NWX-OS-OPHS-OEP-OER

Moderator: Syreeta Evans
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7:36 am CT

Coordinator: Good morning and thank you all for holding. Your lines have been placed on a listen-only mode until the question-and-answer portion of today's conference. I would like to remind all parties the call is now being recorded. If you have any objections, please disconnect at this time and I would now like to turn the call over to (Gustavo). Thank you, you may begin.

(Gustavo): Good morning. Welcome back. Hope everybody had a good night. We have once again a full house. I have two announcements to make. The first announcement is that as you all know and the people listening on the phone, last year we only had one meeting which was in May. It was a Webinar and it wasn't an in-person meeting.

Because of conflicts and issues we have finding a room, this meeting is in fact the second meeting that was supposed to take place in 2016. As you all know the charter calls for two meetings in this year in 2017 where we'll be having two more meetings so in fact we have not had officially any 2017 meetings.

Most likely we're looking at early summer for the next meeting and as the DFO and this be my first meeting not everything is perfect so my apologies if

there were any issues with the Webinar and seeing the live streaming. We'll try to get our act together in the summer for the next meeting.

The other announcement that I have we put together at HHS a document outlining all the activities that the department and its agencies conducted between 2013 and 2016. That document should have been handed-out to you guys at the table and this is a copy still in draft form but hopefully by the time we put it up on the Website it will be final.

It basically and I'd like to thank all the ex-officios and helped me put this document together. It's basically all the activities that were conducted by the department between 2013 and 2016. Those are the two announcements that I have. I'm going to turn it over now to our chair Sue Levine and she will do roll call. Thank you.

Sue Levine: Okay, good morning, everybody. We will now do roll call starting from the left to call, go ahead. Yes, go ahead. Just say present. Say your name and present.

Janet Maynard: Janet Maynard, present.

Alisa Cox: Alisa Cox, present.

(Amir Salie): (Amir Salie), present.

Beth Unger: Beth Unger, present.

Faith Newton: Faith Newton, present.

Carol Head: Carol Head, present.

Donna Pearson: Donna Pearson, present.

José Montoya: José Montoya, present.

Fred Friedberg: Fred Friedberg, present.

Drew Helmer: Drew Helmer, I'm here.

Dane Cook: Dane Cook, present.

(Ted Ganiats): (Ted Ganiats), present.

Sue Levine: Okay, and I think Dr. (Scott) and (Beth Collins Sharp) are here as well. Okay, well you see before you we have a fairly busy schedule today. We're going to include some things that we left out yesterday including coming to a final resolution about May's CFSAC recommendation.

We're going to try to wordsmith that one and I'll try to find time probably in the afternoon to get that done and we're going to get to (Faith)'s working group and hopefully hammer out a couple of recommendations from there and I'd like to also think about although I do have some suggestions some possible future working group suggestions as we'll probably be left with one Dane's group for next time and that's all I can think of right now.

And Gustavo already mentioned that this is really a meeting for 2016, our second meeting 2016 so we will have two meetings at least in 2017. Okay, without further ado, let's proceed to Dr. Whittemore and her update.

Vicki Whittemore: Good morning everyone and thank you, Sue so I'm going to I'll introduce myself first for those who don't know me, I'm Vicki Whittemore and I'm a Program Director in the National Institute of Neurological Disorders and Stroke and the NIH representative to CFSAC.

I'm going to be talking on behalf of the trans-NIH working group which is composed of representatives from 24 different institutes, centers and offices across NIH that's chaired by my boss, Walter Koroshetz who's the Director of NINDS and I help with coordinating the activities and the meetings.

So I was sent a very long several e-mails with questions so I'm going to start with those and then end with the update so I'll try to go through this as quickly as I can so the first question that came to us was addressing clinical care crisis and I think in the previous recommendation there was a part of the recommendation for the centers of excellence was to provide access to care.

NIH does not fund clinical care in our research programs and so we can fund clinical research and clinical studies which very often provide access to individuals to testing that they may not otherwise have access to but that's clearly different from clinical care.

We're hoping that the collaborative research centers that we will be funding will incorporate education involvement and participation in chronic fatigue syndrome research of young investigators both clinical and basic scientists and through this mechanism we hope that they will help to educate and train the next generation of clinicians and researchers.

So secondly I guess what did I do, I guess I didn't advance, did I? I went the wrong way.

((Crosstalk))

Vicki Whittemore: There, okay, so increasing funding, clearly there are many barriers to access and receiving funding for research dollars these days. For example in our institute well most institutes but not all have a set payline based on what we anticipate the budget will be.

As you all know right now we're operating under a continuing resolution which means we're operating at the same level as our budget was last year and in many institutes its individuals are not allowed to put forward new initiatives. Since we had already been working on the RFAs, we're allowed to move them forward.

But in this uncertain budget time, our institute had been funding grants to the 15th percentile and what that means is if you rank all the grants from best to worst, the top scoring 15% were funded and so that means that everybody who's submitting grants to NINDS is competing against one another for those very precious dollars.

And it varies, the payline varies between different institutes depending on primarily what they're already committed to funding in long-term projects and large projects so we in terms of the RFAs, the long-term goal clearly is to identify effective treatments but we are not going to get there until we understand the underlying cause and causes of ME/CFS.

And so I'll come back to talk more specifically about the dollars that we're putting forward - will be putting forward - for the RFAs so NIH accepts investigator-initiated grant applications at all times through what we call our parent grant mechanisms and these are our standing grants that any investigator can submit a grant.

These go from disease-specific to basic science grants, clinical, translational research across the board. I have to say there has been an update in the number of individuals that - investigators - that I've been talking to especially young investigators which is really exciting who are interested in submitted grants to NIH.

So another barrier to research is a lack of a research case definition and the question was will the common data elements be enough to overcome this barrier and I would answer that no. I don't think the common data elements are designed to overcome that barrier but I think it will help to identify individuals with common symptoms that are likely to fall into subtypes.

And one of the things I think that's been interesting from the CDC study is the heterogeneity of the patients not just within sites, across sites and clearly this has been my experience with talking to individuals with ME/CFS and so I think that this new information will help us eventually to develop new diagnostics hopefully biomarkers and the ability to develop more well-defined evidence-based diagnostic criteria.

And it will be important I think to identify which case definition was used in each study so that a cohort of patients whose data is entered into any database is clearly identified along with that data what criteria and case definition was used.

I think having a discussion about which diagnostic or which case definition to be used for research is something that we're having on an ongoing basis at NIH and I think something that we would like to expand that discussion to ME/CFS stakeholders.

Reversing the stigma, clearly stigma is a problem in ME/CFS and stigma is overcome with awareness and education and I do think the agencies need to work together to educate healthcare providers, researchers and the public and the advocacy and professional organizations should play a role in this as well to overcome the stigma of ME/CFS.

There was a specific NIH RFA for grants to address stigma and elimination of stigma that has since expired but there is a new RFA that's going to be issued that I think if people are interested in this area, it would be a good area or a good RFA to people to respond to and try to think about how to address the issue of stigma in ME/CFS so this is a lot of text.

This was a question about long term so publishing our long-term commitments for funding for ME/CFS research broken-down by institute with a special focus on commitments of the key institutes and I can't remember if it's here, no. I'll come back to this because I do have this data for the RFAs.

I think I have it in my update so the NIH institutes who are participating in the new RFAs have committed to funding of these centers for the five-year awards and I think on top of that all institutes are committed to funding investigator-initiated research that comes-in as I said through our regular mechanisms.

And except for when funds are Congressionally appropriated and mandated, institutes do not set aside funds for specific disease areas so it's not as if we have if you look at the NIH Reporter that reports-out in categorical spending how much money has been spent on disease areas.

It's estimated that it was $7 million in 2016, Fiscal Year 2016 which I think is going to be a little bit higher that but the figures will be out I think in February

and for it's estimated that for $7 million again in Fiscal Year 2017 those are simply estimates and there is no set-aside of $7 million.

That number is what gets funded through grant mechanisms and grants that come-in are peer-reviewed and funded so if $50 million worth of good research comes-in, $50 million will be funded so I think that number is there but it's not especially the estimated number it's just based on the previous year and really has no meaning at this point.

Publicly released the protocol for the intramural study. I talked with Avi Nath and people who are part of clinicaltrials.gov and typically the whole protocol is not published. There are incredible details in the protocol that really are meant for the study investigators.

But if you look at the consent forms that are actually posted on if you go to the NIH chronic fatigue syndrome Website and go to the intramural study and go to the consent forms, this is kind of a long URL but this is where it is.

If you go to the consent form, it lists all of the tests and all of the procedures that will be done with the individuals who are study participants so that inform is publicly available so I'm going to move-on now to the updates so just to remind everyone that at NIH there are really two major parts of NIH.

One is the intramural research which is the research that's performed by NIH staff located on the NIH campus in Bethesda or at other NIH locations. I know that there are certain institutes and centers that have locations at other areas outside of Bethesda but if they're NIH staff, that's called intramural.

They have their own separate intramural budgets. Extramural research then is what I work with which is research that is funded by NIH but performed at institutions across the U.S. and sometimes at foreign institutions.

So it's the funds that we give out that go outside of NIH so to first talk to you about the intramural study which is now funded remember by the intramural program, this is led by Dr. Avi Nath who's the Clinical Director of NINDS.

They have started - that have now I believe - had at least three if not more healthy control study participants who have been to NIH and they've held focus groups specifically to talk to people about their experience with post-exertional malaise to learn more about that.

And once the procedures are finalized, they'll begin recruiting the individuals who have post-infectious ME/CFS who are within five years of the onset of their disease to begin to start coming to NIH and my understanding is that if this hasn't happened already, it's going to the first individuals with ME/CFS will be coming soon.

So as many of you know there'll be extensive analysis by a specimen collection data collection that will be done and you can go to the Website there and learn more about that study.

The intramural group has also started the special interest group which is designed primarily to educate and provide prospective for the intramural programs and staff but many of us extramural program staff also attend as we can and I've seen a list of the upcoming folks that they're considering inviting and I think it's really been a good exchange of information between the individuals who come to speak and the staff who participate in these meetings.

As I said the trans-NIH ME/CFS working group continues to meet at least monthly. Many times we have calls in-between and we're primarily focused on developing strategies for extramural research funded by NIH.

We've developed and are implementing short, intermediate and long-term goals and I'll come back to that in a minute and we or several of us participated in the recent IACFSME conference, NIH, several institutes at NIH actually helped to co-fund an R-13 conference grant for that conference.

I was asked well actually Walter Koroshetz was asked to be the keynote speaker and he was unable to attend so I filled-in for him. Several of us ran an NIH grant-writing workshop that was well-attended, lots of great questions and lots of good exchange at that meeting.

I was a panelist for a discussion on community engagement in research. Beth Unger and I had an evening session to discuss the common data elements project and Catherine Bennett who is the Scientific Research Officer who runs the review panel for chronic fatigue syndrome ME/CFS was at the conference as well.

So these are our short-term, intermediate and long-term goals and they kind of keep changing and shifting as new things come-up that we want to add to the list. I don't think we've taken anything off. We keep adding and this is actually posted on the ME/CFS Website as part of my presentation from the IACFS meeting for those of you who want to look at this in more detail.

So a short-term goals update so we issued a notice of availability of administrative supplements and this was a quick way for us to get some additional dollars out the door in Fiscal Year '16. These supplements were

awarded seven awards, were supported by the National Institute of Allergy and Infectious Disease NIAID and NINDS neurological institute.

We have been working very hard to foster collaboration so we organized and held the federal partners meeting in May and several collaborations were identified and some have already been initiated. The meeting summary has been posted on the Website and I appreciate comments and corrections to that.

We will certainly update and correct any mistakes or misinformation that's in the report and we'll identify - we're working to identify - research priorities so we had a request for information that was released in 2016 and received a lot of really excellent input and I'll talk about what we're hoping to do with that in a moment.

The common data elements project has been initiated. Trading meetings are set to begin toward the end of January. We have had some interest from individuals who are either have ME/CFS or are advocates that we will also be adding to the working group. We had an open call for people to volunteer so it's not a secret club.

It's not by any means meant to exclude anyone so if we had a call at the conference for people to let us know if they're interested in participating and have several people contact us and then Beth and I put together an additional list of individuals that we wanted to invite so we welcome participation in that project so and I'll come back to that project in a moment as well.

And we're also fostering international discussion and collaboration so I've had ongoing discussions - we - I should say - have had ongoing discussions with the Canadian Institute for Health Research who's interested in partnering

with us in the centers program potentially funding a center in Canada that would partner with us.

And we've also had ongoing discussions with folks in England and Australia so the NIH request for information as I said we got lots of great information from that and have really kind of sorted through that information in terms of priorities that people put forward in terms of developing biomarkers, identifying symptoms, looking at causes and treatment, developing new treatments.

And we really think that the next step is not for us at NIH to tell the communities these are the research priorities but to involve our federal partners and other ME/CFS stakeholders in this discussion to really hammer-out what these research priorities should be going forward and work on this together.

The ME/CFS common data elements project as I said is getting underway and our timeline for that is that these will be worked-on over the next nine to 10 months finalized. It's interesting this will be the first time I think. I don't want to speak out of turn here that advocates will actually be involved in the process.

The typical process is that these are developed by content experts and then posted for comments so we're looking forward to the involvement of the community in and advocates in this process and then the CDEs will be utilized in our collaborative research centers and hopefully other NIH-funded research.

Our intermediate goals, trans-NIH working group is really developing our research programs meaning the RFAs and as I said we encourage investigator

-initiated grants. We're working on ways to develop the pipeline of young investigators.

As I said we had many excellent meetings with your investigators both basic scientists and clinicians at the IACFS meeting. They were participated in the grant writing workshop and we're encouraging that as well. We now have some grants come-in for post-doc so that's great news.

Our funding announcements, as you all know, what we're hoping to do is to fund multi-disciplinary, multi-site collaborative research centers and one data management coordinating center. We're looking forward to the research centers that we fund to be the main word here is collaborative.

We want this to be a collaborative project that really moves the field forward in significant ways. We're hoping that where possible the centers will partner with the clinical science translational awards or CTFAs that provide infrastructure at many institutions for clinical research and clinical training.

And we are encouraging - we will encourage - the applicants to involve young and new investigators in their applications and as I said yesterday will require community engagement and involvement in the project.

The timeline is that they're currently going through a nine-step approval process in the Office of Extramural Research. I think we're at Step 8 or 7 or something like that so they will be released hopefully in January and we'll have a Webinar in early February to answer questions, explain in more steps and to answer questions from potential applicants.

The deadline for the letter of intent will be 30 days prior to the deadline for applications which will be in May. They'll be reviewed in July and approval

will be done at the appropriate NIH advisory council in September with earliest funding to begin in September.

So this is a pretty tight turnaround but we've got the folks at the Center for Scientific Review teed-up and ready to help us with the review of the applications when they come-in so these are the commitments that we have for the specific RFAs, the centers and for the DMCCs.

So they're not broken-out by the two RFAs except for NCATS which as specifically - this is the National Center for Accelerating Translational Science - has specifically asked that their funds be utilized to support the data management coordinating center but overall there's a total of around 29,750,000 over five years.

So we're hoping that this will turn into the data management coordinating center plus two to three centers at least depending on what the budgets are so we'll have to see how that turns-out so our plans for 2017 obviously our big focus is to launch the centers.

There'll be lots of program involvement, lots of meetings, lots of energy going forward so I think that will be very exciting for everyone, continue to work with CDC and others to develop the CDE project. We're also as I mentioned yesterday in the discussion phases and planning for an interagency what we're calling interagency collaborative for research on ME/CFS.

And so this would be the goal would be to enhance communication and collaborations between the federal agencies and between all ME/CFS stakeholders that have an interest and support research on ME/CFS so we would work together to identify the research priorities, areas of collaboration.

This would be composed of representatives of the federal agencies and ME/CFS stakeholders and I use that word broadly. There are a lot of definitions as Dane pointed-out but I'm using that term broadly at this point and so we will be working to plan this.

And I was talking with Dane yesterday about having a small working group of our trans-NIH working group that would work together with the CFSAC workgroup to think through how this fits in with what the potential recommendation coming from CFSAC would be regarding stakeholder engagement and involvement. Long-term goals continue to be the same.

Obviously these are a ways out to expand our collaborative research center as funding allows, development therapies, support clinical trials and ultimately to improve the quality of life for all individuals with ME/CFS and with that I'll stop and I apologize for taking so much time but had all those questions at the beginning I needed to get through so thank you.

Sue Levine: Thank you Vicki for an excellent update. Is this material available? It's not in our binder is it?

Vicki Whittemore: No, I'm sorry. I didn't get it turned-in in time. Yes, yes, I can...

((Crosstalk))

Sue Levine: I'm wondering if some of the URLs in particular would be available.

Vicki Whittemore: Yes, sure.

Sue Levine: And then I'm asking perhaps an inappropriate question but do you have an example, has anybody submitted any protocols for prevention of ME/CFS?

Vicki Whittemore: Not that I have seen.

Sue Levine: Is that one of your initiatives for prevention on this disease? I thought I saw that up there.

Vicki Whittemore: Well, that was so not at this time. I think we need to understand the causes before we can get to prevention but I think absolutely that would be a long-term goal.

Sue Levine: I just saw it up there and I was curious to see what people were thinking but okay, thank you. Any questions, Dane?

Dane Cook: Hi, Vicki, thank you very much for the presentation. I have one question concerning the collaborative research centers. When you say collaborative are you talking within the center or across the centers themselves or both?

Vicki Whittemore: Both.

Dane Cook: Both, and so can you speak a little bit more how within the application process and putting-in an application for a center how that might work?

Vicki Whittemore: So right so this is done quite well by some of the consortia that are run out of NCATS especially out of the Office of Rare Diseases and we're sort of taking from lessons learned from them in terms of once the applications are funded, we will bring the investigators together to talk about the research that's being funded in each of those centers as well as then what could be done collaboratively and across that might help.

So for example if somebody's doing a genomic study and planning to recruit 5000 people, maybe an additional five recruited from the other center or centers would be helpful so it's really looking at how the centers can enhance their research across and potentially studies proposed in one center but not another could be again samples shared, information shared across centers.

And to both enhance research to also limit the amount of duplication in studies being done in the centers.

Dane Cook: And just as a follow-up to that so you have your first round. Will there be a second round if you don't fund all the centers right off the bat and that second round we would allow new applications?

Vicki Whittemore: So if we don't fund all the centers the first round, yes, there would be a second round and yes, we would allow what was your second part of the question, sorry?

Dane Cook: Well, say you get a bunch and they get, you know, they get they put in their A-1 so they put in a second response to reviewers. Will you then also allow new applications in that second round?

Vicki Whittemore: So...

Dane Cook: It's a tight deadline and some, you know, if you're going to try to increase the number of scientists and research at ME/CFS we're going to also need a second chance.

Vicki Whittemore: I can't answer that, we haven't discussed that. That's an excellent question. I've seen it done both ways where there's a limited competition which only allows people who have submitted once to resubmit. I don't know

if that's what we would do in this situation. I don't know Dane. That's a good question though.

Dane Cook: No, thank you.

Donna Pearson: Hi, Donna Pearson. Thank you so much for answering so many of our questions in advance, that was very helpful. I have one last question then I will be quiet.

As you know CFSAC submitted a detailed recommendation for centers of excellence and (Gary)'s group did a lot of work on that and basically their response is we're really not getting centers of excellence but we're getting this research consortium.

Can you basically explain how you see the difference and perhaps why that decision was made rather than other than financial reasons? What may be some of the advantages of the approach you're taking?

Vicki Whittemore: I think so the biggest difference from what was proposed was that as I said we don't fund clinical care which was a part of the centers of excellence and I did inform the committee when they were developing their recommendations that the number and the cost for the centers of excellence they were proposing was not feasible, just not given our limited budget.

It was I have to say a challenge to get the funding pulled together for the RFAs that we did. I think our biggest thing was that was the word collaboration and collaborative. We did not want to set these up as standalone centers of excellence that didn't work together, that didn't move the field forward together and so kind of stuck with the word collaborative.

But what we are hoping for is an open sharing and collaboration across these centers and it is our goal that these centers would become centers of excellence eventually in essence so would involve new investigators, new clinicians in their research centers to bring them into the field of chronic fatigue, ME/CFS research and eventually clinical care.

José Montoya: Thank you Vicki I think that it sounds like these are steps in the right direction and although modest in their magnitude having additional research fundings is important in this illness so again I think it's still more to see what needs to be brought into the disease.

My point is more specifically on what efforts are being made at NIH to make sure reviewers, the grant reviewers had really bigger to deal with the uniqueness with the advances of the illness? For example it's common and it's rightly appropriate at the NIH that disease mechanisms are presented in grant applications for a disease for which we have very little understanding.

And it takes me back for example hundreds of years ago when we had no idea what diabetes was, perhaps in those times simply finding blood sugar high, there is no mechanism in elevated glucose would have been extremely or was very important to then understand the disease later.

So it strikes me that efforts need to be made at deliver at the NIH if more funds are to be coming and hopefully more would be coming that grant reviewers understand that ME/CFS is an illness, is an entity that needs to be understood at the more basic levels and as for mechanisms where we don't even have biomarkers is illusory.

I wonder what is being made to make sure that grant reviewers are really trying to understand what are we adding (in's) to.

Vicki Whittemore: So that's a very good question and I think Cate Bennett has done a very good job of recruiting knowledgeable reviewers for the study section that's reviewing the investigator-initiated grants. I think we've already had the discussion. It's going to be a challenge depending on who submits applications.

