Telephone number Operator is 803-634… Is that wrong? Oh, because I'm doing it…

((Crosstalk))

Syreeta Evans: …you're right.

Faith Newton: I'm thinking you shouldn't publicly be giving her…

Syreeta Evans: Thank you. My apologies.

Faith Newton: You should probably see if the Operator can get the number another way?

Gustavo Seinos: Syreeta email it to her and probably she has…

Syreeta Evans: My apologies.

Gustavo Seinos: The problem is that some people want to speak but they don't provide the (SESAC) inbox with a number.

Syreeta Evans: Yes. I'm getting information the people were very confused by the instructions. So, I think that may have been part of the problem.

Faith Newton: Right.

Coordinator: Okay, and we did - and the same goes for Miss (Mary Dimick) as well as (Lauren Phillip). If you dialed in, please dial Star 1 so that we can open your line.

Gustavo Seinos: Miss (Demick) is here with us in the room it's on the list we share with you.

Coordinator: Okay.

Gustavo Seinos: Can we have (Marshall Gresco) on the line?

Coordinator: Yes. Miss (Gresco) your line is now open.

(Marshall Gresco): Okay. Can you all hear me?

Faith Newton: Yes, we can. Go ahead please.

(Marshall Gresco): Okay. This started for me about 18 years ago and I will tell you that I got sick with six other people. Three of us have this.

I am in San Diego, California so there is no doubt in my mind that there is something that travels in a cluster like a virus that -- for some people who are genetically predisposed -- it will occur.

I have been through more doctors and more situations than you can imagine and I'm one of the people who does speak up for themselves - which is how I got myself stuck in a psychiatric hospital because I was physically sick.

I can tell you that I am probably listed by doctors as somebody who's difficult and would be considered malingering. The reason that I know so much is because I've had absolutely nobody to really sit down and even tell me that I have ME.

We have medicine in this country that is for profit. If there is one thing that insurance companies know is that to open up treatment to a wide - a variety of people with multiple needs - it will cost them more money.

I can tell you that -- at this point -- I take one ten milligrams of Lexapro. I have never been psychotic - although I have had medications thrown at me that you would not believe that I've refused to take.

Before I was diagnosed - yes, maybe I was an overachiever - maybe I did want to do a lot of things - and sure - when you - the person that you were is not the person that you are.

There would be something wrong with you if there wasn't a little bit of depression going on. But, you know, I -- in my life -- I look at my - most people know - recognize when they have a bad day. I'm waiting -- for the past 18 years -- to feel good.

I live in my bed. If I go out and do one thing for three hours I pay for it by being in bed for two days. This is a pattern with age that does not get better.

I can remember working in a clinic -- south of San Francisco -- before we knew what HIV was. It was a methadone clinic and people were dying and I can remember how relieved we were when there was a test - a confirmatory test.

Because that gave a standard and it told the world that there's - yes, there is something here. We found an antibody. We can now work on figuring out what to do.

With this missed polio -- or whatever neuro immune disease this is -- most of us - you will not see us unless we're feeling better. I have such horrible white lab coat fever when I go to see a doctor.

As it stands I probably was treated better 18 years ago when a neurologist looked at me and said - I don't know what's got a hold of you but we're going to make you feel better.

Now I just get farmed out to specialists until one is too -- either pissed off -- or courageous enough to tell me that they can't help me. I have asked a psychologist for something to help me with brain fog and a psychiatrist to help me.

A small dose of Adderall helps me. They look at me and say - that'll get you addicted. I go to pain management and they say - because you have ME -- or something else -- no matter what we do for your spinal (synopsis) balding and herniated disc - you're still going to have pain.

So, we're going to give you nothing. So, the pendulum of pain medication is swinging to not giving anybody anything is affecting ME patients - terribly. So, as it stands - I have nothing for my psychiatric cognitive impairment. I get nothing for pain and I have doctors who will not see me anymore because unless they have a test - they can't justify treating me.

And that comes from an insurance company - and that comes from medicine for profit. I get most of my information from countries where they have "socialized medicine" and that's because maybe they aren't so consumed about the bottom line.