It's going to be challenge to find reviewers for the center's applications because we may tie-up all the good potential reviewers in the application so I think that's something we're already thinking about.

And when it's a special mechanism like the center's mechanism, typically what happens is I, as the program person, talk to the reviewers in advance of the review at the beginning of the review so they clearly understand that exploratory descriptive kinds of studies are where this disease area is at.

And so that we set the playing field at the very beginning of the review. That typically doesn't happen in regular study sections but would definitely happen in the review of the centers and the data management coordinating center. Did that answer your question, José?

But I think, you know, I think that we do need to expand the pool of people who we tap to come to review that ME/CFS grants and I think that's certainly something I'll take back and talk to the folks at CSR about how we might be able to do that. Drew?

Drew Helmer: Drew Helmer with the VA. Two questions, one is, is a center necessarily physically located in the same location or could a center be a collaboration across sites and then second are your numbers that you're reporting there

strictly related to this call for the centers and then there's the other investigator-initiated research proposals are still invited in or separate?

Vicki Whittemore: On top of that, yes, so I'll answer that secondly, yes, so the numbers I reported are specifically for the RFA and we expect that we will continue to fund between 7 and $10 million is a good estimate of other investigator-initiated research going forward. Hoping that expands, absolutely as time goes on.

To answer your first question, a center can be within one's institution but doesn't have to be. I think what we'll be looking for is the best investigators, the best science, the best projects to move the field forward and so if that means that the investigators are coming together from different places, great. I mean, we certainly know excellent collaborations can happen that way. Fred?

Fred Friedberg: Yes, very well-presented, Vicki. I guess looking from a glass half full perspective, putting in context of $5 million a year for this illness, this is $29 million in one year. I know that's not $250 million but from a researcher perspective, researchers generally are told don't go into this area. It's not a career. You're not going to get recognition. It's not going to go anywhere.

Now what can redirect people? Well, if there's real genuine support at the NIH level for something of this magnitude and these the way you've constructed this with cross-collaboration among the centers, to me this is the way you do it.

Massive collaborations are more likely to create new ideas and synergize new research so to me this is a vast let's say apart from individual researchers doing this thing which is fine, to me this is a building block toward more creative research, more thoughtful discussion among multiple researchers

perhaps drawing-in new researchers for which we are desperate for new researchers.

You need to incentivize people to come in this field. That incentive has not been available. Generally you come into the field because you know someone who's ill. We need more than that going on.

We need actual real financial incentives, high-level scientists signing-on to projects like this so you get a more general appeal that this is a field that is a potential career for a researcher, that it's going to go somewhere, that you have formal recognition at the RFS level at NIH so to me this is a very, very significant step.

Vicki Whittemore: Thank you. Carol?

Carol Head: Again, thank you Vicki for all this. It's certainly a significant step forward. I just have one question for clarification so the roughly $30 million for five years is for the single RFA for the consortia and I believe is then there a second RFA that will be let regarding data collection and analysis?

Vicki Whittemore: So the roughly $30 million is for both so it's the data management coordinating center plus the center. It's just NCATS is the one institute that has signed-on and asked that their dollars specifically go to the data management coordinating center. The rest of the dollars are just in a big pool of dollars.

Carol Head: And just a follow-in to that, is the how does it so there are two RFAs, one is for the consortia and the other's for the data analysis center, are they do you anticipate that the data analysis work would be potentially be included in one of the five consortia or is it clear that that would be a separate entity?

Vicki Whittemore: It well I mean, one of the centers could also apply for the data management center. I guess we've thought about them as different entities because there are currently several excellent data management coordinating centers up and running for other projects that could easily take this on but that's not to say that it's, I mean, the call is open to anyone who wants to apply.

So the data coordinating part of it should not be part of the center applications if they're meant to be separate RFAs but we'll work together.

Carol Head: Yes, thank you.

Vicki Whittemore: Okay, so we'll move on to a report from the Health Resources and Services Administration.

José Montoya: So we have Commander (Ketsorelli) here and she is representing Joe Nelson who is unable to come today. I told Joe to tell the commanders and we're going to open the floor if there are any questions to be addressed to HRSA but we don't have a firm representation.

Sue Levine: Do we have an update at all or...

Vicki Whittemore: So the update from HRSA is that we don't have any specific ME/CFS investments.

Woman: Are you working on any particular projects or, I mean...

((Crosstalk))

Vicki Whittemore: Not specifically in the area of ME/CFS. If you in HRSA we have five bureaus and we have one of those bureaus that is focused on a disease and that's the HIV/AIDS Bureau and that bureau is based in legislation so that's how HRSA is able to focus resources and dollars on a disease but outside of that, we don't have any other investments that are disease-specific. Hey Carol?

Carol Head: Thank you for being here. Just one question for you and it's I hate that - so I don't know you and it's lovely to meet you - and I hate to start with a question that is a bit pointed. I'm surprised I was not aware that you didn't have any programs but I must cite one document that has been created that's come-out of HRSA.

I believe it was done by a contractor from HRSA and I don't know if you're familiar with this flyer that is well maybe I'll leave a copy for you but it's a flyer that's meant to be educational about ME/CFS and as I understand it's relatively new and I will it so incorrect in so many ways about this disease that many of us who know the disease from the inside out rather read it with great anguish so let me share this with you...

((Crosstalk))

Carol Head: ...and I would love to hear your comments about it at this point?

Man: Carol?

Carol Head: Yes?

Man: Is this in reference to I remember at the May meeting there was a HRSA grantee who was developing...

Carol Head: Yes, yes.

José Montoya: ...okay.

Carol Head: Yes, so maybe you can correct me if I have a misunderstanding about it.

Beth Unger: This is Beth Unger and it's my understanding that that is still in draft form and I don't they sent it to us - shared it with us - and we were discussing it and I've been trying to get back in contact with the PI because we agree that it could be improved so if you've got any specific comments, I think I'm not 100% sure we sort of broke communication but I think there's probably still time.

Carol Head: Well, let me say I mean, this is sadly an example of the concept of nothing about us without us. It is live currently on the Website as information to individual and if I could quote...

Beth Unger: Summarize in a couple of sentences...

((Crosstalk))

Carol Head: So it really it says that there are elements of this disease that are related to pregnancy. It says that sleep is an important problem for this disease. Quote and that one suggestion for leading a healthy lifestyle if you have this disease is the smell of lavender oil also helps sleeping.

You may try two or three sprays of lavender oil on your pillow at bedtime and so I hope we all understand how really offensive that is so I'm glad it is in draft form and I would love to provide additional feedback and, you know,

obviously hopefully that change could be made very quickly and it could be pulled down so it's no longer live and available to the public.

(Gustavo): So Carol I will - this is (Gustavo) - I will get back to you on this once I talk to Joe and this is the reason why as you know we have ex-officios in this committee and if we can do anything to put Cdr. (Ketsorelli) the contractor who has developed this in contact with members of this committee so this issue could be addressed.

Carol Head: That's helpful, that's great.

(Gustavo): Okay, Carol.

Carol Head: Thank you very much.

Sue Levine: Thank you. Any other comments?

Vicki Whittemore: I'm just going to clarify that we can't have, yes, they don't get - sorry - the committee if the committee is communicating with each other outside of these public meetings, then it is contrary to the FACA rules because all meetings have to be public.

So we would have to go through a workgroup or some other mechanism to share the information but we'll figure-out the logistics to that but I just wanted to make sure that we didn't leave this thinking that there was going to be an appearance of another meeting of the committee.

Carol Head: If I can get clarification, this is important because one would hope that as a committee we would use each other as resources and tap into the deep knowledge of many both as from the ex-officios and the members but are you

saying that the Commander and I could not have a conversation about this or we couldn't have a phone call about this?

Vicki Whittemore: Well, if the Commander or if Joe agrees that it's fine but officially communication is supposed to go through the DFO.

Carol Head: Okay, okay.

Vicki Whittemore: And that it cannot include a group or a subgroup of the committee itself unless it's an established workgroup.

Carol Head: So I think I am hearing that even I wanted to send an e-mail to her and copy (Gustavo) just for...

((Crosstalk))

Carol Head: ...through (Gustavo) and as individuals we could do that so long as we copy (Gustavo) on everything we do; is that fair?

Vicki Whittemore: That's fair. The thing that I heard was I think you're thinking of something different that we would get the ex-officios, the ex-officio in contact with the committee members and so I just wanted to be careful about that and then (Karen) had an issue...

((Crosstalk))

Carol Head: I just want to also ask that we clarify it so I'm sure there's a way to work this out to get the feedback but we just got to figure-out the right steps and working collaboratively with HRSA and along those lines I also want to make sure that we're clear in terms of how the communication goes back to a

contractor and my sense is that it's likely through our HRSA representatives rather than us speaking directly to someone else's contractor.

Woman: Well, in thinking about this also and moving forward, how do we prevent something like this from happening in the future, let's say a project that may not be appropriate, you know, in the future? Is there a way we can address that so that we don't want to continue to have inappropriate projects or if it's anything that would belittle ME/CFS?

Anyway I think it would be good to develop a strategy to prevent anything like this from happening in the future.

Carol Head: I agree I think...

Vicki Whittemore: And unfortunately I don't have any of the details behind this particular education document but we can definitely do better in the future so I'll get some specific details on feedback and work with...

((Crosstalk))

Vicki Whittemore: Hey (Ted)?

(Ted Ganiats): Is it appropriate for the HHS agencies that don't have a disease-specific program or a disease-specific program for ME/CFS to try to bring content to this group? I mean, legislating and all that might be difficult but for example (ARC) doesn't have a disease focus in ME/CFS.

You say you don't and yet it's clear you could have a contract and the agency could have a contract and so you don't have the internal expertise to review

things and you depend on your contractor. That make sense but we could also, I mean, I don't know the mechanism.

Is there a way for it to be sort of brought here if you don't have the internal expertise within your agency? That's not a recommendation. It's a question.

Vicki Whittemore: Well that might a question that we can discuss like discuss, yes. All right.

Woman: (Unintelligible) stakeholder engagement, I mean, that's another (common direct).

Woman: Yes, just to build on that, this is clearly a stakeholder engagement issue and you know, one of the we didn't make any decisions about that yesterday but we know that we're going to finish discussing that today and, you know, one clear way to ensure that the expertise of this group is used is to make certain that CFSAC sees documents before they are made public.

Woman: Excuse me, Carol. Can you clarify where the document because obviously you have some knowledge of where the document can be found on which Website?

Donna Pearson: This is Donna Pearson. I had found this when I was following-up based on the HRSA comments in the minutes of the meeting from last year and then I had followed-up with (Erin Fowler) by e-mail just individually and in one of her responses she said that at least it was good to know that this is the National Center for Integrated Primary Healthcare.

It was good to know that at least they were now going to have something ME/CFS so when I found this, I assumed that this meant this was the new thing because they didn't have something ME/CFS before. What's the...

((Crosstalk))

Donna Pearson: And it's the National Center for Integrative Primary Healthcare. You have to register. You don't have to pay anything but once you do register just with an ID and a password, you can go to the patient and public link and you'll find CFS there. Hopefully anyone who's listening will not have a heart attack when they see this because I did and hopefully we can get this rectified.

(Ted Ganiats): Go ahead, Beth.

Beth Unger: Yes, this is Beth. I can't say for sure that it's not final but I think even if it is final they seem to be open and to (Ted)'s point I think that just for the agencies and everybody to realize they don't have the expertise and the contractors might have the expertise.

It's the beginning and how the agency saw that problem I think just recognizing and this whole conversation makes it clear that there does need to be more communication and I think one of the best things I've seen progress in the CFSAC committee is the increased interagency communication about all things ME/CFS and I think we're moving in the right direction.

Vicki Whittemore: Go ahead.

(Gary): This is (Gary). Is there a usefulness to create a standing committee within CFSAC that would be a go-to committee for other agencies that want to be able to run the wording of public material that they're planning to put out on CFS.

So that there's at least a full and you go to your contractor and you say oh, these people are resources for you so here's a mechanism by which you can do that and we've got a standing committee that's prepared to address those issues.

Donna Pearson: This is Donna. Maybe Beth could help us out with the answer to that question because I understand that Eileen Holderman had a group that was consulted by the CDC something along those lines and I understand that a subcommittee would never speak for the CFSAC. They can only bring recommendations but perhaps and I think they made individual suggestions.

Woman: So this is old ancient things that happened but this is (Mike Miller) was the ex-officio and he asked a subgroup of CFSAC to specifically read and comment on the CDC Webpage and that mushroomed into an ongoing, you know, sort of confusing. It was not done quite optimally but that was a specific question to address a specific concern that came up and exactly how what is the best way for stakeholder engagement?

I think we need to just keep working on because we do have the engagement word is really good, advisory is not, is more problematic because of all the FACA kind of issues surrounding it and formalizing it that it must go through is also somewhat difficult but, you know, there should be some happy medium where groups can get the input that's very valuable, you know, even knowing the content down to the exact words and how the words feel to people or something that there's no substitute other than getting input in some way.

And whether a standing committee is the best way or just again being aware and being sure that you have a mechanism to, you know, CDC has used what we call our informal feedback approach but it's a way of engagement and a

way of being sensitized to things that micro versus big aggressions, you know, that happen, yes.

Man: Beth, go ahead.

Beth Unger: So I have visions in my head of all of the hoops to jump through of having an endorsed federally-approved list of "experts." However, we already have links to advocacy groups.

And I assume particularly in this situation since individual situations change and that types of participation vary so much that if the advocacy groups were to maintain some sort of consult list or some way a referral list, I've seen this done in professional associations that someone could come to them and say this is the type of person I'm looking for.

Who do you know and then the agency can or the group can handle an essay which they may have a list themselves. They may want to suggest somebody from their own group or they may want to put-out a call somewhere but I think putting it inside a FACA is going to not be satisfying.

Woman: You know, it's funny, I still don't completely understand so this item appeared and it appeared to be endorsed by HRSA or just a contractor went ahead and...

Beth Unger: My understanding it was funded by HRSA.

Woman: ...and yet HRSA is not aware of it?

Beth Unger: And when we were speaking with (Erin Fowler) she kind of made it clear that HRSA wasn't really in charge of it but that they just funded this group so that this group could create education materials so we can't say HRSA did it...

((Crosstalk))

Woman: ...kind of filtering mechanism for all the agencies so that, you know...

Woman: It depends on the mechanism as well. If it's a grant mechanism, the content belongs to the person who developed it. If it was a contract mechanism, then that's a new football game and that there are disclaimers and the like that would apply so if this came from grant activity, you know, that may be the case that HRSA's hands off. I can't speak for them, of course.

Beth Unger: And this is Beth Unger. You know, our experience is that the advocacy organizations have always been willing to engage and you know, provide content or comments or, you know, topics and the other thing that we found useful is reviewing the Webpages of those organizations as they just about all have informational materials about ME/CFS.

And that's helpful because that obviously prioritizes what they feel is important and you get some of the language and the approach so I think there is help out there and it was really a group that was not familiar with the illness and this was one of several many I don't know how many brochures that this group made as part of that whatever mechanism and I do think it's just a matter of we need better communication.

Woman: If I could make two comments. I just would like to be more clear about where the accountability lies. If this was and I understand you have not seen this and still haven't seen it but if this was funded by HRSA, does not HRSA have

accountability for the work of its contractors and if not, how do we get our arms around this thing?

So that's Number 1 and I think that's an important procedural question that we on CFSAC must address and then secondly I would just comment that I work with a research organization that also does advocacy and I have this sense that there's a feeling that like other diseases, you know, if you look at autism or if look at AIDS or if you looks at MS or Parkinson's, there really are multiple, you know, multimillion dollar advocacy organizations in all those diseases.

That does not exist in ME/CFS. I am with one of the larger organizations, perhaps the largest and I can just tell you that we do not have the resources to do the kind of work that you're discussing, I mean, I think really perhaps an audit or an understanding of CFSAC among the extraordinarily limited resources both financial and time that exists among the "advocacy" organizations is really are all in a deficient situation (to happen).

Woman: Yes, go ahead.

Man: I did some research and it's not as bad as we think but it's worse. The National Center for Integrated Primary Healthcare is funded in part by HRSA and the Webpage has the disclaimer that the contents herein are not HRSA's not responsible. They don't take credit for, etcetera, it's just the typical I'm a grantee.

I have some money from a lot of different places including HRSA and HRSA can't be held responsible which is appropriate at one level and that's what I mean. It's good it's not a HRSA statement but it's bad because now you have

independent grantees able to produce what they want which is I think that's a different issue. It is...

Woman: It seems to be short-sighted that they would allow themselves to do that...

Man: ...well, I mean, it's from the University of Arizona, the Arizona Center of Integrated Medicine and the academic consortium of integrated health and medicine asks in people including HRSA to help fund their collaboration and then their collaboration created the document.

I am personally disappointed that it came out. I'm anxious to find out if lavender how well that works but I don't see it as a HRSA problem per se as a problem with whether the system is just it's impossible for the federal agency to be able to monitor everything that comes-out of every consortium that's been...

José Montoya: Especially HRSA who is primarily a grant-giving organization.

Man: ...but it shows a problem. I mean, I'm not minimizing it but just saying that at least it's not on a HRSA site as an official HRSA statement.

José Montoya: Yes, doctor...

((Crosstalk))

(Yari Kapp): This is (Yari Kapp) and I just want to put out as a clinician as an expert in integrated medicine as one of the founding members of the academic consortium, this is (hob not) offensive.

This totally it disrespects the seriousness and severity of the disease, cut and paste stuff that could have been pulled from any of the number of integrative centers and you know, (unintelligible) it's just it the issue is it's almost it actually is misinformation and it's offensive both to me as a clinician and certainly the level of offense that the community has got to take it's got to be complete outrage at dismissal of the seriousness of this.

And as an integrative practitioner, it's also offensive because it's Pablum so this is not about this is the contractor clearly who put this out but I don't want to put on the record simply that this is inappropriate piece of information to be putting-out (unintelligible).

Woman: Well, I think it's clear that we need to have further discussion on this.

Vicki Whittemore: Yes, let me take a couple of more questions and then perhaps we can address this even as part of a working group or subworking group. Donna?

Donna Pearson: So the only role that I would say HRSA would have here and I know (Tara) is not the person - she's the one in the hot seat - but I know it's not something that she can be involved in but part of the response that I had received from (Erin) was that based on CFSAC's request, she had connected the grantee with Dr. Unger and advocated for subject matter experts to be part of the flyer and the grantee was extremely supportive as the flyer was still under development.

So I think that I don't think Dr. Unger - I think that grantee - just probably skipped over the whole Dr. Unger consultation completely and moved forward without getting any input. That's what it seems.

Vicki Whittemore: And so that grantee was invited to be part of our roundtable, couldn't come and I've had several e-mail exchanges and I was just telling (Gary) I didn't want to say in an e-mail what I felt but was we just never quite, I mean, he just never was very responsive and for a, you know, so I'm sorry I wasn't more assertive or, you know, but...

((Crosstalk))

Woman: Okay, let's have a couple more comments and then maybe we it sounds like we should address this issue some more, okay, yes, why don't you speak, Commander?

Cdr. (Ketsorelli): So I've been doing a little bit of research too and getting information from my colleagues so it looks like HRSA does provide some funding, some grant funding to that national center underneath the Bureau of Health workforce, the Division of Medicine and Dentistry so I can certainly connect with the project officer who is assigned to that particular grant program.

And we can address the issue from our lens. I wonder if this group might be able to reach-out to the national center the committee as a whole to say we've got some real concerns with this?

(Gustavo): I don't think this group in retail but Carol your organization is one of the leading ME/CFS could probably reach-out to them and say you guys are totally wrong on this.

Woman: (Ted)?

(Ted Ganiats): That was my question. Since this is outside of HRSA, what is to prevent Carol from just on her own not as a member of this group just writing a letter enacting that it wouldn't have to CC (Gustavo)?

Again I'm asking there's a question that she can just say I don't like this and Donna can say I don't like this and I can say I don't like it, I mean, we can act as individuals without representing this group since it's not part of the federal government. I mean, I'm asking the question.

Vicki Whittemore: I guess that'd occur, I mean, I think we should consider, maybe not make a decision at this moment but we should consider developing some strategy to prevent something like this from happening not only at HRSA but at other agencies that independent contractors voice an opinion that's just totally unsubstantiated regarding this illness. Carol, and then we have to move on. I think we have one more agency, go ahead.

Carol Head: And look, you know, certainly yes, we can reach-out to them and they have no prerogative to listen to me to pay any attention to what I say. They may regard they may not even see why I contact them, they may regard me as another crazy ME/CFSer but I will still certainly do that but I just I really think it's important that we develop...

Woman: Yes, we need to do an official position on this in some way.

Carol Head: ...processes and procedures that prevents this from happening. I mean, I assume it's obvious that, you know, when we are going backwards in the understanding of the disease which occurs with flyers like this, backwards and clinicians see and patients become, you know, a chorus feel underlined by their own federal government so yes, I will take action on this. I have no idea if it will have any impact whatsoever but what's important is that CFSAC put

it on our agenda to work on how to change this systemically so it doesn't occur again.

Sue Levine: Sure, I agree. I agree, okay. Okay, let us move on to AHRQ, please.

(Ted Ganiats): Yes, this is (Ted Ganiats). As I mentioned a few moments ago, we don't have a disease focus just like HRSA doesn't have a disease focus for ME/CFS. I will say on a personal note outside of (ARC) I have dealt with patient advocacy groups for decades and many of them are a huge pain in the butt, highly emotional, not evidence-based, irrational and the ME/CFS people are much different.

And so I think you're fighting somewhat of a I don't understand the disease and somewhat oh no, another advocacy group that just doesn't understand science and neither of those are the case for you so I want to compliment you and recognize that you have a difficult job.

Now back to my official statement, my name is (Suchi Ayer) until a couple of months ago and then I became (Ted Ganiats) so those of you who have been here in the past I am (Suchi) and (Suchi) when I came to the agency since I was on the IOM panel, I'm a family physician.

I do not have a lot of clinical experience in terms of a lot of what's around the table but just what a normal family physician would have. It was decided within the agency that I would become the liaison and I was able to go to the CDC meeting in September, the roundtable that Beth has mentioned several times.

The we talked yesterday somewhat but the other thing was the report that was put-out in May at the May meeting about the physician's guide and the

patient's guide and that (ARC) was going to be working with CDC to make sure that that was going forward.

And as I mentioned, the (ARC) budget did not survive well in the last year and so there were some cuts and CDC was already working on it from our understanding so we have not made any progress on that for the purely financial reasons. Certainly the agency believes in ME/CFS as in the report that we put-out before.

We don't need to be impressed with the science but rather it's just the funding to be able to do that particular project and that's all that I have to add that I haven't already mentioned earlier in the meeting so I'm open for questions.

Sue Levine: Questions?

(Ted Ganiats): And I'm enjoying (unintelligible).

Sue Levine: People take a five-minute break before a couple of comments, go ahead, Carol.

Carol Head: So again, thank you, nice to meet you and I'm enjoying the meeting too and I appreciate that so if I understood what you were just saying that sadly the budget has been cut and (ARC) is not able to develop a physician's guide.

We all understand that a physician's guide is desperately needed. Are you aware of any current plans in any of the other federal agencies to pick-up that work that you're not able to do?

(Ted Ganiats): I wasn't at the May meeting obviously but in my understanding of what I've seen is that CDC was also working on something similar. Is that true Beth or are you only doing the patient guide?

Beth Unger: This is a big, big issue and I don't have a simple answer to it but it's an active point of our discussions this year. We're spending a lot of thought and time trying to figure-out what is the best way to approach this issue because we understand that it is critical and the problem is doing a literature review as I mentioned yesterday is not going to solve the problem.

We need to figure-out how what process we can use to come-up with the guidelines that can be formally graded, accepted. The fact that it's going to be at the level of expert opinion in kind of a move forward and be able to provide a legitimate format to do that and that's probably more than CDC can do alone but with other groups interest and that's why, you know, this form and other settings were so all I can say is we're working on it and I don't have an answer yet. We're working on it.

Donna Pearson: This is Donna Pearson and that's one of the recommendations that CFSAC submitted in August of 2015 so I assume you're kind of basing some of that hopefully on that recommendation we can get our 7% success rate up a little bit maybe.

Beth Unger: Yes, yes, yes. We listened and even when CFSAC doesn't make a recommendation and we hear concerns that are raised, that does inform that's part of our needs assignments. Every time we come here, it's a needs assignment. We do take all of this very seriously.

(Ted Ganiats): This is (Ted) again and I not being part of the conversation earlier, I'm not sure what the physician's guide is. If it's meant to give expertise a short lesson

on what is the disease and how do you manage it, I just don't know if we're ready for it. If the majority of the clinicians do not believe in the disease, why would they read a document about it?

And so my sense is that I don't know where the majority of the clinicians are in the country and perhaps CDC has a better understanding but that's my concern.

Beth Unger: This is Beth Unger and the problem that we run into is if you educate clinicians on how to diagnose it, then you're left with well, what do I do and so you need the parts, you need at least some beginning of what do you do in that and the IOM committee was tasked solely on diagnosis and largely because I think everybody recognized they couldn't do a literature review and come-up with a decision on clinical management.

And there are as I mentioned yesterday (Alberta) has a clinician guide with treatment and the IACFSME has a primer that has treatment in it that and so we need to figure-out how to leverage those resources, perhaps bring both groups together and come-up with a kind of a consensus, then weigh the evidence.

And yes, I mean, I wish the literature was there that we could do a perfect treatment guideline and have controlled treatment trials and it's just not there.

Carol Head: If I could just follow-up on that, this is Carol Head again. (Ted) I do beg to differ on this point. I do think that a physician treatment guide is desperately needed. There are physicians who, you know, believe that "this is real" and we hope that you know, as time goes on there'll be more and more.

And so some information is needed for them at least to affirm their knowledge that their view that it's real and additionally to provide them what information we can about it and then just a second point that's unrelated.

This is so it's not often that I can give enormous thanks. I do want to give enormous thanks to AHRQ for the change you made recently in the understanding of the disease and removing some old inappropriate information from the understanding of this disease so thank you so much to AHRQ and I don't know if that was you personally or...

(Ted Ganiats): It was I promise you it was not me personally but I do take full credit and you didn't notice my non-verbal recognition of Beth's comments. I agree with everything that she said and there were nods and also there was no disagreement about the physician guide.

Carol Head: Great, thank you. Just and I'm sorry, just one quick follow-up and given that the AHRQ has made that change, ideally it would be included then in the annals as quickly as possible. The annals.

((Crosstalk))

Fred Friedberg: Yes. May I jump in, this is Fred?

Sue Levine: Okay, yes, we have like three more minutes, go ahead, yes.

Fred Friedberg: It's Fred Friedberg. I'm sorry, is this (Larry)?

(Ted Ganiats): (Ted).

Fred Friedberg: So sorry. To me this demonstrates how important it is to bring-in clinicians who are not involved with this illness and to give (Ike) I think a very nice fresh perspective and a realistic perspective. There are less than a dozen physicians as Carol has pointed-out who specialize in this illness so who is it that we're trying to reach?

Well, the general physician now we wrote a primer and we said it could take several visits to do a proper evaluation on these type of patients. Physicians will not take that time. Let's face reality. You need something quick and dirty physicians I've been to the ones who would take an interest on this on any level will say look, this is what I suggest to you to the patient to do to try.

In other words, they have something formulaic that may just work but they recognize and give credibility to the patient on some level, not the full embrace of the illness. I think that's a little unrealistic so you have to be able to address those non-CFS physicians if you hope to spread the word about this.

I think we have to get beyond the echo chamber of speaking to each other about what people who don't believe in this illness need. We need to reach them on a level that they're willing to go. In the primer we had some statement from a patient which I really didn't want to have in there about physicians have to open-up their minds.

If you try alienate physicians with accusatory or even suggestive remarks, they're not supportive. They see patients voluntarily not because they're cajoled into it or shamed into it so you have to appeal to them on a level that they will respond to and say look, this will help you with your practice.

You see this patient we don't know what to do? Here's what to do. That may just work so we don't so getting outside people like (Ted) involved to meet is pretty critical so we're not just talking to each other.

Carol Head: Yes, I would basically I believe Fred I know what you're saying with the problem of reaching beyond our group here but I think it could be a disservice to the patient to just let them go to a primary care provider who may not take the time to really delve into the details and exclude other disorders for instance and mistreat the patients. I know what you're saying but I'm not sure that...

Fred Friedberg: Well, let me just respond to that.

(Gustavo): I'm sorry, if you could make it quickly, it's 10:28.

Fred Friedberg: I get requests every week of wanting CFS physicians. I have no one to refer to except people whose practices are usually already completely full so they have to be referred somewhere. Now who is it they're going to be referred to and how do we get those physicians onboard on any level so they will deal with these patients?

Carol Head: I completely agree, I'm just extremely concerned about misdiagnosing someone as well and I think one still has to take the time. I don't know how to solve that problem but I just don't think a quick and dirty type of visit to any physician is the right way to go but I don't want to start an argument.

(Gustavo): Thank you. We have to bring the operator on so we can start our public comments at 10:30. (Elan) are you on, please?

Coordinator: Yes, I am available.

(Gustavo): If you can please call Mrs. (Robatye) who will provide her comments.

Coordinator: (Kristin), your line is open.

(Kristin): Thank you, can you hear me?

(Gustavo): Yes, we can. You have three minutes and we will time you.

(Kristin Robatye): Okay, well thank you so much for taking the time to listen to my story. My name is (Kristin Robatye) and my friends call me (Roby). My dad is (Robert Robatye) and he is there among you right now. For the past 14 years I have suffered from fatigue.

I spent 12 years of that time just trying to figure-out why I was constantly tired and here I'm just going to go over a little over my three minutes and just adding that, you know, talking about a physician treatment guide is so important because we are CFS people are going to primary care physicians and we're being turned away for years upon years upon years.

Just trying to figure-out what's wrong so I bounded from doctor to doctor for 12 years and just trying to find relief from the unrelenting sensation of moving through mud and thinking through fog, I saw physicians, acupuncturists, chiropractors and a hormone specialist, tried veganism, the Paleo Diet, a numbing agent injected into the back of my head, antidepressants, Chinese herbs, neural retraining, chakra alignment and lots of different supplements.

My condition has gotten worse over the years. What little social life I had stopped a few years ago. I am unable to work and I am no longer able to exercise. I can't read more than a short article. I am mostly housebound. If I

do go out for an event or a family gathering, my condition deteriorates even further. The resulting crashes now usually last about two weeks.

During these periods, I am constantly nauseas and feel physically very ill. I've become ultrasensitive to light, sound and visual stimulation. I experience severe headaches and emotional instability. I can only move between my bed and the bathroom and feeding myself becomes a challenge. The most painful of all is that I completely lose the ability to read.

So not only am I unable to escape my broken body by diving into a good story but I also lose the connection to my online community of fellow housebound sufferers of individual illness of invisible illnesses.

These crashes are terrifying. On top of feeling like death, I have to balance a positive outlook with the reality that if I continued to push myself to enjoy the things that I love, I could end-up completely incapacitated. My father who as I mentioned is among you told me that you all heard yesterday from a woman who is frustrated that ME/CFS is keeping her from completing her Ph.D.

I'd like to add that I'm dealing with something very similar. Four years ago I began a master's of counseling psychology program at Texas A&M University in Central Texas. Two years into my program I did my practice on where I served as a counselor for men, women and children.

It was like a dream come true but I was so sick. Between clients I would curl-up on a couch and cry because it was so hard for me to sit up and focus during sessions. Once a week throughout the semester I would spend the night sleeping in my car near the counseling center in order to spend less time driving and more time sleeping.

You all talked about the stigma attached to this and I know that this whole time people are seeing me as lazy despite the major efforts that I'm making to function.

(Gustavo): (Kristin), you have 15 seconds, thank you.

(Kristin Robatye): Thank you so I have a 4.0 GPA and two classes and two internships left. I believe I would be a great therapist. However, I will be most likely unable to complete my master's degree because I have ME/CFS. Instead of working for my dream of helping others through their own difficult times, I spend my days lying around by myself trying not to dwell on the fact that life is passing me by. This condition started when I was 26 years old. I'm now 40 years old and planning to move halfway across the country because I am no longer physically or financially able to live on my own. Of the estimated 2-1/2 million Americans with ME/CFS, draining our economy by an estimated $17 billion, how many of them are being held back from aspirations of helping others, of creating art, of becoming a parent or of being a leader in the community? Millions of people around the world full of potential are wasting away day after day on a couch or in a bed because research for ME/CFS does not receive the funding it requires to discover treatment options.

So thank you all for your time and I really appreciate getting together and trying to work a way to help us to get better.

(Gustavo): Thank you.

Sue Levine: Thank you for your comment.

(Kristin Robatye): Thank you.

(Gustavo): (Leah Williams) if you're on the line, can you please press star 1 so the operator can open your line?

Coordinator: (Leah) was on the line. Her line just now disconnected.

(Gustavo): (Robert Miller), if you are on the line, press star 1.

Coordinator: One moment, please. (Robert Miller), your line is open.

(Robert Miller): Thank you. Good morning chair committee members. I've come before this committee many times over the past 17 years, always with two pleas. One, approve Ampligen as the first medication for ME/CFS, our AZT.

And two, increase NIH research funding so that patients can dream of 21st Century medicine. Every time they've shown Ampligen's restored some of my functionality allowing me to raise my son and meet with federal officials to seek a better response to our disease.

Every time I stress how important it is to approve the first medicine for ME, without a HRSA approval pharmaceutical companies will not invest in our diseases. That's been true for 25 years and it's true today.

Every time I've pleaded with NIH to fund clinical trials, there's a most serious gap in care for patients so today I must inform you that Hemispherx who runs the lone FDA trial for ME is now forcing patients on Ampligen to pay a 167% price increase and it's reducing access so that I and others will not be able to resume the drug that saves us from being bedridden.

It's eliminating the small compassionate care program and it's reneging on promises made to the double-blind trial participants that we'd always have access to the medicine.

Hemispherx is entering an impossible situation and it's taking it out on a desperate patient population causing harm to the patients it's supposed to be helping. Many responders will stop the drug because they can't afford to or won't have access to it.

I've been lucky to have access to Ampligen at a great sacrifice to my family. If Hemispherx retreats from clinical trial, this clinical trial and forces (stop) Ampligen, we have no hope for an approval for an ME drug within the next decade.

There's plenty of blame to go around. FDA didn't believe my disease was serious when it rejected Ampligen that's been given 90,000 times over 25 years and works for a subset of patients.

I protested that denial with an 11-day hunger strike as I knew it was devastating to a million patient who have no treatment and to a small company with no resources.

I was worried the drug would disappear so here we are. FDA learned more about our disease after that but four years later there's no approved medicine, no other clinical trials, no pharma investment and nothing meaningful in the pipeline so I seek help for everyone here.

I ask FDA to urge Hemispherx to restore the original Amp511 trial parameters and move to conditional approval to save a medicine that's so close to the finish line. To NIH, Doctors (Collins), (Collins Sharp) and Whittemore, I ask

you to fund clinical trials this year including but not limited to a well-designed , well-executed trial of Ampligen.

I'm pleased that the renewal of ME research at NIH. I applaud the upcoming RFAs. I've met with you a number of times to discuss a smart approach - thank you - to clinical trials using our experts who have the ability to conduct a well-designed trial.

All the parties are willing. Imagine what we'd learn about Ampligen and why it works in the responders, a point Dr. Unger has made many times but it can't be put-off for years. We're out of time. There's a real human cost to this hole in the plan. NIH funded trials to AZT for AIDS and it's now funding a rituximab trial for (Myacenia gravis) and 20 other clinical trials.

ME patients deserve equal treatment and we need it before Ampligen disappears. The imperative to find treatments is on everyone in this room. Lastly, Hemispherx. You need to put patients first. Rescind these predatory changes and stay on the side of patients. I thank you all for your work. Thank you.

(Gustavo): Thank you, sir. Eileen Holderman? If you're on the line, please press star 1.

Coordinator: I do not believe Eileen is on the line. (Leah) has dialed back in, though.

(Gustavo): Can we hear her comment, please.

Coordinator: Certainly. (Leah) your line is open.

(Leah Williams): Hi. My name is (Leah Williams). My husband and I live in Cambridge, Massachusetts. Both of our children have ME/CFS. My son now aged 21

became sick when he was 12. He had what seemed like an ordinary cold expect that he never got well again.

Instead he suffered increasingly from headaches, joint pain, unrefreshing sleep, overwhelming fatigue and difficulty concentrating. He missed most of high school because he was too sick to physically attend school. His health has improved somewhat over the last few years and he is attending college but he does not have the energy or stamina of a healthy kid his age.

My daughter now aged 18 also become sick at around the age of 12. Her symptoms were similar and equally debilitating and have gradually gotten worse. She has enrolled at our local high school but is much too sick to attend. She is taking online classes and has a tutor at home.

We have had a wide range of experiences with schools from warm and supportive to benignly neglectful to openly hostile. The best experience was the grammar school that my son attended for the first three years of his illness.

The school staff were able to accommodate his highly variable attendance. Some weeks he could go a few hours every day and some weeks he was too sick to attend more than one partial day. They worked closely with us to send work home for home, to accept work late and to modify assignments.

These accommodations enabled him to successfully complete sixth through eighth grade. The worse experience was the school my daughter attended for eighth grade. In spite of the Section 504 plan describing her illness and the accommodations she needed and in spite of letters from her doctors, the school staff made everything as difficult as possible.

The principal said that my daughter could not make-up work that she missed in class and I was not allowed to come-on campus to drop-off or pick-up assignments. The school social worker told my daughter that she had to either throw-up or faint before she would be allowed to leave a class.

The assistant principal filed a truancy claim against my daughter in juvenile court. Finally eight months into the school year, the school administrators agreed to the accommodations we wanted all along, a waiver of attendance policy, partial school days and modification of assignments and my daughter was able to successfully complete eighth grade.

I think that awareness and education about ME/CFS would have made a huge difference. If the school staff had known what ME/CFS is and how it impacts schooling, they might have approached our situation differently. This was a few years ago but it would have helped if they could have found accurate and up-to-date information at the CDC Website.

It would have helped if the school nurse had attended a continuing education program on ME/CFS. It would have helped if the public health department's school health manual mentioned ME/CFS at all.

And of course it would have helped enormously if there were a diagnostic test for ME/CFS and for that we need more research funding. Thank you for this opportunity to comment and thank you for all of your efforts on behalf of patients and their families.

(Gustavo): Thank you so much for your comments. (Jennifer Spatilla), if you're on please press star 1.

Coordinator: One moment, please. (Jennifer) your line is open.

(Jennifer Spatilla): Thank you. Start is you mean to go on. This is a commonly-used phrase at New Year's. It's supposed to be motivational I guess. It means be intentional as you begin the New Year. Start reading more books or taking more walks or whatever your goal may be because how you start influences how you will continue forward.

I'm going to take my own advice and toss my prepared comments because based on the discussion this morning, I want to scream let's start now. Let's start by tossing what's been done. Let's start by thinking outside the box. If you want to design better educational materials, if you want to recruit new investigators, if you want to progress a treatment to approval within the next 10 years, then it is time.

It is time to roll-up our sleeves, work hard and work together. I've been an activist for close to two decades. We have got to do something different in order to achieve different results.

I think it's time to ask how can we achieve the results we want instead of following the same path and procedures that are entrenched in the system. There's so much uncertainty right now with future budgets for research and assistance on any patients are extremely vulnerable now.

Many are wholly dependent on SSDI, Medicare and Medicaid and all of us including those of you who don't have ME but have something else, we all rely on the protection of the preexisting condition rule to obtain health insurance. You already acknowledged this morning the vast majority of patients with ME can't get appropriate diagnosis and care.

They don't have access to the handful of specialists nationwide and we can't even decide apparently what appropriate care is because we're looking at how we've always put guidelines together before instead of saying we need guidelines, how can we get that done?

The vast majority of patients are dependent on full funding of NIH research in general and ME research in particular. If we don't do this, if we don't do something different then I'm worried because we are losing people with ME to suicide because they are too sick to go on.

Efforts to help us are still too slow, too small and too easily ignored. Promising scientific ideas gather dust while we wait for funding and the ME researchers and clinicians alike are still having difficulty finding experts to replace them as they retire out.

If we don't do this, then I'm actually scared. I am scared that I will recite variations of this litany year after year as I get older and the last of my supposedly productive years leach away.

Let's demonstrate forward-thinking leadership and set a high standard with which to measure federal agencies performance. Let's sit down at the table as equals and quickly we need to start taking action. This is the only way I see to create a better future for people with ME.

I am ready, I am desperate. I have volunteered for every volunteer opportunity that there is because this is my mission in life, to make sure that someone else doesn't get sick at age 26 and is now pushing 50 and still just as sick and no hope of change.

It's on all of us. It's on all of you in the room. Let's do something different. Let's roll-up our sleeves and get to work because time's a wasting. Thank you.

(Gustavo): Thank you.

Coordinator: Sir, Eileen has dialed-in now. Would you like to take her line.

(Gustavo): Sure.

Coordinator: Eileen, your line is open.

Eileen Holderman: Thank you. Good morning to the committee members and stakeholders. I'm Eileen Holderman, an advocate for ME, GWI and other neuro immune diseases. I formerly served as the patient advocate on CFSAC. We shared two subcommittees.

One was for the review and improvement of the CDC Website. While I believe advocates' efforts should always be ongoing to improve government policy, I am dismayed when I see efforts that are redundant and seemingly futile.

Specifically I am referring the efforts advocates are asked to make in regard to the TW - sorry, the TDW - for the improvement of the CDC Website not only because of my subcommittee's work for four years but because of the efforts of all my predecessors. Today I will read into the public record excerpts of an open letter I wrote to Dr. Beth Unger of CDC at the time I completed my four-year term on CFSAC.

Here are the excerpts which unfortunately still apply today. Dear Dr. Unger...As I prepared to write my thank-you letter, I checked-out the CDC Website so my final remarks would be accurate. To my surprise and dismay, I noticed CDC created a new Webpage to feature May 12 awareness day.

I say surprised because there was no mention of it to me or my review panel and there was an opportunity to mention it as recent as last Friday during my subcommittee teleconference when I asked if there were any announcements from HHS. You will recall that my inquiry with an awkward silence.

Had CDC communicated to me that they planned to feature May 12 awareness day with the erroneous content of the CDC Website, I would have objected. Furthermore, our national and international ME/CFS and FMS organizations do an exceptional job of raising awareness for these diseases so CDC need not undermine those efforts.

I appeal to CDC to remove the new Webpage as advocates have already begun to voice their justified criticisms of the content. For the past four years, my review panel and I have made countless suggestions to improve the CDC Website.