I can understand -- when I see a doctor -- I have to provide testimony like I'm in court. I've got to prove that I'm sick. And if there's no confirmatory test - my lab work makes me look like a rock star - except I can't get out of bed.

I'm dizzy. I don't have any quality of life. And you all need to start looking to Stanford and funding the Open Medicine Foundations Care and Investigation.

There are a lot of us out here who are sick and we are disconnected because until the internet we didn't realize that this has been going on for a very long time.

Faith Newton: Can you bring your comments to a close please?

(Marshal Gresco): What I can say is - please - if you treat - if you go to any group of clinicians first - you have got to get psychiatrists and psychologists to stop focusing on their belief that this is somehow a psychiatric manifestation - or a hysterical episode.

I might sound passionate now but I can tell you it comes from just the frustration and fear of not being believed and listened to. I want nothing more than to have a life where I can go out and do things.

I want nothing more than to wake up and for once -- in the past 20 years -- say - you know what? I feel like I got a good night's rest, you know? I'm tired of treating - being treated on a dance with a (lemming).

It's like we're all these (lemmings) that get passed around to doctors until we just fall off, you know, the edge of the earth because we get so exhausted and frustrated and afraid of being told that either it's in our head or that there's nothing that somebody can do.

And I keep…

Faith Newton: Thank you very much for your comments this afternoon.

(Marshal Gresco): Okay. You're welcome. Bye.

Gustavo Seinos: And the last speaker is (Lily Chew).

Coordinator: And we were able to reach back out to Mr. (Estevan) as well.

Gustavo Seinos: Okay. Can we go back to him then? Miss (Lily Chew) will have to speak next.

Coordinator: Okay.

(David Estevan): Hello. Can you hear me?

Gustavo Seinos: Yes sir. Go ahead.

(David Estevan): Okay. My name is (David Estevan) my wife has been living with ME for six years. We have two young kids. For six years we've worked to figure out how to rebalance our family's life - change our goals - our future plans and our dreams.

We've worked to find solutions - accommodations - and appropriate medical care. Through cycles of good days and bad days and even good years and bad years. Hope and hopelessness.

We've fought as best we can for her and for our family. We are privileged in so many ways - and it's only because of those privileges that we survive. I can be a strong ally for my wife. I have a flexible job and as a tenured professor - a steady job that I won't lose.

I have a good income so we can get the support that we need. I have friends and family that support us emotionally and financially. We have good health insurance. We are well educated. I can read the literature on ME/CFS research.

We can filter out the quackery from the helpful information. I can take the time to do things like prepare statements for government agencies. I can be as important as I can to help my wife and my family.

But what about the others who don't have the same privileges? People with ME confront barriers to every step of the way. Doctors that tell them there's nothing wrong with them and that they just need to get in better shape - or correct some character defect.

Doctors that are sympathetic but uninformed and unable to provide adequate care. Families and friends that don't believe -- or understand -- their illness. Confronting the microaggression some people commenting - you don't look sick. Or, I've seen you walk so why are you in a wheelchair?

Having to correct misunderstandings of doctors and agencies that should be supporting and helping manage your health. Having to navigate an application for social security disability and staying informed about treatment options and ways to manage the disease.

You're having to pay for health - not the babysitter or house cleaner or meal deliveries - when finances are strained. These are barriers that are nearly impossible to overcome without significant help from (strong allies).

So, as the (CFSNT) needs to consider recommendations for HHS. Consider what is needed to support all patients. If surviving ME/CFS of living a full serving list with chronic disease requires an ally with a PhD and a flexible well-paying job - then people with ME/CFS are not getting what they need.

If patients are the only ones educating their doctors - they're not getting what they need. If people with ME/CFS have to accept their less than full rights - then they're not getting what they need.

Thank you.

Faith Newton: Thank you sir for your comments.

Gustavo Seinos: Operator can we go back to our last speaker Miss (Lily Chew)?

Coordinator: Miss (Chew) your line is now open.

(Dr. Lily Chew): Thank you Operator. Good afternoon. My name is (Dr. Lily Chew). I am speaking today on behalf of the International Association for CFSME regarding International Classification in Diseases -- or ICD coding -- here in the United States.