While CDC did make changes to the general sections of the Website, my opinion is that most of the changes were cosmetic, not substantive. The CDC Website still resembles the Website for the condition of chronic fatigue instead of the Website for the neuro immune of Myalgic Encephalomyelitis.

Below on my specific though not my complete list of recommendations to improve the CDC Website that need to be but have yet to be implemented. Remove the resource guide, remove the toolkit, remove the expired and delist emergency preparedness Webinar.

Remove the expired CDC medscape video online course. Remove all references to the Oxford case definition in the CME online courses. Remove references to CBT. Remove references to GET. Remove reference to St. Parks and ICE guidelines. Remove all links to CDC's psychosocial published studies on ME/CFS.

Remove all implications both subtle and overt to ME/CFS as a psychogenic and/or fatigue condition. Hopefully the CDC Website will get onboard with our 50-plus ME/CFS experts and adopt the CCC in their CMA courses and in all their content and reference the 5000 plus biomedical papers on ME/CFS and offer links to the IACFS/ME primer and the ME ICC primer and a section on pediatric ME/CFS. The CDC Web site needs to reflect the serious disabling nature of this neuro immune disease affecting nearly 1 million American men, women and children and 17 million worldwide.

Again, thank you for the time and consideration you, (Armeus) and (John) have given me and the review panel in regard to improving the CDC Web site. Best regards, Eileen Holderman.

I wrote that quite some time ago. And I realized that most of it most it still applies. And I find that very disheartening as do many, many advocates. So our hope is that we will stop, like, the homework and the busy work and do the real work. So thank you very much for your giving me this opportunity to speak today, and I wish all of you well.

(Gustavo): Thank you so much. Nancy McGrory, if you're on the line, star 1 please. Or are you in person? Sure, come on up.

Coordinator: Nancy is not on the audio portion.

(Gustavo): She is here in the room. Thank you.

Coordinator: Okay. Thank you.

Nancy McGrory: Hi. I'm Nancy McGrory. Most of you know that I work with Hemispherx. I'm a consultant and contractor, but I have been with them for 10 years now. Hemispherx has chosen not to speak at this time, but I will speak for myself as a patient advocate and someone who does advocacy in other arenas.

I will clarify one point for Hemispherx. There has been some question about whether we produced the product. Ampligen has been produced. It is in the inspection processes. So we have moved on with those. So I just want to clarify. There's been some confusion by patients.

I'll make this very quick. I started here 10 years ago. And the same thing. Had all the hopes that everybody else does that something would happen. I actually at the same time started a PTSD program with my husband and a few friends. It's basically been a shoestring budget for the 10 years that we've been doing it. And what I do know is that stuff can get done.

We were told in the very beginning that they wouldn't be able to do it. You know, that the VA wouldn't allow it. We were outside the realms, all those other things. I'm proud to say that today we've done over 60,000 hours of training. We have had over 8,000 veterans through our program in that 10 years. And I'm talking on a shoestring. We've managed to get in contact with the VA and work with other things.

What I do know about regulations, and I'm very good at doing my homework on the regulations and understanding how government works. I've done

government advocacy for almost 25 years. I'm very clear that you guys have lines and rules and all those. Most of us are really good though at figuring out how to stay in the lines and still move things forward.

So I would ask you to look very hard at where we just get stuck with just a common rule of saying well, it's not what we do. It's not how it's done. Blah, blah, blah. You know, it's just being relentless about the fact that we can move things forward. Rules are put in place so things don't get messed up, but they're also put in place to keep guiding us forward.

And I will tell you every day if you get up and you figure out one way, one way to help one of these patients, it will make a difference. And it's sad to watch people like (Bob Miller) year after year be this sick. And it just makes me ill that we can't - just can't do anything. And I know that we can. That's the part. I actually know that because I've done it on my side. And I will tell you, it's been a labor of love and hard work, but every day I'm really glad that I can say that I did it.

(Gustavo): Thank you, Ms. McGrory. (Gabby Klein), if you are on the line, star 1.

Coordinator: One moment, please. (Gabby), your line is open.

(Gabby Klein): Hi. My name is (Gabby Klein). I'm a patient advocate and blogger. I've been ill with ME for 14 years. As I sat down to write, I thought about the current situation as ME patients at the start of the year 2017. I thought about the comparison of the state of ME patients today to a decade or three ago and became aware that there have been next to no improvements made throughout the years due to HHS neglect and misdeeds.

Over 30 years after the Lake Tahoe outbreak, few doctors nationwide have the knowledge and experience necessary to properly diagnose and care for patients in the same harmful way. GET and CBT therapies continue to be recommended by HHS. There are no FDA approved drugs. NIH still spends a miniscule amount of money on a disease with an enormous economic, mortality and quality of life burdens. The CDC and other HHS agencies continue to spread incorrect harmful information on their Web site and in their continuing medical educational material.

They're all scientific. And amazingly, CFF is still being used. And the government still controls and fabricates incorrect and overly broad definitions like the IOM. HHS continues to cover up their negligence and malfeasance with the creation of more committees, workshops and working groups, giving the false impression that they're actually doing something for the patients.

Due to the continuing lack of transparency as well as a withholding of crucial information from the patient community, the recent incident of NIH's invitation by Dr. Wallace, with Dr. Nath's approval, can he deny Dr. Shorter's lecture on the false history of the disease is a prime example? False promises are frequent as in Dr. Cowen's promise for a considerable increase in funding for ME/CFS. It has in reality resulted in mere crumbs, an increase of $7 to $8 million for a million U.S. disabled patients.

Moreover, in his eight years of service, NIH Director Dr. Cowen has never mentioned the ME/CFS when speaking to a senate appropriations committee advising of sufficient increases in NIH funding. Until HHS publicly apologizes to the ME community for their pleas that came from neglect and malfeasance and until the time when HHS exclusively uses our expert criteria which is the CCC, ICC or Ramsay's, uses the correct name, myalgic encephalomyelitis, properly educates medical practitioners, appropriates NIH

funding to a figure of a minimum of $250 million a year, which is on par with other similarly chronic diseases, I will continue to challenge and hold the federal government accountable.

Thank you.

(Gustavo): (Mrs. Klein), you've got 15 seconds. Thank you.

(Gabby Klein): Thank you. I'm done.

(Gustavo): Thank you for your comments. (Luetta Van), is she on the line or in the room? If you're on the line, can you please...

Coordinator: (Luetta), your line is open.

(Luetta): Hi. Thank you for this opportunity. And I would like to thank the incredible patients that have spoken before me that worked so hard on this. It just blows me away what they're able to do.

I'd like to call your attention to the January 9 blog written by patient Tina Tidmore called Just My Honest Opinion entitled Wallit Invited Shorter and Nath Approved Him. It begins on November 9. Dr. Shorter of Toronto gave a presentation to NIH officials on the history of ME/CFS. The fact that this was going to occur was not shared with NIH conference call with patients just seven days before. Dr. Nath, the NIH official leading the new clinical study on ME/CFS, was there and on that patient call.

When patients later found out about the talk from someone not at NIH, several letters were sent. The speaker's comments were already known to be disparaging of patients and discrediting the biological basis of the disease. I

have participated in several studies focused on Lyme and NIH over the past 17 years. In 1998, 13 years after my first diagnosis of ME, I was bitten by a deer tick and quickly developed an encephalitic form of Lyme's disease. The doctor who admitted me to the hospital in Bethesda had ties to NIH where I was transported, where I have benefited from the knowledge of outstanding doctors.

Dr. Shorter had a dual appointment in the faculty of medicine at the History of Medicine Program at University of Toronto and is widely published in the field. His presentation was illustrated with old cartoonish figures as he characterized psychosomatic illness as the sum of patient's view of the illness with that patient hoping to convince the doctor of organicity through visual appearance.

The audience was tutored in globus paralysis, the 19th Century rife with whole body functional motor complaints and functional paralysis and later motor disorders emerging with World War I as part of battle fatigue. Shorter recognized a great shift when pain and fatigue replaced paralysis in the symptom pool because he claims doctors cannot prove a patient is chronically fatigued or dizzy. The part of the talk that addressed the social dimension of pain and socialized experience included 19 points that concluded the day hypersensitive patients reinforced each other in support groups.

CFS is a toxic diagnosis that brings decades of illness, breaks up marriages, loss of jobs and fits the pattern of illness attribution and spreads virally. If I were to pick out a single most important thing in Dr. Shorter's presentation to NIH, it would not be the cartoons he used to depict the patients or the intentional attempts to distance his lecture from the study group or the failure to communicate directly and forthrightly to patients during the conference call.

What concerns me most is Dr. Shorter's blatant recommendation during the Q&A that would effectively disenfranchise study participants from their community. Dr. Shorter clearly told the doctors to get rid of the name CFS. It legitimizes them if you study them. Some might not already be stamped. And to paraphrase, some might not yet be involved in patient communities. He said you can study them by changing the label, but not the illness belief.

My interpretation of these words would bar patients from knowing the name of their diagnosis and thus barring them from knowing each other via social media and the extent body of literature about their illness. It would also bar patients from seeking appropriate medical care. This proposed suction and isolation depriving incoming patients of the very name of their illness that they are diagnosed with is a tactic of an abuser.

That Dr. Shorter is of an era where doctors and patients are not partners, but rather a paternal relationship with doctor knows best and the patient is devious and will attempt to choose illness rather than embrace all that one loves about his or her life punctuates the need for patient stakeholder involvement if we are to build bridges at NIH.

Thank you.

(Gustavo): Thank you so much for your comments. And that concludes the public comments for this morning. To all of you listening on the phone, if you submitted your comments by the deadline to the SF-SAC inbox on January 5, your comments have been added to a binder and shared with all of the committee members.

And now we're moving on to - I'd like to introduce Dr. Karen DeSalvo. She's the Acting Assistant Secretary for Health who will give you greetings and welcome. And then we'll move on to one of the war group presentations. Dr. DeSalvo.

Dr. DeSalvo: Thank you, (Gustavo). And good morning to everybody. Thank you all for your forbearance as my schedule is changing. We're in the last few days of our time here as appointees. And so there's so much work to be done. I just want to thank the committee for making time for me to make a few high level remarks.

I want to thank Dr. (Levine) for her leadership and her ongoing service not only to this group but to the public in general. And I want to thank (Karen Scott), who I think has just really been terrific for the last few months in helping us put some new structure on this group.

I do have some written remarks. I will make sure I try to touch on everything in there. I wanted to just begin by saying I come to you all directly from leaving the Secretary. One of the topics that we discussed was ME/CFS and this committee.

I raised with her as part of my exit conversation the importance of the work that we've been doing in partnership with some folks from this group and from beyond to really give a hard look at this charter and how this group is comprised, how we receive input at HHS in a structured fashion and also how we work as collaboratively as possible not only across HHS but with other partners like at the VA and the DoD to build as much science and cultural change and understanding on the part of the scientific and healthcare community so that we can bring change to bear as quickly as possible.

So I just want to assure you all that I come directly from carrying that message to her as a part of the exit and that similarly I have this as a priority issue for the incoming ASH that I want to make sure we don't lose the momentum that I believe that we have been building. I will probably not read my remarks then and just say that one of the questions that we asked ourselves and others starting last spring was if the charter needed to be renewed just to get concrete about this body, which is the way that we have punctuated opportunities for input but also for engagement in conversation and how we help keep on track the work that is happening again at HHS but in inner agency fashion.

I certainly felt strongly that we needed to continue the FACA. And I will say there were others in leadership across HHS who agreed. We felt that even though it was imperfect in the way it may be structured, we wanted to iterate on it to improve knowing full well that what we would hope that this group would do in its new formulation is take the charge on of really reflecting back not just on the content issues around science and clinical care as examples but also on the how we communicate and how we hold people accountable and have clear milestones that we're tracking on and moving forward.

So that's reflected. And in the charter it's also reflected that we've asked to add more patient and advocate input. I tell you that the processes being what they are at the end of an administration, we were unable to get the package across the line. The clearances are all completed. But it's still in process. That's in the hands of career officials mostly.

And it's not - I'm not trying to - the reason I point that out is because there are stable people who are still working through it to make sure that it will happen. It's one of the reasons I left it as a priority item for the next Assistant

Secretary so they would be on the lookout for it and make sure that the new membership can be added and we don't again, lose the momentum.

So I want to assure you all that this a high profile area that we are not going to lose track of what we did in terms of iterating on the charter knowing full well that there's going to be - I hope that you all will come up with an additional opportunity to further strengthen and clarify the direction and the expectations around milestones and how we get input, but also that we're doing that with a table that includes people who are more directly impacted. And my experience in other work in this space is that that enriches the conversation pretty significantly because you're doing things with people and not for them.

I want to really commend my colleagues at the NIH. I think that in the last - I know it's not where people want it to be so I'm just going to lay that out. But I will say that it's come really far in the last year. I believe that their recognition that there needs to be nodes of scientific grounding across the country that are not only helping to build longitudinal cohort data to help understand not only that the diagnosis but the trajectory of disease to help improve diagnostics and therapeutics and advance the science. And hopefully if we can sort it out, that would be a way -- or I'll be gone -- but they can sort it out in a way to advance the cultural change and expectations that we need to have in the clinical environment.

It's an important step in. And I think that I really thank them for that work. And also we have some ongoing partners like CMS and the CDC and the FDA and the HHS family who have been a part of this. HRSA as well, who has such a strong opportunity around workforce education and development. And I want to thank the folks at the VA and --I don't see them around the table -- and the DoD who are joining us. I reached out to my colleagues there in those other agencies knowing that they have additional scientific opportunity,

resources, clinical experience and opportunity. I think as much as we can bring to bear on the getting clarity around, again, diagnostics, language, culture, clinical care. And the more we can do that together. the better off we're all going to be.

I think I would convey back to you all that this sense of urgency and pressure has been well conveyed to me. So I want to reassure you that I heard that loudly and clearly from people who are carrying your voice. And thank those folks who took the time to come in and meet with me a couple times over the last few months and help us put some understanding inside of HHS.

So I leave feeling hopeful and frankly positive that we're moving in a really good direction. That we have more work to do, but I see us turning the crank, as Secretary Burwell would say, to get better understanding about who needs to be at the table, how can we bring the best thinking not only in this national capital region, but across the country and really turn this into more of an evidence based and cultural change endeavor than I think we've been able to have the momentum to do before.

So I thank you all again for your passion, for your work, for your education of all of us and others. I thank our partners for being ready, willing and wanting to really put their shoulder to the wheel. And I look forward to continuing to follow this work as it goes along in wherever I re-emerge in Louisiana into the future.

And again, thank you all very much.

Do I take questions?

(Gustavo): We can take five minutes of questions.

Dr. DeSalvo: Okay. And thanks to whoever wrote my remarks. I did read them. I did try to incorporate them all.

Woman: Well, I can't resist asking. Thank you so much, Assistant Secretary, for being with us here today. It's very much appreciated. And your very positive comments reflect the experience that a couple of us who had the opportunity to speak with you before demonstrated at that time.

I have questions that I know you can't answer, but I just, you know, obviously, this is a strange and odd and interesting time in Washington. And it's very difficult to predict what will occur next. But if for the moment we assume that Mr. Price may become our new Secretary of HHS, can you help us understand then in terms of timing when we might expect someone to fill your spot?

I know you've committed to make certain that that new individual, whomever he or she might be, will understand from you directly the importance of ME/CFS. But can you help us sort of understand how that path was forwarded? Any speculation you might have about timing would be helpful.

Dr. DeSalvo: Certainly. The typical scenario is that the Assistant Secretary for Health post is occupied by a new appointee somewhere in late May or in June. That's what as I've looked back historically it seems to be about the time window.

And so in that circumstance, our expectation is that there will be an acting career official who will be able to make announcements about that pretty soon. I'm expecting it to be someone who already works in HHS in my office who's knowledgeable and wonderful. But we leave that to - the incoming team also has to weigh in. So we don't want to get ahead of the process there.

I would say something general and then I'll give you a story that I actually heard earlier this morning from someone that may give you all some cause for reflection. The kinds of public health professionals and medical professionals whose names I have seen floated to become Assistant Secretary for Health are really qualified, thoughtful, caring, scientifically sound individuals. I feel really good about the kinds of potential succession that there is likely to be for the ASH position. And I think that's true in many of the other agencies, OPDIVs and STAFDIVs, operational divisions and staff divisions.

I think that's sort of grounded in the idea that the work that we do is grounded in science. And we want to build strong policy that's grounded in that. So I am an optimist, but I also knowing what I know about the potentials feel positive about that what that will look like.

You know, I heard a story this morning about C. Everett Koop, who was the Surgeon General in the Reagan administration. And I remember - what do you all remember about C. Everett Koop besides the beard and the uniform?

Woman: Tobacco.

Dr. DeSalvo: Tobacco. And NHI, of course, you're going to get - that's my girl. So she's raising this issue about - for those who can't hear - that C. Everett Koop came in and did some great things on smoking, but he is remembered in the public health world also for his work in - in the HIV world for his work in HIV. And including him using the bully pulpit to send a mailer to every single household in the country to give them information.

And he was probably fighting against some political wins and didn't necessarily - had to really convince, I think, some folks inside of government

about, including maybe in the White House, about how aggressive to be in the HIV space. And the story - and change the trajectory of how we understood that there was science, how to advance the science, how to change the culture, how to educate every person.

And the reason I share that story is that there were many in the public health world who were very worried about C. Everett Koop because he had a very conservative track record, including one where he was very conservative about reproductive rights. But he made it through the confirmation process and then in the end surely has saved millions of lives because of his work he did in HIV as a result.

And so it just was a good public health reminder to me that where there's strong science and good public health professionals, good clinical professionals, that prevails. So we should not be so worried about what we read in the paper. I think at the end of the day people will do good work.

And the last thing that I'll say is about the courier employees. I just am floored by the talent that you all are supporting in the federal government, that we're all paying taxes for. There's just - it's not just about scientific talent or policy talent or programmatic talent. It's really also just a very mission driven group of folks no matter ideology. They know they're here to serve the American people. They know the people in America. They know they're here to, you know, improve the health and wellbeing of people in this country. That's certainly for the HHS folks.

And so as I walk away from time at HHS, what I feel really great about is all the people I have met in my journey here in three years who I know really care and want to do the right thing as a default and will. And so I just leave with a lot of confidence knowing that you're in those great hands.

Man: (Unintelligible), Stanford University. Thank you for your presence here. This is really important. Given that any CFS has reached, I think, a historic momentum where government agencies and academic centers like mine are really interested in solving this puzzle and finding really what ME/CFS is and finding effective cures.

But what really is needed is what has not been there for so long, which is important significant support for research dollars. And we are talking funding the order of hundreds of millions of dollars a year that really are needed to make an impact and a difference to attract new researchers to do a state of the art research with newer technology and multi-disciplinary teams. And I could not agree with you more applauding the NIH initiatives and desire to do this.

But the research dollars for this is really quite limited. So what would be your advice for this committee for the incoming administration? Where can we go to request that level of funding, hundreds of millions of dollars? I know the President can have initiatives like for the brain, like for Zika, in the orders of billions of dollars. What would be the most effective way for us to seek that level of funding?

Dr. DeSalvo: So as Beth knows, I have - there's only so much that I can say about that while I'm here. I guess my sense is from a strategic standpoint you can imagine that - so let me put it this way. The budget for HHS comes from the Hill. So we are in many ways responsive to the resources that we receive.

We also try to build a case and a foundation for why there are public health or medical or social services or other needs in this country so the evidence base helps to build the case. And over time, I think you see that in some areas that

begins to build the resources and foundations. So it's an iterative process. There are many players involved and they go beyond HHS.

I will go back to the VA, DoD, not that I'm trying to take money from them. But I do think that where you only have a, you know, a few nickels and some friends, or a few millions and some friends, and you're trying to really build a foundation and let it snowball, getting more friends is helpful. So even if they only have existing scientific agendas in the area, having them understand opportunities. They have different populations, different ways of developing their scientific portfolio, their clinical portfolio, looking for cures.

So I think maybe what I'm trying to say is it's a system. It's iterative. So there's many parts in it. It's iterative. And there are many players outside of HHS who I think can also help us think through some solutions to the big problem of how we make sure we get to clarity on disease and cure.

I should probably go. But I want to thank everyone again. And I thank you guys for your time. And I'll let (Susan) get back on her agenda. Thank you all.

(Susan): Thank you.

(Gustavo): Thank you. Beth, you're up.

Beth Mattey: Actually, Carmen's going to go first.

(Gustavo): Okay.

Faith Newton: While she's getting ready, this if Faith Newton. And I was in charge of supporting the pediatric needs of educating students working group. We've got two presentations this morning. We may only get through one. We may

end up doing the second one when we have the 3 to 4 o'clock recommendations. Beth's fine with that and she can stay. So that will give Carmen a little bit more time.

Carmen Sánchez is here from the Office of Special Education Programs. She manages the Parent Training and Information Centers across the nation. And one of our charges was to evaluate the need and the feasibility for a cooperative effort between HHS and DOE to improve physician's awareness of their role in assisting pediatric CFS patients and their families to acquire appropriate special education services in the school. So welcome, Carmen. And we appreciate you being here.

Carmen Sánchez: Thank you everyone. I'm Carmen Sánchez, and I work in the Office of Special Education Programs at the U.S. Department of Education. And I'm going to go over some materials that maybe many of you are familiar with and maybe some of you are not necessarily familiar with, which is essentially how does the educational system work for providing services for children who have disabilities or chronic health conditions? And then also talk about specifically the program that I manage which has to do with Parent Training Information Centers to support families with children with chronic health conditions and also disabilities to get the most benefit out of their education.