The ICD system is an International Standardized tool used to record diagnoses. The newest version -- ICD 10CM -- was just issued in 2015 to improve the accuracy of documentation.

However -- for ME/CFS -- this latest version is a step backwards and does not reflect current scientific knowledge - best clinical practices - or the 2015 National Academy of Medicine Report.

Current arrangements are also inconsistent with World Health Organization standards. As expressed earlier by some (SESAC) members - incorrect coding practices can have a significant negative impact on disability determinations - tracking a diseases prevalence's and mortality rate - healthcare policy - resource planning - and insurance coverage for care.

Consequently, this July we submitted a proposal to CDC's National Center for Heath Statistics to rectify the situation. We had hoped the NCHS would discuss ME/CFS at their September 2017 ICD meeting.

Meetings like this are held regularly so that stakeholders -- such as professional medical societies -- can give input. We proposed several actions and these are detailed in the written submissions that we gave in your folders along with their scientific rationale.

First action - remove chronic fatigue syndrome from chronic fatigue unspecified in the symptoms and science chapter. As many of you know chronic fatigue is a symptom that even healthy people can experience - while CFS is a disease of many different symptoms and not only fatigue.

The prior ICD version did not conflate these two categories so we're perplexed why ICD 10CM does this.

Secondly, add chronic fatigue syndrome to the neurological chapter at the Code G93.3. Third, modify the G93.3 title term to include post viral fatigue syndrome - chronic fatigue syndrome - and (myologic encephalitis) and provide separate sub-codes for each of these terms.

And finally, fourth, remove the word benign from benign (myologic encephalitis). In September NCHS' (Donna Ticket) informed us that the discussion about ME/CFS might be delayed to March 2018 and that there was some questions -- or clarifications -- they wanted about our proposal.

We responded that we would be happy to answer any questions or comments but since then -- despite numerous calls and emails -- we have not received any further information.

We appreciate (SESAC's) endorsement earlier this morning and hope that (SESAC) can help us secure a position for ME/CFS on MCHS' next meeting agenda in March.

ICD coding may seem like an obscure issue, but every encounter that is coded incorrectly is another missed opportunity for improved care.

Thank you for your attention.

Faith Newton: Thank you (Lily) for your comments.

Gustavo Seinos: And Miss (Chew) was our last speaker.

Faith Newton: I would like to take a minute to thank the Commoners from what we've - that we've heard from today. I know that many of you -- like many of us on the Committee -- are passionate because you -- or your loved ones -- has been dramatically affected by ME/CFS.

In consideration of that I would just like to take a couple minutes to give the Committee some time for discussion in regards to the insightful comments that we've heard here today.

We're a little bit ahead of time and I thought we could take that time to just have some discussion about what we heard.

Donna I think your hand was up first…

Donna Pearson: No, no, no.

Faith Newton: …or (Lily). I'm sorry. Terri.

Terri Wilder: Hi this is Terri Wilder. Thank you everyone who called in or sent in your public comment. I know for those of us living with ME it can be challenging to sometimes get our thoughts together and be prepared to do this. And for some of us it can be a little nerve wracking.

But I do want to reflect on a couple of things that was said. Miss (Christina O.) - I am horrified that there is a physician that has been hired by private insurance who is saying the horrific things that he is saying.

I am so angry I'm shaking. I absolutely cannot believe that this guy gets paid to harm us. I would also like to thank Miss (Colleen S.) for bringing up the Mayo Clinic.

My great grandfather was a physician. He founded the hospital in my hometown. I cannot believe that the Mayo Clinic -- which my grandmother - his daughter - got - gets their Mayo Newsletter and read it like People Magazine -- has medical providers at their institution that are saying those things to people with ME.

It is not at all what I would expect from an institution that has a historical reputation. I just feel like when these things happen - we're being systematically killed. Because we are not being paid attention to.

We're not getting what little medical care we can get with a disease that's so poorly understood - and there absolutely has to be a full force clinical education plan that targets anyone who has a medical degree after their name.

I don't care if you work in a hospital -- as a hospitalist -- or you are the medical provider who reviews our cases for disability. We have to get in touch with these people. We have to get in touch with primary care providers as a gateway.

That I am horrified to hear these stories and it's just heartbreaking to me. So, I appreciate people bringing it to our attention.

Faith Newton: Other comments? Donna?

Donna Pearson: Donna Pearson. A couple of things. Number one - (Lily) had a suggestion and I'd like to know -- maybe this is something to talk tomorrow -- but how do we -- or what can we -- do as a Committee to try to get this issue on that March Agenda for the ICD Coding?

Is there some recommendation that we can make - or is there some ex-officio in the room who can help us get this thing done, because this is probably an opportunity that's going to come and go and it's very important that we do everything that we can?

Faith Newton: I would like to have that question answered by the Dr. (Onlew) or Dr. (Balay) or Dr. (Woodmore) whoever can get us that information.

Terri Wilder: I know in the past the Committee asked (Donna Pickett) -- or a representative of that H - NCHS -- to come and present to the Committee about the process and I think that would be good to ask again. That's something the Committee can do.

We have had conversations of - with (Donna Pickett) and so I think she's got - I can talk with her again.

((Crosstalk))

Terri Wilder: (Unintelligible).

Gustavo Seinos: I invited Donna to come to the January meeting that we had at the Casa Foundation early in this - in the year. She told me she could come and then she said she had something to do and then she was (unintelligible) out and unfortunately could not send somebody else to speak.

If she's having this meeting and reconsidering ME then -- in March -- then hopefully at our summer meeting she'll be able to present.

Donna Pearson: But will that be too late at that point?

Faith Newton: Yes. For her March meeting. So how do we - what do we do to get on the agenda for her March meeting? So maybe that's something we can think about tonight and figure out. Is there a way to do that?

How do we go about doing that?

(MES): To what (unintelligible) this is (MES) (unintelligible) from CDC. To what (Dr. Andrews) already said - we can - we could communicate this information back to NCHS. So, we can bring it to their attention.

I'm very encouraged that (Dr. Lily Chew) has already (encased) them because that's very, very important. I know it's time consuming. I know it's never intensive - but engaging them directly is very important - very critical.

But yes. So, from CDC we would bring it to their attention - to (Donna Pickett) specifically.

Faith Newton: So, the CDC can bring it to their attention - but can the advocates also bring it to their attention?

(MES): Yes. And I would strongly recommend that.

Faith Newton: Okay. So, a strong recommendation that the advocates also bring it to the attention -- as well as CDC -- and then we can talk to (Vicki) tomorrow about NIH as well. Okay.

Donna Pearson: Any professional organizations I think also NCHS who's really looking for input from physicians who use the coding and how it impacts them. So, I can direct testimony from clinicians that are using it would be also helpful.

Faith Newton: So, (Cindy).

(Cindy Bennon): Yes, I was just wondering if our recommendation could be a little stronger in that we recommend that someone from this Committee attend that meeting. Someone who has experience and can represent the cumulative opinion of the Committee.

We have the National Association - we have (IECFS) ME making this recommendation and then if we could add the body of people in this office - or someone to - this Committee - or someone to represent us.

Faith Newton: Yes, it would need to be a clinician or a researcher…

(Dr. Atten): I'll go.

Faith Newton: …who can speak. Yes, on that topic.

(Dr. Atten): I'm not saying, you know, I'd be willing to go. This is an issue that really needs attention. There've been many revisions to ICD 10 already and we're getting pushed to the back and this is a disaster for our field to have no ICD 10 coding.

So, and most physicians don't even know because there's no code there. So, they're just, you know, fishing - only people who are insiders can understand how to work the coding and that's not very helpful for the purpose of coding.

(Ted): So, how would we go about getting - if (Dr. Atten) has volunteered - I'm not sure if that's within the purview of (SESAC) although I'm totally in favor of doing something like that. How would we go about that - would be a question?

Faith Newton: Why don't you let me have a conversation with (Commander Samuels) and (Beth Collins Lap) and see where we can go from there and I will let the group know.

Gary Kaplan: Can I bring up one other issue and then I'll be done?