Let's see now. Oh, here we go. Okay. Children with CFS can be served if found eligible under either Section 504 of the Rehabilitation Act of 1973. One of the public commenters mentioned that their children have a Section 504 Plan. And they can also be served under the Individuals with Disabilities Education Act, which is otherwise known as IDEA.

You see here in the handouts what are the requirements to be eligible under Section 504, which is to have a physical or mental impairment that

substantially limits one or more major life activities or having a record of such an impairment or being regarded as having such an impairment. And then also under IDEA that students eligible for special education services must meet the criteria in the statute to be considered a child with a disability.

So what is a Section 504 impairment? What is a physical and mental impairment that substantially limits a major life activity? I'm not going to read this all out, but this is actually the language that's there in terms of how you determine whether or not you have a physical or mental impairment that limits a major life activity. And then within that, there's also a definition of what is a major life activity and that includes things such as eating, sleeping, standing, lifting, bending and so on.

I also want to point out - and the bold is my bold. It's not actually in the language. It's just sort of draw your eyes to what's most important from this language. There's a list of examples of what constitutes major life activity in Section 504 regulations are not necessarily exclusive. They're fairly expansive. And they're meant to be also now a sort of measure of people having their own ability to say that they have an impairment that affects their life.

In IDEA, for a child to be with a disability you must meet these categories. And you see that again I have highlighted other health impairments. So again this is a fairly expansive list as to what can be considered a child with disability. But the second part of being a child with a disability is in addition to having either one of these conditions under these categories you also need special education and related services in order to benefit from your education.

Section 504 is a civil rights law that applies to all programs receiving federal funding, including public schools and charter schools since they receive

federal funding and prohibits discrimination on the basis of a disability. IDEA is a law meant to assure that children with disabilities have access to a free and appropriate public education and improve their educational results. Currently, actually, there is a case being tried right now in the Supreme Court about what does this mean for some children.

Children eligible to receive IDEA services are usually also covered under Section 504. They still have rights under Section 504, civil rights. And because they're covered under IDEA, they're not required to have a Section 504 Plan because the individualized education program is part of that.

State and local educational agencies have policies and procedures for complying with both Section 504 and IDEA. As I just mentioned, Section 504 requires the development of a plan for access, accommodations and services for eligible children. IDEA requires the development of an Individualized Educational Program, or an IEP, for eligible children.

Section 504, as I just mentioned, doesn't require a separate plan for children who are eligible under both with an IEP who meet the requirements of Section 504. Each of them, however, have different due process procedures. And within the Department, it's our Department's Office for Civil Rights that monitors compliance with Section 504 while my office, the Office of Special Education Programs, monitors compliance with IDEA. So there's different systems for monitoring compliance with these laws and different systems for due process. I just mention this not necessarily to get into the nitty gritty of it but just to make you aware of the fact that that exists.

So how as a family would you navigate this? How would you go in and say my child needs services and how would you navigate this? IDEA provides funding to states to our discretionary program. Well, to our formula grants to,

of course, provide special education services for IDEA eligible children. But we also provide discretionary funding to states, institutions of higher education and non-profits to support the provision of special education services.

In IDEA, institutes assistance of Parent Training Information Centers and Community Parent Resource Centers, which are collectively called Parent Centers, to help families navigate systems. We also have a system of Parent Technical Assistance Centers, or PTACs, to support those parent centers in doing their jobs.

So I'm going to go into what constitutes their jobs. This is again, just for your reference, Section 670 of IDEA which institutes these Parent Centers, say that the purpose of the Parent Centers is to help parents receive training and information to help their children meet their needs, need challenge in academic achievement goals and lead productive lives. It's also to help parents understand their rights, their responsibilities and protections under IDEA and to cooperatively and effectively participate in planning and decision making.

I also want to point out as I go through this language that even though it is sort of centered on the IDEA, the actual statutory language is most Parent Centers are also obligated to serve families of children who are suspected of having a disability. So they also have to be knowledge of that Section 504 even though it's statutorily not referenced.

So who do they serve? They serve children with disabilities, parents of children with disabilities living in the area served by the Center. And they have to serve parents of children with a full range of disabilities. They also have to serve parents and children who may be inappropriately identified.

They have to serve underserved parents, such as low income parents or parents of limited English proficient children. And they can serve teachers and other professionals in helping them learn how to serve families and children.

Specifically, they provide training and assistance to help Parent Centers understand their children's disabilities and their educational needs. Again, understand their rights, responsibilities under IDEA. The third part, communicate effectively and work collaboratively with educators can also be fairly expansive. It also includes administrators, nurses, other health professionals, participate in their children's education, resolve disputes with the schools and participate in activities at the school level that benefit their children.

I also want to point out the last bullet, help parents participate in school reform activities. Parent Centers can also help parents do work around helping their local educational agencies develop policies and procedures that are most helpful to the families that they serve. The variety of the services they provide include one-on-one assistance, workshop, publications and Web sites.

We have 63 PTIs that serve states or areas within states, the District of Columbia, Puerto Rico and the Virgin Islands. We have 23 community parent resources services that target underserved communities. And I give you an example here of what we mean by targeted underserved communities. These are five year competitive grants. Having said that, because there's very few non-profit groups who are in position to do this kind of work and be this expansive in terms of serving all disabilities and all families, we tend to have the same non-profit groups be funded year after year after year. Not always but we do have a great continuity in terms of the actual groups that win our competitive grants here.

This is an example of Colorado's federally-funded PTI, their Web site. This is an example of a CPRC's Web site. The Parent Technical Assistance Centers are to help these Parent Centers to more effectively coordinate their parent training efforts, disseminate research and information, reach underserved populations and provide many other supports to better serve families.

We currently fund nine Parent Technical Assistance Centers. The Center for Parent Information Resources is the national one. Six regional PTACs, one that's focused on the needs of Native American families and another on the need of military families.

Let me give you an example of the kind of thing that they do. They may sponsor a webinar. Most recently we sponsored a webinar about traumatic brain injury and what the implications are for children with traumatic brain injury as they learn. And that was not aimed at families but at educating the staff that work at the Parent Centers about what that means in there for the kinds of questions or resources they can provide to parents.

This is on the Web site. This is the CPIR site and it tells you that. I'm going to go quickly through that. The CPIR site we refer to as the Parent Center Hub url, parentcenterhub.org. And you're free to explore that and see the kinds of things that they have on there. One of the things I can show you is, for example, they have resources there on Section 504.

So they are a central repository for a lot of information around a lot of different disabilities. The families can access directly. But mostly we promote to have the Parent Center staff access them.

Before I get into this, I want to make another comment, which is our funding levels for all these centers has been $27,400,000 for several years now. Our

Community Parent Resource Centers are funded at $100,000 a year. Our Parent Training Information Centers are funded at a minimum of $200,000, but our largest only receives $750,000, I believe, now.

So that gives you an idea of what kind of funding levels they have annually. They are resourced. And, of course, we can now hope that they can be resourced better because the need is so great. But this gives you some idea. Having said that, that is not often for these organizations their only source of funding. For example, the Parent Training Information Center in New Jersey, I mean, I think, their overall budget now is hovering between $4 and $5 million because they are able to leverage our original funding to get funding from a lot of other sources, including the state. And therefore, that builds their capacity to do work around some health issues and education issues.

So I just wanted to say that some of the things I was thinking about as to how we might be able to do some collaborative work is that Parent Centers can provide information to parents or children with CFS about their educational rights, that's their job. PTAC can provide Parent Centers in their regions and nationally information about CFS and how that may impact children's education.

The CIPR, we can always have them include a page specifically about CFS on the Parent Center Hub Web site. But having said that, and going back to the resource issue, they can't create those materials. They have to really receive reliable information about CFS and receive reliable materials in order to share that throughout the network. And then it's important that CFS organizations and programs to also refer families to Parent Centers and advertise their services around educational issues. And they're still around health issues, but around educational issues and how to navigate educational systems.

I will have questions. But on the last slide, besides thanking you for allowing me to speak to you, I just wanted to let you know that the Office of Civil Rights just released a Parent and Educator Guide to Section 504 in Public Elementary and Secondary Schools. It's pretty comprehensive. And that also can be something that you can share with families and others as they think about how they would get good educational support for their children.

I went through this quickly because I didn't have a lot of time and I really wanted to see if there's any questions or anything we can hear.

Yes?

Donna Pearson: Thank you very much. Donna Pearson. Can you explain to us what you consider reliable resources or reliable information for you to put information on your Web site and to get it through those Web sites? And secondly, we are trying to get consistent terminology across agencies. And the term is ME/CFS rather than CFS. How do we get that accomplished as well?

Carmen Sánchez: So they are grantees. They are not contractors. So the reason why I mention that is contractors do the work of the government. Grantees have a lot more leeway. Our Parent Technical Assistance Centers are actually - there's something called a cooperative agreement. So we have a lot of say in what kinds of things they put on there.

We have no restrictions to them posting links or anything else to any other government site. So if the CDC had a whole lot of things on it and so on, that would be posted. It is a little trickier when they're posting to sites that are advocacy organizations. It's a little looser to post to foundations. But that is subject to a certain amount of scrutiny in terms of whether or not that would

be something that passively would be understood as being proposed by the Department.

So I'm not sure I'm really answering your question. And I understand, yes, that the constant terminology - we have had places where on the Web site where we have a discussion of terminology for certain conditions or something and explain that to parents with being fairly neutral about it. So that would be fine.

Donna Pearson: So I guess my follow-up question is who initiates these things? Who initiates the concept of adding a link? For example, there is the ICFS primer, a form of it, on guideline.gov, that's a government Web site. So I would assume that means you could add that. Who asks for you to do that?

Woman: So let me step in there. So this working group just got started. We only had a couple meetings and because of holidays and everything else. So the recommendation later this afternoon would be to continue with the working group and then make the recommendations of what should be on the Web sites and work with the CDC and go from there.

Carmen Sánchez: And let me just say that it's actually not necessarily very cumbersome. I am the project officer for the Centers for Parent Information Resources so it really would be a discussion with them in terms of the resources and so on. It's not a hard process. They're always looking for news resources around a lot of issues.

Carol Head: Hi. This is Carol Head. Again, thank you for joining us here today. I would echo Donna's question. And I know you're early on and you're going to continue and hopefully when we meet again can report. But it would be important for us to really understand how we tap into all the resources that

you do offer so that every parent everywhere understands what ME/CFS is and how your services can be used for them. And I think so much of it often points back to the core information that is present on the CDC Web site. And that's why obviously there's so much concern in the community about it.

Just one question, so you didn't particularly refer to the educational local planning area that the mechanisms for transmitting information to parents. Is that just you were covering the top points rather than all the detail?

Carmen Sánchez: And that also changes from state to state. Some states have these educational local planning areas. Some states don't. It's all very district-wide. In Virginia, we don't have that, for example. That's where I'm in. So, you know, that's part of the challenge. Part of the challenge why it's really useful for Parent Centers to have the correct information is they know their states and how their states are created.

So for example, I mean, it changes so much that for example, an IEP is not called an IEP in Texas. It has a different name. So a lot of it is just having those local and statewide organizations who know their states really well.

Woman: Any other questions? I don't know if you covered this, but what if you have a child in an institution who has ME/CFS and the principal in the school is giving them a hard time in not believing the illness. Is there any recourse that the physician has not providing the accommodations?

Carmen Sánchez: Again, the role of the Parent Center would be to help the family figure out how to negotiate that and negotiate their due process rights. So sometimes families know, for example, that they have an IEP or that they have a Section 504 Plan, but not necessarily know what their rights are or how to go about exercising those rights. I'm not necessarily saying that.

Part of what they do is help families resolve disputes at the lowest possible level. So a lot of the work is around communication around how to do, for example, letter writing, how to track the requests that are being made to educators and the rest in order to build the case for what is needed.

In addition, which I didn't cover here, because, again, because of the time, we also fund several technical assistance centers. And one of them is called CADRE, which is the Center for Alternative Dispute Resolution, which does a terrific job of talking through dispute resolution around educational issues. And they provide a lot of information to Parent Centers. And Parent Centers really use that in working with families in order to figure out how to resolve these disputes, you know, given the fact that it's a complicated system and who wields the power and who wields the same in any given situation.

Woman: Now, Faith, what did you want to...

Faith Newton: That's a good question.

Woman: Did you want to do something before?

Faith Newton: Beth, did you want to? It's quarter to twelve.

(Gustavo): Yes, I mean, we have to...

Faith Newton: Let's do her - yes. Let's have Beth go now. And then what we'll probably do is have questions at that 2 to 3 o'clock time. She can stay. And then I can work the recommendations in with that.

Carmen cannot stay. I wanted to thank her. She has been a godsend and just given us a wealth of information. And I'm really hoping that she can continue to work with us for a couple meetings in the spring because we value your expertise. And I think we can really make a difference. And there's going to be a recommendation also coming with working with the CDC.

Thank you again.

So, Beth Mattey is coming on speaking now. She is President of the National Association of School Nurses. And one of the other charges of my working group was to see if we could work with the Association of School Nurses and what difference can we make in ME/CFS in getting that information out to school nurses. There's about 36,000 of them across the states and how can we make an input - actually, an impact on them. And so Beth is here to speak about that.

Beth Mattey: Okay. Thank you, Faith. Now, I am Beth Mattey. I am the President of the National Association of School Nurses. And I am a very longtime school nurse. I have been a school nurse for 30 years. So I have quite a bit of experience. And I appreciate that I'm able to follow Carmen because it really dovetails well together. We work very closely together.

You know, I've called this boots on the ground. I mean, that's where we are. We are in the schools interacting with kids every single day. The National Association of School Nurses has about 16,500 members, but there are approximately 65000 to 75000 school nurses across the country.

We have two professional publications, the Journal of School Nursing and the Clinical Journal, the NASN School Nurse. I'm telling you this just to share with you how we share information with our constituents. We communicate

with our members through a weekly digest. And we have a discussion list for all of our members.

We host an annual conference every year. And we plan to host regional conferences in the next several years. In addition, we host webinars through our association and have various e-learning opportunities online.

So, what is school nursing? It's a specialized practice of nursing. It protects and promotes student health, facilitates optimal development and advances academic success. School nurses are grounded in evidence based and ethical practice and are the leaders who bridge healthcare and education. We provide care coordination. We advocate for quality student centered care. And we collaborate to design systems that allow individuals and communities to develop their full potential. NASN recommends that a school nurse have a minimum of a bachelor's degree in nursing.

This is our new NASN framework that was just released in 2016 and really describes the scope of our practice. You will notice we have the students in the center of the circle. And surrounded on the outside of the circle are our standards of practice. We have a scope and standards with which we use and guides our practice of school nursing.

That's one of the five key principles of this framework. We also have quite a bit with care coordination, public and community health, quality improvement and leadership. If you think about it, the school nurse is the only health professional in the school setting. And we are the leaders of health in the education setting.

In a survey by NASN about what school nurses do in their office, the majority do provide acute illness and injury care. But just as many provide care for

students with chronic conditions. We do a lot of immunization tracking, a lot of documentation, attending meetings and writing reports. And we also write individual healthcare plans and individual emergency plans for students with chronic conditions.

So, how many school nurses are there in the U.S. and what's the status? This information comes from the CDC from their school health policy and practice survey. Eight-two percent of the schools say they have a school nurse. Eighteen percent say they don't. And as a school nurse, I always wonder what do those 18% do?

Digging a little bit deeper, of the schools that have the school nurse, about 51% have access to an RN more than 30 hours a week. And about 60% have an LPN more than 30 hours a week. Of course, different parts of the country it depends because the RN can delegate services in different states. State laws differ across the country so it depends on the model within each school.

And we say that 82% of the school are covered, but the workload of the school nurse really varies across the country and really affects what they are able to do and how they can care and provide for our students. It's affected by the number of students they have. In Oregon, one school nurse has 4,000 students, 4,000 students. So it really - the number of schools that they cover - 33% of the school nurses in the NASN survey cover more than three schools. So there's a lot of travel time involved in there.

And, of course, the acuity of the students. What kind of students are in your building and what kind of care do they need? There is more coverage on the East Coast. As you head further west, there is less school nurses per student. Delaware, and Faith and I are both from Delaware, is the only state in the country that mandates a school nurse in every building even though the

American Academy of Pediatrics recommends that there would be one school nurse in every building. Other states recommend ratios. Several do require certain ratios.

Where are school nurses employed? Eighty-three percent in our NASN survey are employed by public school districts. So that's where the majority of the school nurses are employed in the public school district.

And who funds school nurses? Primarily, the school budget, the local education agency provides funds for the services of the school nurse. We are beginning to see more funding come in through Medicaid services. School nurses for a long time have provided a hidden healthcare in the school setting. And we've been able to bill Medicaid for certain services through the years, but now we're able to do that a little bit more expansively. And as states begin to look at that, we hope that they'll begin to access that funding to increase the number of school nurses available.

So what do we do to support students with a chronic condition? School nurses link health and education. We help the educators understand the health needs of our children and ease the fear and anxiety in both the staff, students and the family members. We support the accommodations for students so they can attend school, but still receive the support necessary. And that's why I was so glad to be able to follow Carmen because she could explain the different accommodations that are needed and where do you fall within this - whether do you need a 504 Plan to implement the accommodation or do you need a special education program with an Individual Education Plan?

School nurses are members of the team. This requires in order to get a 504 Plan or an IEP, an Individual Education Plan, it requires a team. A team including the student, the parent, the teachers, the staff, the school nurse, the

counselor in the meeting so that we can all bring our expertise to the table to help bring what is best for the child. What accommodations does this child need?

We, as the health professional in the building, are called in to the accommodations that are needed for other health impaired. And we would be called in for the ME and the BFF children with ME/CFS. And I don't mean we'll be called in. We, at times, often initiate this. You know, it comes to our attention that a child is struggling, that a child has been ill or that a child has this diagnosis. And the school nurse institutes, listen, we need to do something about this. We need to help this child get the education that they need.

So, you know, I speak so strongly and highly of school nurses because we are there on the ground and recognize the needs of these children and the accommodations that they need. And we recognize as many of you have discussed and those on the call that the symptoms of ME and CFS really are hidden so that you really do need a strong advocate in the school.

And because the school nurse would have this information about the symptoms, they can give the list of accommodations. They can say, depending on the individual child, what does this child need? What needs to be included in the 504? What needs to be included in the IEP? And that may include some of the accommodations that I've listed here. You know, do they have trouble getting their homework done? Do they have trouble getting up in the morning and getting to school by 10? Do they need a rest period during the day? All of these are important considerations and accommodations that school nurses will advocate for in their 504 or in their IEP.

Do they need a flexible schedule? Do they need to have half of their work provided by a tutor? Or do they need online education? Whatever it is that we

need to do to accommodate a student within reason, but we want the child to get the education. And we will advocate for that student to make sure that they get these accommodations. It's a physical education. Can they take physical education or does that requirement need to be waived? Could they have a modified physical education program?

This, I just put this up here because this was the charge of the IOM committee. And the first two, of course, are very important. But what I really latched onto was the charge to develop an outreach strategy for disseminating the new ME/CFS criteria nationwide to all health professionals. That speaks to school nurses as well. I will say that in my years of school nursing, I don't know that I have cared for a student with ME/CFS. Maybe I have and I didn't know it because we are truly learning more and more as we go through and learn more from you all as well.

So we really need to be able to provide education to the community and to the education community and to school nurses. So school nurses are advocates for our students. And like I said, we link health and education. We raise awareness of chronic conditions and educate school staff.

And the other thing that we do, and Carmen spoke to this, about who monitors the 504 accommodations and the IEP. And it's the Office of Civil Rights or the Department of Education. And I will tell you that school nurses also monitor that. They are the point person within the schools that the child can check in with and say I need help. This teacher didn't remember that I was supposed to have this accommodation. Can you help me? So we really, really look to our school nurses to support the students within the school setting.

We're the champion for our students. So what do we need? We need more education on the signs and symptoms and the treatment. You know, I say this

that we're the canary in the community. You know, if a child is having difficulty, we're seeing these symptoms that are coming and what's happening. Parents are too, but parents may not know right where to go at that point in time. The school nurse has this information. It raises the bar and gets the child where they need to go to get the diagnosis and treatment that they need.

So we also could use the tools and toolkits to communicate with parents and families to share information. You think about that, I said this in the beginning, we're the boots on the ground. We reach kids. We reach families. So I certainly appreciate you all letting me come and talk about school nursing today. And I look forward to working together so that we can really get this information out and support our students.

Well, thank you.

Faith Newton: Questions for Beth?

Woman: Again, thank you so much. Do we know how many students there are in our country who have ME/CFS and it sort of really goes back to CDC and our not having a prevalent study recently for the disease overall, which would then allow us to segment out how many students there are who suffer with this disease.

Beth Mattey: We do not have that information.

Woman: No, as you were giving your presentation, I just thought about the potential of trying to develop a collaboration with the school nurses to ask that kind of a question that would be a natural possibility.

Beth Mattey: We do have - I will tell you we have a study going on now that just started. It's in our second year called Step-Up. And we are getting data from schools. Right now we're just getting basic data, the number of schools and the number of school nurses and what type of school nurses are in the schools. And we're also looking at chronic conditions. And we are looking as asthma, and children with diabetes, children with life threatening allergies and epilepsy. So those chronic conditions. We're just into the second study. But we hope as that grows and we are able to really dig down and get deeper and get this information, we really have some good data. But that's down the road. But we could use help with that.