Faith Newton: (Absolutely).

Gary Kaplan: This is about the Mayo Clinic -- which this comes up constantly -- and I know advocates have reached out to them and I know that the CDC has told us -- and maybe NHS has -- that they can't tell medical institutions what to do.

But I just wonder if a phone call from the CDC to the Director would make a huge difference - I would think, you know, a personal phone call. You certainly can't call everybody but the Mayo Clinic is a big, big deal.

Even add in the Cleveland Clinic -- or whatever ones -- a phone call explaining what's wrong on their website and that it should be changed. Go ahead.

(Beth): I'd like to add to that if I could - and that is I got a blurb online for CME from the Mayo Clinic and they don't even espouse the IO web criteria for the diagnosis of ME/CFS.

They're using older criteria. At least in the one I read.

(Cindy Bennon): I can't promise. I can look into what's possible. Do you have a name that's specific associated with the…?

Gary Kaplan: If I can find it.

(Cindy Bennon): Okay. I mean I guess I'm not familiar with the website or - I can start the (process).

Gary Kaplan: It's got to be public information, you know, there must be public information posted there (Mary).

((Crosstalk))

Faith Newton: Okay. What (Mary) said…

Gary Kaplan: (Mary) and repeat that?

Faith Newton: (Mary) can you come to the mic…

((Crosstalk))

Faith Newton: …and repeat that please? If you're okay with that? And say your name again too.

(Mary Dimick): (Mary Dimick). I can provide the name of the person at Mayo that was quoted as the expert for this disease in a recent communication and an article that they have.

We've the same exact problem with Up-To-Date. They're using the new IOM criteria but they continue to say things like - patients who think they have a viral (eldos) have a prolonged impairment and recommend CBT and (GET).

So, as (Dr. Gary Caplan) said it's a real battle out there.

Faith Newton: Thank you (Mary). (Ted)?

(Ted): The last couple of comments undermine my point - but that's okay. It's clearly a lack of education Mayo - Up-To-Date - et cetera. Don't want to counter that - but I do want to go back to (Terry's) comment that an expert witness can be called and talk from a state -- from a place of ignorance -- and undermine the care of a patient with Chronic Fatigue Syndrome.

And I don't think that's right. I don't think that education is the - because I don't think the person's necessarily uneducated. I've been an expert witness on multiple malpractice cases and the people on the wrong side -- according to the jury -- were not necessarily ignorant.

I think they were just paid enough. And so, I think that we need to recognize that there's more than education -- that's going to be needed -- and I think that making the Mayo Clinic change their tune - making ICD change its tune - making Up-To-Date change its tune.

NAM has already made its -- the National Academy of Medicine -- has made its criteria. HHS, CDC - if you have enough of these things saying the right thing then the hired gun has less power.

And so, I just don't want to under - I don't want to support the idea that this is just all bad education. Sometimes it's a deep pocket.

Faith Newton: Thank you (Ted).

(Ted): You can fight that a little easier.

Faith Newton: Thank you everyone. It's been a lovely afternoon - lovely day. I think we've gotten a lot accomplished today. Appreciate every bodies time. We are going to dismiss this afternoon - we have an ethics meeting. Fifteen-minute break and we will reconvene tomorrow morning promptly at 9.

Could you get here please tomorrow morning maybe by 8:40 - so we could start promptly at 9 am and we will go from there.

Again, thank you. And thank you from the audience those of you that could participate with us this afternoon.

Gustavo Seinos: So, I was told that I need to make this announcement. We have a closed session -- an Administrative Session -- for members. The rest of you are dismissed.

Thank you for coming. However, the members will meet downstairs in the office of Woman's Health Conference Room for a training.

Faith Newton: In 15 minutes. We're taking a…

Gustavo Seinos: Just the members. Voting members. No, non-voting - no, just voting.

Terri Wilder: Only voting.

Gustavo Seinos: Yes.

Terri Wilder: So Terri can go lay down. Is that what you're saying?

Gustavo Seinos: You can go lay down.

Terri Wilder: Okay. Got it.

Gustavo Seinos: Lucky you.

END

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