Man: Aside from what (SFTA) comes up with a recommendation, do you think your organization will be willing to work with some of our associations in terms of education because we have someone in the room, President of the Massachusetts Association? And they've done some school nurse seminars and actually have asked school nurses how many of you think you have this type of a patient? And only a few hands come up. But after the seminar, a third of the hands come up.

Beth Mattey: Exactly. Exactly. Yes. Very much so. And I'm so glad to hear that we have some wonderful school nurses in Massachusetts that are really very proactive. So absolutely.

Faith Newton: One of the recommendations that we're going to discuss this afternoon is working with the school nurses and the CDC or outside in developing a webinar that can be sent to all school nurses nationwide. We've got a couple other - I'm hoping that some of you have got some other ideas of what we can do. But we'll do that in that, I think, it's the 2 o'clock timeframe or whatever it is this afternoon.

Other comments from the group?

Man: I just want to join in saying thank you. It's refreshing to see a presentation like this full of pure good intentions. And, you know, healthcare environment and resource environment where we only hear difficulties and politics and logistics, hearing you is refreshing. I feel safer because knowing that my son is in a school where there is a school nurse.

And by the way, you're slide where you had the framework for the 21st Century is so fascinating that you put the patient, the students, right there at the center. And I wish we did that for ME/CFS, where we put at the center of our framework our patients. So thank you.

Beth Mattey: Thank you very much. It gives me chills. We do. The kids are our focus. And, you know, you aren't in a school setting if you don't love children. Thank you.

(Gustavo): (Armeus)?

(Armeus): I just wanted to take this opportunity to raise up an issue that we've been struggling with at CDC and that is how to engage the American Academy of Pediatrics. They're a very important group. We talked about how many cases of CFS there are in the schools. But there are probably more cases that are not diagnosed. And that could only happen if we engage, you know, the right physicians.

And Beth knows we've been struggling on how to do this. And I just want to bring it up and for people to think about how to engage them. We're trying our best. And we'll continue to do that. But it's critical that they come to the fold. And they have a huge platform for a lot of other diseases that could be

communicated through the association to the general pediatric practitioner community. So I just wanted to throw that out.

Man: That's a great point. I just finished working with them with the American Academy of Pediatrics on a position paper for congenital toxoplasmosis. This is one of my expertise. And so I could bring to the right party an idea with Beth and you with me to their attention to do something similar to what we did on congenital toxo. So we worked with them for like four years. And the publication of this white paper major source of what is the bottom line on congenital toxo. We would be saying much and maybe we can attempt to do something similar in CFS.

(Armeus): That would be great. That would be wonderful.

Faith Newton: Yes. Education is critical. It's just critical for the school nurses and for pediatricians. Right. So. Yes?

Man: One thing that would be wonderful. I'm a physician. One of the things that would be wonderful is if we would listen to you.

Beth Mattey: Thank you.

Man: I know that most doctors are smarter than me, and they will never listen to you. But, seriously, it would be wonderful. Two comments. One, it would be wonderful if the nurses would be able to find a way to slap the doctors around. Because you have a hard enough time, I would imagine, getting the principals to do what you need, but if you don't have the physician kind of backing you up, that's hard. So I think that - I'm obviously supportive of what you're doing. And I recognize there's even more that needs to be done from a physician side.

Speaking of that then, the American Academy of Pediatrics - one insight I have because I've done a lot of work with them on guidelines and it shocked me when I was doing one of them. It's getting better, but they don't take care of chronic disease. If you think about it, diabetes is increasing. The ADHD is increasing. Toxoplasmosis, really rare. The amount of a practice in pediatrics dedicated to managing patients with chronic disease is growing, but it's still very small. Whereas, internal medicine, family medicine, I mean, you see it all the time.

So you take something like chronic fatigue syndrome, which is not only a chronic disease but is a chronic disease "we can't diagnose" and "you can't treat." And it's going to be really hard for pediatrics to get their hand around it. So I don't have an easy answer, but maybe that insight will help you in your approach to them in recognizing that it is in part just in their DNA to have a hard time with chronic disease although it's improving.

Beth Mattey: They are the gatekeeper though.

(Armeus): This is (Armeus) again. One of the things that we wanted to do is get into their Red Book. I don't know if people are familiar with the Red Book. The Red Book basically describes a lot of diseases, the infectious diseases, ordinarily pediatricians will go to. That's their go to book. And they don't have a chapter on ME/CFS. So as we bring it up with them, that's one concrete thing that we could do is put in a chapter in the Red Book.

Man: I couldn't agree with you more. I'm a regular contributor for that Red Book for the toxoplasmosis that although it's rare, it's potentially devastating. I mean, we see kids with hydrocephalus, eye loss, brain calcifications every year in the United States because their moms did not pay any attention to the

toxicity of their pregnancy and their babies were born this way. So, yes, approaching from maybe from the Red Book standpoint first and then going to a position paper then. I would love to team up with you on that to make that formal request.

Beth Mattey: Thank you all very much.

(Armeus): Thank you.

Faith Newton: Thank you very much. Thank you, Carmen and thank you, Beth.

(Gustavo): It's five minutes after 12 noon and I'm sure all of you are hungry. There are a number of places - excuse me. There are a number of places you can go and eat food. Across the street, just in the corner there is - right next to the metro there is - I forgot. But there is some menus outside if you want to go there across the street. We are due back at exactly 1:00 p.m. because we have a second round of public comments. To those in the audience, I'm sorry, on the phone. The operator will play some music. And we'll be back at 1:00 p.m. Thank you.

Coordinator: Good afternoon. Thank you all for holding. As a reminder, your lines are on a listen only mode until the question and answer session. Today's conference is being recorded. If you have any objections, please disconnect. Thank you, sir, you may begin.

(Gustavo): Well, thank you. Everybody, welcome back. I hope you guys had a good lunch. We are about to start our second round of public comment. And the first person to speak is (Bobby) - how do you pronounce your name?

(Bobby Ausebel): (Ausebel).

(Gustavo): (Ausebel). Sorry. English is not my first language. You have three minutes. Please.

(Bobby Ausebel): Hello. I know that you're working hard here. However, I personally need this committee to refocus. I need you to talk about how to push for bigger government funding and a faster response so that your proposals can be implemented.

I'm the mother of a daughter who's had ME/CFS for 27 years. You are parents. You know it's heartbreaking to see a delightful daughter fall into depletion and desperation tethered to her bed, a wheelchair next to her. We both see her decreasing capabilities.

I'm her cheerleader during the harsh times she repeatedly faces and sadly my very presence now is overstimulating to her. I'm losing her. Where's the hope I can offer her? I'm 80 years old. We both ask, what will happen when I'm no longer here?

There are two younger people in the Bay Area where I live who died this month. Is my daughter's funeral what I have to expect in the future? I got an email from a new friend, (Jan Bernstein). This is her email to me.

My brother, John, died January 3, 2017, after nearly 20 years of deep suffering from ME. In my family now everyone before me from my dad's side has died of ME. My grandma, my dad, my sister, my brother John's only child and now my brother John. It's devastating. I'm in such profound mourning. It is so scary. I've had ME for 11 years. I fear leaving my children without a mother. I fear my children being struck by this horrible disease. I've watched my family members suffer and die one after the other.

Committee, answer her call for help. There's a Web site with the name of those who have died. I just found it recently. Can you imagine now across America gravestones with little placards that say, HHS neglect caused this death. I'm going to give placards out to everybody on that site that I can.

Committee, I challenge you. Demand your requests are heard and implemented. Establish the Centers of Excellence. Push for funding. Not $7 million. Not $14 million. $250 million. Go for it this year. Get a cure. I challenge you. Demand your requests are heard and implemented.

(Gustavo): Thank you, (Bobby). Next speaker is (Diana Gibbspoint). If you're on the line, press star 1.

Coordinator: One moment please. (Diana), your line is now open.

(Diana Gibbspoint): Thank you all for the work that you are doing. I have revised my previously sent comment because I am concerned about my time limit. But please read that also if you can. It gives details that I feel are extremely pertinent. But right now I want to emphasize how everything began to make sense to me in hindsight aided by the fact that I gradually worsened over time even though I believe wholeheartedly that I became ill because of one particular incident.

I know the big issue with this disease is all of the confusion because there are so many things to consider. I started doing online research and asking a lot of questions three years ago after being diagnosed at Mayo Clinic. I am so sorry. I'm really getting winded. I need to continue.

I thought Mayo was my last resort. But then I realized they were recommending the exact same things I had been doing for years and I still got worse. I just wanted to feel better. At first, I was so confused by all the things that were being studied. And then, as I pondered my own experiences, everything started to make sense. I remembered clearly the sudden strikingly odd experience that happened right when my unusual health issues started.

Sometimes my memory is not so good, but that experience always stood out to me. Then much later my blood work from Open Medicine showed viruses present, including EBV. Now I have close family who have developed some alarmingly similar symptoms. My previous comment gives better details, but I forgot to mention that my son's NK cells show 19. Although that is in range, Open Medicine said a healthy adult usually runs around 75. So the virus and cluster research makes sense to me.

My first unusual symptom was hypersensitivity to food. My PCP diagnosed hypoglycemia, but tests were non-conclusive. Years later Open Medicine correctly diagnosed and successfully treated my SIBO after Mayo Clinic and a gastroenterologist completely missed it. So the gut research makes sense to me.

Then I began having recurring infections and I always felt better taking an antibiotic. When I was taking it, I felt better. And when I quit, I got worse. Also, there was a long time when I didn't get sick like other people. When the flu or cold was going around, I never got it. Even though I got infections, I distinctly remember making the comment that it seemed like I had such a good immune system because I never got the flu.

Later as I got worse, my NK cells showed 9 so the cytokine spike (unintelligible) and immune dysfunction research makes sense to me. There

was a particular time when I felt I was getting significantly worse. I had an increase in symptoms like hypersensitivity to smells and medications, heart palpitations and having crashes instead of just having fatigue. It was around this time I had extensive mold exposure at work and at home. So the mold and toxin research makes sense to me.

Yet another time I felt I was getting worse and I began having more neurological symptoms which were also recorded. During that time an electromyography showed muscle weakness. My blood pressure was 225/150 and an MRI showed a mini-stroke. As of today, my symptoms and inflammation have increased even more. My dizziness, cognitive issues, blood pressure issues, heart palps, breathing and weakness are worse. I am more sensitive to drastic weather changes and my symptoms are even more exasperated, similar to people with arthritis or migraines. So the ME, brain, spinal cord inflammation and vagus nerve research makes sense to me.

In hindsight, I can see the different stages of my disease progression and the tests that may have helped with diagnosis. In the initial stages of my illness, I could have easily been diagnosed using the SCID criteria if it had been available. Even if my doctor was uncertain, he could have monitored me if he had been properly informed and educated. As of today, I truly believe a two-day exercise test, tilt table test or current MRI would show definite issues. But I have checked with several doctors and no one will do these tests.

My blood work also shows particular abnormalities which are similar to other ME/CFS patients. But doctors aren't aware they may actually mean something. So the different stages of disease progression and appropriate corresponding diagnostic tests makes sense to me.

I hope I'm not repeating anything you don't already know. But all of these pieces coming together was such a revelation to me. Although my comments have focused on making sense of things, I in no way want to diminish the colossal importance and urgent necessity of continuing research, funding that research and widespread education of the medical community and the public on current information.

So many are still living in the dark ages and think this is all in our head. I continually read horror stories online about patients being dismissed, treated with disbelief or disrespect or not being treated at all. And I have experienced these things myself. Doctors plead ignorance or say insurance won't pay so they refuse to treat or run tests or even refer to specialists. They need to be reminded they took an oath to do no harm.

It seems like most doctors only want to cover the basics, but with current cell level research things may not be so simple anymore. Many patients have blood or abnormalities but doctors say they aren't significant enough so they ignore them. Mayo Clinic ignored the same blood abnormalities that Open Medicine knew to consider. Do we need to review and revise blood tests' normal values or expand the CBC list or alert doctors to the importance of thoroughly investigating all abnormalities? Or do they simply need to be made aware about the reality and significance of this disease?

People with ME/CFS did not choose to be sick. We want to be well. We want our lives back. We want to be productive members of society. Please help us. Thank you.

(Gustavo): Thank you, (Diane), for those thoughtful comments. (Mary Dimmick)? (Mary)'s going to read somebody's comments who chose to be anonymous.

(Mary Dimmick): Thank you. I am speaking to you today on behalf of an ME parent who really wants you to understand the stigmatization and paucity of medical care for ME patients.

My son is a young adult male with very severe ME. Before his illness, he was incredibly bright, funny and kind. Now, he cannot speak, chew food or tolerate light or sound. Despite his severe physical conditions, there have been many instances where he was dismissed by doctors or ostracized as if he had a psychiatric illness. His last emergency room visit illustrates this well.

It started when we tried to stand him up one day to prevent muscle atrophy. The following day he could not move his legs. And the next day he was not only unable to move his legs but also developed a fast heartbeat, 120 to 130, accompanied by terrible intermittent shaking tremors of his upper body. He hand-signaled, take me to the ER. His heart rate there is 120 to 130 for four hours. He is given IV fluids. And his heart rate is monitored. But not once during the entire visit did anyone conduct any physical examination.

After a few hours in a get out of my emergency room tone, the physician tried to discharge him. I'm still extremely worried at this point so I decline leaving. I break down crying in his room as it's the middle of the night, and I've had no sleep. And the tone and the manner from this physician in charge is negative, dismissing him as psychiatric illness despite the fact that I had provided him with information about ME.

The physician gives him more fluids but then tells me that he is going to discharge him home. I respond, he can't move his legs. He was brought in by ambulance. And the physician then tells me, that's okay. I will get the transportation service to take him home and put him back in bed. There was

no physical examination. There was no questioning why he can't move his legs. There was no care for this patient.

I cried all week after this ER visit. Foremost was the pain of how inhumanely we were treated. But there is also the pain of having an extremely ill son with no one to turn to that understands this disease or cares enough to try to help.

Thank you.

(Gustavo): Thank you, (Mary). (Darla Nagel), if you're in the audience - over the phone, I'm sorry. Press star 1.

Coordinator: One moment please. (Darla), your line is now open.

(Darla Nagel): Thank you. My name is (Darla Nagel). And I feel like a 70-year-old who body slammed a brick wall. Seven years ago I was a healthy 19-year-old college student with two part-time jobs. Overnight, my case of myalgic encephalomyelitis, ME, began.

Because I am one of the fortunate with an effective ME specialist caring for me, the concern I'm focusing on today is the lack of quality medical education of ME. This illness affects 1 million Americans according to a conservative estimate and maybe millions more who haven't been diagnosed.

That makes the low number of trained specialists and the refusal of any medical specialty to take responsibility for caring for ME patients alarming. We need a higher priority and at least $100 million more in annual funding from the top. This would cause more healthcare educators to learn about this disease.

Last year I asked several professors and deans of high ranking medical schools what they teach about ME. And they said practically nothing is taught. Also, I reviewed over 80 medical textbooks and found not many devoted more than one sentence to ME. Those that listed treatments overemphasized cognitive behavioral therapy and graded exercise therapy. What quality science has shown their potential to harm patients? Whatever happened to first do no harm? And why would someone believe a psychological therapy can cure a physical illness?

Today's medical students can't diagnose and treat ME patients. They aren't taught the various sets of diagnostic criteria. They aren't taught about beneficial treatments. They aren't given funding to study ME. It's no surprise that virtually no students are interested in specializing in ME in their research or clinical practice.

If today's few ME specialists retire with no one to replace them, any progress patients have experienced will be reversed. I will not sit and wait for that to happen. I will not wait patiently for the CDC to remove cognitive behavioral therapy and graded exercise therapy from its Web pages about ME. I will not wait patiently for ME's inclusion on Board certification exams. I will act because we can't wait any longer.

I am not a malingerer. I want to be well, to work full-time and to be useful to my country. If money talks, consider this logic. If I could work full-time, the American government would get more tax money from me. Multiply that by 1 million patients and there would be that much more funding available for government programs. The income could even surpass the amount of money that needs to be given to ME education and research.

I thank the advisory committee for letting me speak. The time for the Department of Health and Human Services to listen and act was decades ago. So I say this directly to that Department. Don't wait any longer.

Thank you.

(Gustavo): Thank you for your comments. (Elan), do we have Mr. (Jim Mills) on the line.

Coordinator: Yes. (Jim)? One moment. (Jim), your line is now open.

(Jim Mills): Thank you. Good afternoon. My name is (Jim Mills). First, I'd like to say that I agree with all of Carol Head's comments yesterday. My request is that NIH ramp up funding, fast track research and cure ME. My 26-year-old daughter (Lindsay) has suffered from ME since 2005. I'm speaking to you from Johns Hopkins Hospital where (Lindsay) is undergoing a seven-hour treatment which she has every three weeks. The daily life of ME patients revolves around this illness.

Each ME patient is subjected to her or his own individual symptoms. Obviously, the symptoms vary in severity, but they all disrupt one's life. I hope this committee fully recognizes how debilitating this disease is for patients. It is imperative to fast track research and find a cure.

If members of this committee have not seen Ryan Prior's documentary, Forgotten Plague, I urge you to do so. Jen Brea's documentary, Unrest, which is being released this month at the Sundance Film Festival, also chronicles the plight and suffering of ME patients.

Both of these documentaries will help inform the general public and policymakers about ME. Please encourage all of your colleagues to view these

documentaries. Both the IOM report and the P2P report identified the critical need for increased medical research to cure ME.

I request that this committee recommend to the incoming Secretary that NIH funding for ME research be significantly increased so that on a per patient basis funding is on parity with other diseases of similar severity and disability such as MS. Unfortunately, despite promises by NIH leadership since October 2015 to ramp up ME research funding and issue RFAs, nothing has yet occurred.

This lack of urgency by NIH leadership in funding ME research concerns me greatly. My daughter and the other 836,000 to 2 and one-half million Americans who suffer on a daily basis from ME deserve an aggressive full throttle fire in your belly approach by NIH to fund research and cure ME as soon as possible.

The lives of ME patients are on hold until a cure is discovered. ME patients are imprisoned by this disease. I understand that RFAs are now scheduled to be issued by the end of January 2017. I hope that this occurs. Again, my request is that NIH ramp up funding, fast track research and cure ME.

Thank you.

(Gustavo): Thank you, Mr. (Mills). (Mary Switzer)? Is she on the line?

Coordinator: (Mary), your line is open.

(Mary Switzer): It's open now? Okay. Hello?

(Gustavo): Go ahead, (Mary).

(Mary Switzer): Okay. Thank you for allowing me time to speak. I have testified about Ampligen to this committee for almost two decades. I have been on it most of the time since 1999. When I first went on it, I made sure that I had biomarkers, not just symptoms, to judge its effectiveness. I tested positive for the 37 KDA RNA cell abnormality and a very high viral load of HHV-6 variant A. After six months on Ampligen, the defective RNA cell was gone and HHV-6A was dormant. I could walk. I could drive a car. I could read a book. I danced with my son at his wedding. My head was clear and the pain was gone. Miracles.

Over the next 17 years, I was off Ampligen twice, 18 months the first time and 2 years the second. Each time, abnormal immune biomarkers returned and so did active viruses. I am a 30 on the chronicity disability scale without Ampligen. I'm a 70 when I'm on it. That is the difference between being a bedridden invalid who must be cared for and somebody who can take care of herself even with three feet of snow burying us up here at Lake Tahoe.

During my last relapse in 2008 off the drug, I flew to Tahoe to see Dr. Peterson with my daughter helping me from my home in Delaware. He found I was positive in my blood for cytomegalovirus virus, Epstein Barr and HHV-7. I had abnormal SPECT scans, CPET scores and an abnormal cytokine pattern.

In the summer of 2009, he did a spinal tap and found I had HHV-6A and cytomegalovirus active in my spinal fluid bathing my brain. No wonder I was so sick. Peterson tried this time a powerful antiviral so that I could get treatment and still live in Delaware. Unfortunately, my liver rejected it.

I was back on Ampligen in 2010. And I did get better again. But in the summer of 2013, my sweet husband died of cancer. So two years ago, I sold my home in Delaware, bought a house here at Tahoe. And now I get Ampligen at Dr. Peterson's, two miles from my house.

Now we are getting word out of Hemispherx that we are going to lose Ampligen. There is no more of the drug and when they do start producing it again, it will go overseas to Europe where they believe it stands a better chance of being approved. We've also been told they might let us have it, but the price would rise from $16,000 a year to $40,000, which is prohibitive.

Ampligen needs to be provisionally approved for patients with ME. The old FDA Modernization Act from 1997 has four criteria for fast tracking a drug. Ampligen fits them all. First, ME/CFS is a significant life altering disease and I hope everyone in SF-SAC agrees with that statement. Two, there's no other drug like Ampligen on the market. Three, there are no major toxicities. FDA has admitted this in writing. I have been on it for 17 years. We patients are the guinea pigs. We took the risk. Let us stay on it. Four, it must have dramatically helped at least one patient.

I hope I've convinced you of that. I'm part of a small group of patients here at Dr. Peterson's who will relapse into hell if we lose this drug. I don't want to be an invalid again. I don't want to go back to living in pain and confusion. I don't want to be a burden on my children. Please help us. Thank you.

(Gustavo): Thank you, (Mary), for those comments. (Joe Lantzon)?

Coordinator: I don't believe (Joe) has dialed in. (Joe), if you're on the line, press star 1.

(Gustavo): I'm sorry. He's in the room with us.

Coordinator: Okay. Thank you.

(Gustavo): Go ahead, sir.

(Joe Lantzon): Good afternoon. I'm (Joe Lantzon). I've been sick with ME for 12 years. Welcome to the new faces here at SF-SAC. (Commander Sans), (Dr. Helmer) from the Department of Veterans Affairs. I'm a Navy veteran and former Arabic linguist. With this disease, I could translate for maybe an hour if I'm lucky and then lie down for the rest of the day. So I don't work and my clearances have all lapsed. Without this disease, I might still be translating for DoD or other agencies.

The VA clinicians I've met know absolutely nothing about this disease and don't want to, this despite having a legitimate ME/CFS expert in Dr. Nancy Klimas at the VA researching and treating. In fact, VA clinicians I've met routinely deny it's even a valid diagnosis. Meanwhile, VA benefits pay me 40% disability for an invalid diagnosis. How does that work?

I got to a VA clinic to be thanked for my service in one breath and told I don't medically exist in the next breath. Second to the NIH, Dr. Vicky Whittemore genuinely seems to be trying to help us. Thank you. However, some of your colleagues continue to cite the work of Dr. Stephen Straus as grounds to ignore us and block research. I checked before the meeting and Dr. Straus is in fact still dead. In fact, he's been dead almost as long as I've been sick.

While he did accomplish much in other areas, Dr. Straus is remembered by patients for the disdain he showed towards us and our disease. ME/CFS is in the state it's in, I think, largely because of stigma, medical, scientific and

bureaucratic stigma which Dr. Straus actively fostered while alive and apparently after that as well.

Even today NIH claims to advance legitimate research and made great plans today -- we'll see -- while still providing aid and comfort to disease deniers. Not long ago, an academic historian who makes a living mocking our misery, spoke at NIH. We begged agency leadership to disinvite him. Not only did NIH allow him to speak, it didn't even offer a counternarrative or challenge his views in any way. Fight the stigma? Perpetuate the stigma? Which will we get today? I submit that this blind prejudice could undermine, if not erase, whatever work NIH carries out or funds.

So either fight that prejudice or don't even bother pretending to help us. In sum, it seems that the VA and NIH might have the same policy towards this disease, which is to say, no coherent policy that I can detect.

Finally, thank you for scheduling this meeting for Friday the 13th. It seems very apt timing. May I suggest that future meetings or statements come on or about April 1. That would accurately reflect where ME/CFS work stands with our government health agencies today.

Thank you.

(Gustavo): Thank you, Mr. (Lantzon). And the fact that the meeting was scheduled today had nothing to do - and our apologies if it happened to be on Friday the 13th. I think sometimes we have to bring some humor into this after all. (Jen Penale), are you on the line? Press star 1 please.

Coordinator: One moment please. (Jane) your line is open.

(Jane Vanel): Thank you good afternoon. (Wittin) testimony was submitted to (unintelligible) - C at SAC just before this meeting. It referenced social security data showing that fewer adults with ME were collecting disability benefits as of the end of 2015 than had been in 2009. This is deeply concerning. Social Security updated the criteria for disability in 2014 but how is that ruling being applied in the field? I have had ME since 1984, I applied for as SEI in September 2013. Last November I had a hearing before a judge. I thought it would be just a formality. My two treating physicians had both clearly stated I was disabled according to the 2014 ruling. The Social Security Doctor (unintelligible) was disorganized and also (unintelligible).

(Gustavo): I'm sorry Miss (Vanel) can you please speak up? We're having a hard time hearing you in the audience.

(Jane Vanel): Okay the social - this better? The Social Security Doctor...

(Gustavo): Yes.

(Jane Vanel): ...who joined by phone was disorganized and unprepared. He rambled on about time monitored medicine in the many conditions that include chronic fatigue in their symptomatology. He stated and I quote, "Chronic fatigue syndrome is one of (unintelligible) diagnoses. I haven't yet accepted it as a solid entity," end quote. The judge interrupted him to her sentence state with the Social Security (unintelligible) disability no matter what is causing them? The doctor said he has not read the ruling, the judge faxed it to him his ink cartridge was empty. While fumbling to replace it he stated my assistant usually does this and then -- almost as a side he added -- while they certainly have drawn a lot of sophisticated labs haven't they? I don't know what half of these mean. The judge released the doctor, questioned my lawyer, and then closed the hearing.

Two weeks ago I received a letter stating that the judge had handed information from a second doctor to my part. This physician concluded I didn't not need a listening, I quote, "Diagnosis of CFS is problematic, the claimant has also been diagnosed with a connective tissue disorder and is treated for depression. The most mainstream -- and mainstream is underlined -- the most mainstream medical records in the file are from UCSS, all UCSS physical exams are normal, " end quote. This remark is (unintelligible). Number 1 I was a patient at the open medicine clinic which is a part of the CDCs multisite ME steps, CDC is pretty darn mainstream. Number 2 no one at UCFS -- which is the University of California at San Francisco -- has expertise in ME.

In fact several years ago I was referred to the rheumatology clinic, they reviewed my records and referred me to their immunology clinic who referred me back to open medicine where I was already seeing Doctor (Kaufman). Number 3 a normal exam is usual for this disease. This consulting physician made no comments that my abnormal lab (unintelligible) MRI. Number 4 the ruling clearly states that patients may have other: incurring conditions, including wastebasket diagnoses like connective tissue disease. The same goes for depression which is often secondary to chronic disease. Neither of the Social Security physicians allowed their erroneous -- excuse me -- both of these Social Security physicians allowed their erroneous belief about this disease to overshadow their duty to follow the ruling. I'm sure my experience is not atypical, please CDC disseminate accurate medical information about ME. And Social Security administration please require that consulting physicians adhere to the 2014 ruling. Thank you for hearing my testimony.

(Gustavo): Thank you Miss (Vanel).

(Jane Vanel): Thank you.

(Gustavo): (Christine Williams) - and she's with us here in the audience.

(Christine Williams): Thank you, I want to thank the committee for the opportunity to provide comments today and I also really want to thank all of the other patients and advocates who have spoken. I think the testimony has been very important and very valuable -- not only for those of us who have this illness -- but hopefully for folks that are going to be helping us. I'm (Chris Williams) and I'm a patient with ME/CFS. I am now on the board of Solve ME/CFS Initiative and I am a former ex oficio on the (Sifsac) from the agency for healthcare research and quality. I spent 30 years in the federal government working on health policy issues.

About half of that time on the hill working for the Senate Majority Leader I was his Health Policy Staffer. And the other half of that time I was at ARC and I had a senior position there as a director of communications and knowledge transfer for the agency. In the summer of 2008 I became ill with what eventually was diagnosed as ME/CFS. It took seven months, many doctors' appointments, and a lot of online research, basically I diagnosed myself. And then I found a physician in DC that did have a practice -- an internist who had a practice -- of including ME/CFS patients. So while I did face the same skepticism and frustrations that many other patients have talked about -- because of my own professional background and knowledge and the context I had -- I was able to get a diagnosis fairly quickly and find a doctor in DC to treat me.

With accommodations from the agency I was able to work for about two more years. And during those two years I got myself appointed to the (Sifsac) as the ex officio from ARC. I was the first person that had ever been an ex officio

who identified publicly as a patient. And I really didn't feel any fear about that because I was 56 years old at the time and I was very close to retiring. And I was not concerned about losing my job which is not the case of many younger folks. I decided I was going to use the limited energy that I had after I got sick to work on this issue. To try to use my own professional background and so I'm really disappointed after eight and a half years that more progress has not been made.

And I guess one of the things I wanted to say is 30 years I worked on health policy. I worked on AIDS, I worked on health care reform -- I worked on many difficult issues -- this is the most difficult issue I have ever worked on. And it isn't just that I'm a patient, it's the stigma, it's the lack of progress, the lack of funding, and the federal investment in this is nowhere near where it needs to be. You know, I worked for the federal government for 30 years, I believe in the role of the federal government. And I know we can do good things, I know we can make progress. I saw what happened, I was on the Senate floor when we passed the Ryan White AIDS legislation. And I saw good Republicans coming up and supporting that bill and that's what can happen when you get people really to understand the problem.

But we don't have that with this illness and we need to move in a quicker direction. I turn 65 next week so I'm now going to be a Medicare beneficiary. My first thing I'd like to note is where's the CMS representative? We need one on the committee whether we're elderly -- which I would never think of myself as elderly -- but whether we're 55 or disabled we need Medicare. So in closing I just want to associate myself with the recommendations that were presented yesterday by our CEO Carol Head first we need to establish a ME/CFS inter-agency task force to lead, plan and execute a five-year strategic plan with specific targeted goals and inter-agency collaboration. Secondly, the government needs to invest in a solution at a level commensurate with the

burden of this illness which is way, way more than what has been invested in the past. And thirdly, all of the agencies and all of the relevant programs in the federal government needs to make ME/CFS patients part of your agencies agenda and part of your programs for success. With targeted goals that we can see whether they've there's been any movement or any positive achievements. So thank you so much.

(Gustavo): Thank you for your comments and she was the last in the list -- Sue.

Sue Levine: Yes I think so we hear now from Fred Friedberg a report of the IA/CFS and some other comments.

Man: Have to call one of the IT people.

Fred Friedberg: Yes search for IA/CFS. Date modified - yes there it is. Here we go - okay - wait. Thank you (Gustavo). I'm first going to give an overview of our organization and then the topics that I'm going to briefly cover from the conference. First of all, I'd like to think (Gustavo) and Sue for inviting me to give this talk on behalf of IA/CFS ME. And also for the good work that this committee does and I think credit that they very seldom receive -- I'll address that later. ICF/ME does do more than sponsor a conference every two years, people think we sort of fade into oblivion and reappear somehow. We publish a periodical journal since 2013 about half the articles are ME/CFS and we're currently under review for Medline indexing and of course we're - that would be a big boost for the journal.

Actually a big boost for the credibility in the scientific sense because if you search Medline and you see this journal come up -- fatigue in terms of ME/CFS and you do a combined search with fatigue journals -- there's only one fatigue journal, this is it in the life sciences. We published a primer 2012

with a revision in 2014 it's been mentioned here and there. It did get well reviewed and we have many views on National Guidelines Clearinghouse over 17,000 it's available for free on our website. If you want a bound copy with a nice cover you go to Book Patch and that will cost you I think $20. We have a newsletter three times a year if you have current events that are ME/CFS related announcements -- research news -- the - Vicki's announcement about collaborating research centers I just gave a hot off the press message to my board to publish this in our January newsletter.

And please send your submissions to (Lily Chu) who's the newsletter editor. We have public position statements on pace trial, DSM5 and we send ICF/ME representatives obviously to hear as well as to the medical education initiative at CDC that's headed by Beth Unger. We support new investigators, we awarded six travel awards to young investigators which we so desperately need in this field. This was funded by NIH/NINDS and again with Vicki's very generous guidance about writing the grant. We had six awardees out of 40 applications, here they're. And we have an enormous board of five people. Are you interested in board membership? You do not need an advanced degree to be considered for - to be a board nominee you just need an interest in this field and the willingness to do some work to support our organization and its various activities. And if you're interested, drop me an email -- talk to me -- and I'll give you a way more in depth of what might be involved.

We had 60 orals, symposia 80 posters, topics ME/CFS and gulf war illness. Almost 300 attendees, 203 professional attendees, 50 trainees or early-stage investigators again gathering that many trainees in this field anywhere is pretty unusual. I believe all of you were sent the PDF of the conference program book, you know, as members of the committee. And I'm just going to summarize and highlight rather than completely list what happened at the conference. I certainly beg your indulgence for mistakes on technical details

which I will warn you I'm going to make, I don't presume to have wide ranging expertise. But I brushed up as much as I can in this presentation.

So here are the various topics, treatments, post exertion MLA's, epi genetics, gut microbiome, autonomic dysfunction and multisite consortia. Again this is not a full listing of all the various research topics. (Boyston Fluga) from Norway as you probably all know he is the (Rutximab) researcher. Plenary speaker and (Vicki Whittemore) was our key note. Vicki - she discussed new ME/CFS developments at NIH and I think I've been upstaged clearly something has happened since the conference. In fact, two hours ago we had that very significant announcement of collaborating centers so say no more that's just great. By the way, as far as this committee goes I think it was instrumental in getting to this point of having almost a $30 million in funding devoted to this illness.

Starting two or three years back and I remember being on a subcommittee about looking at publication rates in this field and researchers making the evidence-based case -- I know (Dadin Cook) was involved -- and evidence-based case that we need more funding. And that that time while (Nancy Lee) was in charge she recognized the call -- from what I understand -- I even heard here that she helped to mobilize the right people at the right institutes NIH wide. Obviously (Vicki Whittemore) got involved that resulted in the P2P and the IOM contracts. I know there is not exact a unanimous agreement about - if that was those refunds will spent. The bottom line is it increased the recognition and the credibility of this illness and I think it's played a very significant role in developing these initiatives that are now just about to be released.

So I understand it can be an exercise and frustration being on the committee but these -- to me -- the developments that we've just heard about here today I

would like to thank this committee for getting us to this point. So please don't feel your efforts are in vain -- I think this has been a very productive few years -- excruciatingly slow yes but productive. Professional workshops again we had a variety of them including Vicki and colleagues NIH grant writing workshop, we need that kind of thing to engage the new researchers, clinicians who want to - will become researchers as I did. I went to one of these workshops it helped me tremendously in writing the grants - the first grant that I wrote.

Now switching gears Rituximab that is a cancer drug that attacks B cells and the B cells in turn produce their own antibody that may play a role -- certainly in something like lymphoma -- it may play a role in ME/CFS. And when you have these two small studies conducted by the Norwegian researchers you found about a two third response rate to the Rituximab. And that's very significant clinical improvement, no small thing. Now were these studies large enough to draw - form conclusions? No. But they pointed the way to a larger study that is now underway. So we -- again run by the Norwegians (Fluga) and (Damella) -- we have a randomized trial where we should know the results by the end of this year. And he's postulated about the mechanisms about what ME/CFS might be based on B cells functioning erratically and how this drug may normalize the antibody response and produce the improvements that we have seen in the first two studies.

So I'm enthused about this result, the thing is I'm -- how would you say -- I'm not jaded but I'm cautious. We've had a lot of false starts in the past I don't know that this is not another one. On the other hand these are two very well-respected scientists, they're cautious. They don't get ahead of themselves, I don't hear any hype coming from them. That makes me encouraged that they're - we can trust what they do. Unfortunately not such a good result for this study that was presented low-dose methylphenidate which is Ritalin plus

a supplement for mitochondrial support. He did that - it decreased symptoms but it was not significant, severe groups did a little bit better. Those with both fatigue and pain did a bit better. No ill effects so I'm not sure what to say about this except, you know, it's a bit of a disappointment.

Now this is an intriguing study and escitil 15 is conducted by (Dakoma Shangu) up at Cornell. He hypothesized that the brain glutathione -- which is an antioxidant very important for the that oxidant antioxidant balance in the body that has so many ramifications for healthy functioning -- he hypothesized that oxidative stress was a cause-and-effect in CFS. He did an imaging study and he found deficits in brain glutathione. So he said well if we can replace that glutathione -- and if that indeed plays a role in CFS ME symptoms -- then we should get improvements. So glutathione is taking orally, does not cross the blood brain barrier but NAC is a precursor of glutathione that does cross the blood brain barrier. See four weeks of daily NIC in pill form over-the-counter stuff he found that the glutathione -- that's GSH -- rose to normal levels of the healthy control, CFS symptoms significantly reduced. Encouraging now not a controlled study with a placebo patient group so yet to be done.

But this, you know, something as benign as NIC or NAC worth pursuing. Okay I know I'm speaking to the choir here when we're talking about this reanalysis of CBT data. Fighting that beliefs do not really have to do with illness impairments, no big surprise there. And exercise based intervention are really a of dubious benefit and is a generically recommended treatment, the whole CBT GE thing. To me if they didn't get ahead of themselves and start proclaiming recovery and making all these extravagant statements I don't think they would be in the hot water that they're in now. But if you tab a therapy curative -- and we're talking restoration of full health -- you do not get that.

I don't dismiss CBT and GDT but I don't want its findings to be exaggerated to the point where what happens to the patient is has no link to what that data or what they think the data is saying. I don't know why they do that but I think it's perhaps that has to do with the delegitimization of this illness that in one fell swoop you have a little talk therapy and your all better and we, you know, that's naïve to say the least. Post exertion MLAs -- this has me enthused. These studies -- clinical pace panel at the meeting -- clinicians said post exertion MLAs was the most commonly reported symptom. If that's so and that produces the debilitation and if it's the core system that when you do statistical analysis of system frequency that's what you find what are the big core symptoms? Why don't we -- in the laboratory environment -- provoke the symptom of post exertion MLA's and see if we can find, identify the physiological changes that take place.

But the abnormal changes that take place to help to get to pathophysiology, etiology of this illness. So these studies -- to me -- will produce directionally different effects than with patience that with healthy controls. So those affects sizes can be quite large. That's why I'm encouraged, there's less ambiguity about what - the findings. So (Lily Chu) -- one of our board members -- she did a survey of 150 ME/CFS participants almost 90% experience post exertion MLA's but what is the nature of it? It's - what term is it? Physical exertion, cognitive exertion, emotional stress, although physical and cognitive physical exertion in particular seems to be the biggest trigger.

And it's not only fatigue that gets triggered but other symptoms like cognitive difficulties, sleep disturbance, headaches this is all from just routine exertion -- very unusual -- in fact I would say unique. I've studied first responders to 9/11 World Trade Center about 20% of them have abnormal fatigue. And they even have symptoms of CFS but they don't have post exertion MLAs yet

some studies call these post trauma affects CFS, they're not. So -- to me -- this is such a distinguishing characteristic it really just should not be ignored and it should be studied in depth. And you have delays, 11% say that the post exertion MLAs is delayed 24 hours. Now that so unusual, why should that be? You know, if you exercise to exhaustion you feel exhausted and the next day you're better.

People do something physical with this illness and they don't really feel it until the next day. That's just a most unusual, I'm not aware of any other illness -- and I've studied other fatiguing illnesses, autoimmune disorders -- I don't see this. (Jose Montoya) did a very large study comparing patients and controls. Twenty-four hours post exercise testing to provoke post exertional response, studied 51 cytokines -- which are chemical messengers of the immune system -- help to fight infection. And he found differences in cytokine profiles between patients and healthies. Seventeen cytokines in particular I differentiated the two groups, 13 of those were pro-inflammatory and they correlated with symptom severity. And he concluded this may substantiate the symptom experienced by patients and to the potential immune nature of this disease. (Mark Vaness) -- to the exercise test -- again the idea behind this is you have many treadmill exercise studies and cycle exercise studies in CFS where they don't really find much.

But (Stacy Stevens) developed this two day protocol and said look you need to exert the patients when they're in full-blown post exertion MLAs and it can't be just once. Twenty-four hours later people often still have symptoms, provoke it two times, you're more likely to get a physiological response that is identifiably abnormal. What (Mark Vaness) found is - he called it chronotropic incompetence, heart rate doesn't increase with increased demands and this is compared to healthy control. So he said that the - this post

exertion or reduction in heart rate might be part of the picture to explain the post exertion MLAs.

Now (Catarina Leyem) -- she's one of our awardees from Norway -- she found that Lactaid was increased above that of healthy subjects during two day exercise tests. When you have Lactaid in the blood that means that you - if it implicates anaerobic metabolism it's a very inefficient way to mobilize yourself during exercise. It's distinctly abnormal, aerobic metabolism is the quote the normal -- the healthy way -- to engage your body during physical exercise. Blood Lactaid indicated a problem. A preference of anaerobic metabolism which is what you don't want during exercise.

(Dane Cook) -- another distinguished member of this committee -- did a 30 minute sub maximal exercise test on a cycle or odometer. Again healthies versus ME/CFS and he found changes -- large symptom changes -- not surprisingly also an effective brain function what I thought was particularly interesting is the cognitive performance on the pay set, the pay set is like a standard way to multitask someone into submission. You give them a list of numbers and you have them start they're hearing the numbers and they're repeating previous numbers at the same time. I've taken the test, I don't even want to know how I did on that. Controls improved 24 hours after exercise they improved. You know, exercise does improve cognitive function in those healthy people out there. It got worse for ME/CFS, so you have a directional difference - there's an interaction. Not just, you know, not just a small effect that frustratingly you often find at resting baseline. But with the exercise you found this big separation of performance.

(Bessie Color) she summarize results from 97 cases ME/CFS two day exercise test and she found abnormalities in aerobic metabolism for the majority. Most of them couldn't reproduce what's called V02 max that's the point of

maximum oxygen consumption on day two of exercise. Whereas the healthy controls they reliably do that on day two. She found autonomic abnormalities, heart rate and blood pressure again on the second exercise test not the first. Ventilatory abnormalities has to do with anaerobic metabolism. She said there are multiple indicators of abnormal recovery following exertion. And I think that's probably right, you know, part of the problem here is we don't have a big, big study of two day exercise test to look at post exertion or impacts. And I think that's what we probably need to gain more wide spread credibility of the significance of post exertion and MLAs in this illness.

Now (Peter Rowe) -- not to think it's only aerobic metabolism that is disturbed -- he just said if you lift your leg off of a table from a supine position for 15 minutes and you have this illness might that produce post exertional symptoms compared to a sham, a leg raise, and he found that it did even 24 hours later. So even something as apparently benign as a leg raise produces post exertional symptoms. To me, the goal is here is to get give some of the most minimal test -- the most convenient, the least expensive -- and produce the biggest bang in terms of abnormalities. I think that's where all of this really should go.

Epigenetic studies -- okay -- from what I understand also the jeans are normal used to think they're, you know, the jeans were the role - royal road to understanding major diseases of the day. It appears very often the gene is fine it's just turned on or turned off at the wrong time -- epigenetics. And you do see different gene expression patterns in ME/CFS then you do controls with respect to immune regulation, hormone regulation, mitochondrial function it's kind of like getting into the likely suspect. Yes and perhaps these epigenetic changes, the gene turned on or off at the wrong time and you produced phenomenal, like, glucocorticoid hypersensitivity that's cortisol in particular

reacting abnormally with other functions of the body. Higher levels of DVB proteins (unintelligible) in another study.

Single nucleotide polymorphisms -- SNIPS -- most very common type of genetic variation. They can act as biomarkers of disease, you locate them and this was done with 23 and me and all those annoying commercial tests. They found three SNIPS out of 203 of interest. And they counted for an energy molecule in the mitochondria. You know, again we're getting - often a lot of these roads lead to abnormal energy metabolism. Now a lot of excitement around got microbiome. The gut microbiome is made up of millions and millions of bacteria far more cells that are foreign -- so to speak -- they're not actually part of our body but are bacteria. They do - have all kinds of functions in health and disease, they synthesize hormones and neurotransmitters. Molecules of information like cytokines so they very well may play a role in this illness.

Here's kind of the theory behind it they have found lower (unintelligible) diversity. Meaning less healthy bacteria in ME/CFS this is a (Ludiwig Ulatol) another awardee. He found an increased number of gut viruses in ME/CFS and he suggested this points to low-level got inflammation. I heard about leaky gut syndrome about 30 years ago, that was kind of a crack pipe theory and all of a sudden people are thinking maybe there is something to it. This leaky gut allows bacteria and toxins to enter the blood. And that process could help - could be part of the reason that symptoms are produced.

The hypothesis -- at least his -- was that the changes in the gut bio - micro biome in an unhealthy way produces intestinal inflammation, a bacterial imbalance and CFS symptoms which often includes G.I. type symptoms. Polar metabolites I someone will have to explain to me what the polar means, I look it up all over the place, I still don't know what it is. However, you do

find differences in metabolized which downstream of the gene and all kinds of other chemical processes that take place you end up with metabolites. And he - (Maureen) identified 29 metabolites out of 361 that were lower in ME/CFS, four were higher. She described this as a hypo metabolic state, she suggested this could be an inexpensive diagnostic test. She rightly points out it needs to be replicated as the studies really need to be done.

Brain studies -- (Ben Naddelson) -- he looked at imaging data and spinal fluid samples -- ME versus CFS -- found impaired cerebral blood flow and glutathione, that was actually the precursor of that NAC study. And ventricular Lactaid higher, again that's a sign of abnormal aerobic metabolism filtering up into the brain compared to controls and this actually is a replicated study. Autonomic dysfunction this is - I guess part of my enthusiasm in this field is focusing on this heart rate variability. That's a window onto autonomic function it's a - you can measure it noninvasively with a very small heart monitor. And it is lower -- HRV heart rate -- that's the variation between heartbeats, it's different from heart rate.

And it seems to be a - an indicator of good health if heart rate variability is high and declining health if it is low. And you do have a basis for this in ME/CFS studies perhaps there are half a dozen studies out there showing that you have lower HRV in sleep in ME/CFS versus healthy controls. You have lower HRV in lower functioning CFS versus higher functioning CFS. This is a - call it a very convenient way to it's like a proxy for health and well-being. The study I'm doing I am proposing that HRV declines might be predictive of behavioral relapses into connectivity and a patient's heart monitors by the way are commonplace these days. If patients can learn how to predict what's going to happen with their functioning and behavioral relapses perhaps they have a leg up on management.

So this could be a biological marker of illness ups and downs before they actually happen. So that's that flyer that you all have that was handed out yesterday. So I'm in the process of recruitment and I certainly welcome patients calling in, you don't even have to leave your home, any level of functioning is fine even people who can't leave the house. So I'd like to gather everyone into the study not just obviously people have to come into the hospital it's requires effort, you don't even need to do that.

Yes criteria for diagnostic test -- I'd say one of the goals here - first of all you need to study to differentiate the patients from the controls. You need to differentiate ME/CFS from other illnesses, that's a higher bar. And you need many replications to relational reliability, and validity and finally you need a test that's convenient, and is relatively inexpensive. You know, clearly with two day exercise test that's obviously way too involved. Something simpler has to be done or has to be studied. Finally, the multisite consortia (Vicki Whittemore) is heading up the common data elements for standardized testing and clinical studies, I think this is a very valuable endeavor. Again we do have common assessments in data elements - it facilitates comparisons across studies. It helps with your analysis, I can compare it to the promise initiative out of NIH a few years ago they produced these standard self-report measures of pain and fatigue where in just a very few items you can get a sense of someone's pain. You know, pain level or fatigue level and many other measures and it - slowly researches are recognizing. You know, we all have our pet measures, it's hard to kind of graduate to something else.

But I think this kind of - this will actually facilitate comparisons. Because even if you are comparing fatigue on one measure or fatigue on another, you know, the comparability really sometimes affects what your findings are going to be and the conclusions that you can draw. And Beth Unger is doing the (MCAM) multisite clinical assessment, seven collaborating centers well

under way -- 700 cases. You know, looking to describe the course of the illness, identify measures that best correlate with clinical differences, and identify what measures best distinguish the ME/CFS in comparison groups. Again these are very important large-scale research projects. And, you know, I for one thank NIH and CDC for doing them.

Okay how many researchers do we have out there? A handful, very few. Still we have gathering evidence from multisystem abnormalities because of newer technologies and innovative studies what we now have are - call them micro-frontiers of physiological dysfunction are being identified. Ten years ago, five years ago probably couldn't have had- the technology wasn't quite there. We now have better understandings, cause, pathobiology, potential diagnostic tests. We have new treatments under way but we need more researchers, funding study replications, I think we're making progress. Certainly after the announcement this morning, the funding thing is just that's just such good news I can't tell you. But also to encourage new researchers to me there's still major challenges that we have. And I'd like to thank all of you as well as national Institute of health, national Institute of neurological disorders and stroke, Centers for Disease Control and Prevention and Department of Defense, certainly all supported this conference and the - we have NIH and CDC here today and I appreciate your support all along thank you.

Woman: Than you Fred sir.

(Gustavo): (Unintelligible) find your presentation?

Woman: (Unintelligible) yes for the - it looks like (unintelligible).

(Gustavo): Yes.

Carol Head: (Unintelligible). So while (Gustavo's) helping us find the right slides I just - I want to - the topic is medical education and I do appreciate being allowed sometime today to discuss this topic. I know it's of interest to everyone, it's certainly of interest to us at the Sole - Solve ME/CFS Initiative and a special thanks to (Donna Pearson) and (Mary Dimmick) and (Emily Taylor) on our staff who really put together this presentation on this issue. And what I've got is a number of slides -- not too many -- six or seven that I will try to go through very briskly with the idea that we really would like to have some discussion.

The important element is the discussion, you know, what we all recognize this as a problem. I shape it with the slides that I described and then, you know, how do we begin to move forward on this? Okay terrific thank you so much. So I think we all recognize the problem with it - we've touched on it many times in many ways today. And ME/CF patients often unable to access quality medical care. Patients report dismissal by medical professionals on average it takes four years to get a diagnosis. On mainstream online clinical guidance is inaccurate it's often misleading and in some cases harmful and less than a third of medical schools include ME/CFS information and only 40% of medical textbooks include ME/CFS.

So a lot of this is due to the intense stigma, representation and represent regarding ME/CFS that exists in the medical community and in the general population. So we have the continued discrimination dismissal and harm to ME/CFS patients. I should've introduced myself at the beginning -- this is Carol Head. So what are some of the basic needs here? We really, you know -- they're basic -- improve attitudes, understand the basics of the disease, and have easily accessible clinical guidance. And also -- so long as it is necessary -- understand the flaws in some of the existing literature. These elements are vital to improving the patient experience, the strength and quality of

healthcare workforce and improving health equity to patients -- we're really talking about health equity for patients.

And just like other diseases that have faced harmful stigma like HIV-AIDS, autism, really a proactive effort to reeducate the medical community is needed. So there are of course many challenges if they were not we would have solved this already. We've outlined a couple here and one is that -- again that we've touched on this morning -- as curricula is developed how is it - who has input into developing? Who has the ability to review it prior to publication? And in some instances - in many instances this has occurred without input from patients, you know, again nothing about us, without us, as it should be a mantra for all of us who - in the patient community. And so one of the topics that we I think need to discuss further is how do we change the way in which medical information is provided.

We know there's the stigma and the, you know, this is a biological disease not psychological and that as we know is persistent. And one of the key challenges here is that as we know -- to my knowledge -- there is no funding, none, zero, zip to develop and disseminate materials at this point for medical education either for current clinicians especially including nurses and to disseminate those materials. And the current bad science continues to stagnate process. So I'm again moving quickly here wanting to leave time for discussion. The content of materials experts at a minimum preferably patients, stakeholders, and (Sifsac). I go back to the theme that I harkened on yesterday that we as a entity who 's charged -- by the department of HHS -- to make recommendations about this should have a key role in developing and overseeing the development of material.

And then the second bullet there is a genuine effort is made to implement the IOM for clinical care there must be as well for the what we call in between

patients who fit previous criteria like Fukuda but not the current criteria. Although we don't have a definitive understanding of what the one single current criteria is we know there are patients who are sort of left out because they don't fit the current IOM criteria and yet have previously been believed to have ME/CFS. And we need to have an understanding about how to handle those folks as well. But that said the IOM clinical diagnostic algorithms should become common practice for now until we convene another meeting to improve it.

Treatment recommendations -- best practices -- treatments recommendations should come from clinical care experts with a direct patient experience. And I know at our organization we've had this fantasy of convening the handful of folks like Sue and Dr. (Montoya) and several others who understand this from clinical perspective in great depth. And begin in building a database based on their knowledge that would become specific information that would be of use to clinicians everywhere even sort of beginners. Internists who are not at all familiar with this disease. Here we go - there we go. Am going the wrong way? Yikes!

Well I am going completely the wrong way I'm going to try this again -- I think I'm getting there thank you though -- so a plan to address the stigma. We really do need to look to the CDC I think on this issue and taking a proactive position on pace style CBT, GET, Oxford psychogenic disease theories that -- thanks to other agencies -- have now been put aside as inaccurate. And we are not yet there where we need to be. We do know the plan for active dissemination and outreach to medical - major medical associations. Again there is -- to my knowledge -- no current plan to do that and we certainly want to partner with medical education providers and premier clinics to correct the disease misinformation.

So the first steps toward making this happen is planning for it. So -- to some degree -- this presentation is about beginning to plan for this. Which I hope the what we can discuss here today before we depart. So what else -- this is my next-to-last slide -- what else needs to happen for us to be successful here? You know, we know that patients are flying thousands of miles because they're so few specialists. We desperately need to fix the ICD code and fix is the right word I think because many of you know currently many people with our disease are lumped under the single ICD code chronic fatigue right? And kind of, we all know, young mothers have chronic fatigue, people who work two jobs have chronic fatigue, many folks have chronic fatigue which has nothing to do whatsoever with this disease.

We need obviously improved science and diagnostic guidelines with disability guidelines many of these things that we've covered today. And then sort of the last one that -- today of all days -- in the history of America probably no one wants to step into but is, you know, health insurance. How do we handle the health insurance issues regarding this disease and those that suddenly become even much more complicated? But they are very real and they are very painful and for ME/CFS patients. So let me try okay here we go. So this is my final slide, first off thank you as I had indicated before to AHRQ you all took a significant step with the addendum. I am curious as to sort of what happens next with what you've done out of the very important statements to be made and I'm not sure how that would be disseminated or what help happens next with that.

Regarding HRSA obviously there's - in your - I believe it's a four year strategic plan for HRSA that says on objective 2.1 quote advance competencies of the healthcare and public health workforce. I would hope that when we would talk again -- I know you're new -- you might be able to report on whether or not that now does explicitly include a plan for ME/CFS as you

are advancing the competencies of healthcare and public health workforce. Obviously we think that's an important way to use the program that's already in place, it's already in your strategic plan that could be helpful to this disease. And then CDC of course information source and dissemination and I think probably -- this has been beaten to death here -- but obviously your work is very important both to have the correct information available and to look at dissemination of it.

So I would just add sort of two points here and then I hope this has been sufficient to stimulate some discussion. First, just back to what I was talking about yesterday we must remember that this is an urgent health crisis. Two-hundred and fifty-thousand Americans -- the whole city of Toledo Ohio or Petersburg - St. Petersburg Florida - suddenly fell ill with a serious disease for which almost nothing is understood. This is urgent and it is a national health crisis. And then - I think the other key question that I that I'll keep harkening on is how do we make sure that stakeholders particularly patients are included in all the discussions that are occurring in all these agencies. So that is the end of my presentation, Donna or (Mary) did you want to add anything as you were both involved in developing this? No, yes?

Donna Pearson: Yes this is Donna perhaps we can tie in a little bit of the recommendation follow ups that Sue said that maybe we'd find some time for. Because I think two of our recommendations from May 2016 were actually related to the issue of medical education.

Carol Head: Yes - yes. Yes good I do believe we have time at the end of the - of this session to (unintelligible).

Woman: I just had a quick question when you are talking about medical education and because you mentioned the word research and there are you talking about, you

know, firstly the clinical case definitions versus the research case definition or...

Carol Head: I think...

Woman: Are you mostly aiming -- targeting -- clinicians or...

Carol Head: Yes - yes...

Woman: ...also?

Carol Head: I think it's...

Woman: Okay.

Carol Head: I think it's real -- yes -- it's much more about the -- in this instance -- about the clinical definition.

Donna Pearson: We were originally intending to talk about the research but we decided there was not enough time.

Carol Head: Right.

Donna Pearson: Which is why you saw that on the slide.

Woman: Okay yes.

Carol Head: Yes Vicki.

Vicki Whittemore: I just realized I forgot to mention that my colleague (Doe Breen) in NI/AID submitted a proposal for a session on ME/CFS at the I'll get it wrong probably international immunology clinical immunology meeting in June that was accepted. And so the plan is to have someone come and talk about ME/CFS and educate the immunologists about the disease and the diagnosis and then have additional people, and talk about research on the immune dysfunction in ME/CFS. So that's, that will be on the docket in June.

Donna Pearson: Great.

Vicki Whittemore: And we're hoping to do more of that kind of thing as it becomes available.

Carol Head: And just a small plug for our organization in a similar vein although not nearly as intense as what you're describing. Doctor (Zaher Noli) and I will be speaking next week at the precision medicine conference. It's a gathering of 400, 4500 individuals from all around the world who have an interest in precision medicine and we're - we're doing a - we somehow manage to wrangle -- this is Doctor (Noli) for you -- wrangle an hour on the agenda to talk about ME/CFS. And we believe that for the vast majority of people there to be the first time they've ever heard of this intriguing, fascinating disease (unintelligible). And we're doing it because we want to, we hope to it provoke a spark the interest of other researchers in this disease. (Ted) did you have a...

(Ted Ganiats): Yes I want to think outside the box. First of all, this is too important a problem to be focused on medical students because you're going to get 12,000, 15,000 medical students a year and you have hundreds of thousands of physicians already out there. I think you've got to do something for the physicians. So a couple of ideas go for both the medical students and the real world of doctors. This committee doesn't have the power to do any of this I'm just throwing it out for the fun of it. In California several years ago they decided that with the

stroke of legislatures pen and the governor's signature they change the way medical education is going to occur in California. If you are going to get a license in California you needed four weeks of family medicine residency.

That's the pending Edison courtship, not a big deal, change to everybody in the country because if you're going to school at Boston in Boston and you might want a California license sometime in your life you're going to need four weeks of family medicine in medical school. There are some ways to get around it and that's a very powerful law on the licensing requirements. It's not an education requirement per se but a licensing requirement. I don't think you can redo that with this disease but it might spur someone to have some interesting thoughts. Second thing, is in California there is and other states there are licensing continuing licensing requirements like I need X number of hours of pain certification, I need X number of hours of AG. I think the IOM report gives very strong ammunition to be able to go to a licensing board and say public health hazard, public health problem, great under as a low understanding in the population and things that can be learned maybe you should require it. And doing it in one or two states committee shake things up. Because I've given CME lectures and I've even given good CME lectures not on not just a small number of them because CME's know not to make a big deal of difference.

Carol Head: Yes.

(Ted Ganiats): Going to give a lecture doesn't make a big difference.

Carol Head: Got it.

(Ted Ganiats): Change the licensing - change - just try to think of it in a different way. May be a way for us to move forward a little bit and the other thing is board

certification. That for changing getting the boards to throw MEC FS questions on their board almost all specialties now are requiring recertification. And if that becomes known it is a another reason for the real world doctors to decide this is a real disease I have to learn something about.

Carol Head: I think that's a great idea thank you so much for bringing forward. (Mary) did you have a comment? You could maybe go to the mic.

Man: Right there.

(Ted Ganiats): I think those actually that first part where you compliment...

Carol Head: Yes I'm going to need to repeat that a couple times.

(Gary): I think that's a great idea (Ted).

(Mary): That (Ted) wanted to - (unintelligible). I think for me it underscores the challenge because I know somebody who is actually reached out to the licensing board the certification board and without supportive HHS to make that happen we're not going to get very far. And so for me it underscores what HHS can do with its leadership position to actually make that happen.

Carol Head: Yes I'm - we - I think that's also a good idea and I think it might have been in part of the IOM dissemination report had that suggestion. And I don't think actually HHS or the government has much influence on the - those committees. It's actually professional organizations themselves which is why it's so important that we were able to include some of them in our roundtable meeting in essence continuing to educate those professional organizations about the importance of this illness, it'll get there. And I - and our Division Director with the infectious disease Society. And there's some credentialing

that they're doing that she said a ME/CFS was included. So I think, you know, we just need to start but I hear again I don't think that's an HHS, we can't make them do that. That's not in our purview. Yes please.

(Gary): I approached when I first got on the committee I actually approached the Family Medicine Board which is one of my boards about adding some questions about ME/CFS. And it's an incredibly difficult and bureaucratic process to get through that. They were not interested at the time we now have a P2P in the IOM and they may be interested if we revisit it with them. I if we can get it accomplished I completely agree with you I think...

Carol Head: (Jonah)?

(Jonah): Well I'm just going to ask (Gary) who is the "we" in that statement if we could get that accomplished, who are you suggesting? Are you suggesting you go back to them again?

(Gary): I would actually be happy to go back to them and we could even create a small working group a to talk about approaching not just family medicine but the internal medicine people of the pediatrics boards. And also looking into what it would take for the, you know, Virginia just required us so my boards of family medicine and pain medicine. Virginia just required us to have two hours of CME on opioids in order to renew our license. Which is fine the District of Columbia requires me to have several hours on AIDS in order to renew my license here in the district. So I think why not, you know, and I think it's a function of maybe creating a working group to start to look into what the process is and how we can facilitate that, push that along. And yes I would be willing to participate in that.

Carol Head: Yes (Jose).

(Josey Montoya): I think that -- following on Beth Unger's comment in fact I'm a member of the Infectious Disease Society American -- actually a fellow. And when I took my boss to recertify in infectious disease since last year there was a question on CME in the ID boards. And in fact that was a question about my trial there and so it was really funny answering that question. So I think that NIS got Beth on the research agenda and setting the tone and they had the best capabilities. And the education part I wonder if we should continue to support the CDC efforts in creating the education and material with all the - I'm sure the CDCs open to the dialogue, to the input, to corrections if they need to be made. I just wonder that when you go to societies like the IBSA, my society too, or the American College of Physicians you have much more weight if you come from the CDC or like Beth Unger suggested from the IOM. So I suggest that rather than creating separate efforts and body groups that we support and have the CDC as the repository of material. Because of the task process that they go through to have something that proves as official - we tend to believe that what is there has, you know, has been guided properly and has been scrutinized scientifically.

Carol Head: So I think as we come to the point later today when we review the May 2016 will look at that as part of the recommendation process then yes.

(True Homer): Once again this is (True Hummer) there are a lot of similarities to some of the VA activities. The White House actually initiated a joining forces task force I think was led by Michelle Obama and that in that was imparted to not anything related to explained illnesses specifically but just to create more awareness about veterans and combat veterans health issues when they come back from war. And so one piece of that was to go to a national board and medical board examiners and actually funded them to develop step one, two, three US medical licensing and questions. And that's a very interesting

process because now every medical student and I agree that's only going to get people to come out. But now it's getting built into the curriculum because there are test questions and that's driving the curriculum.

Carol Head: Interesting thank you. Other comments thoughts about medical education? We know we're coming back to it some (unintelligible) recommendations are for now. All right well thank you so much for the time.

Woman: Donna did you want to make a comment - or - during this time period? No. Well maybe we should use this time then -- and we can push the break until 3 o'clock perhaps -- to discuss if other people agree or if other people have suggestions -- the May recommendation as was brought up or anything else on the agenda? Yes.

Donna Pearson: Okay so this kind of goes along with the medical education issue and it's the two recommendations from May. One and maybe others don't feel as strongly about this as I do but I feel so strongly that we need to pull the disease and the neural immune disease out of the chronic fatigue wastebasket as Fred said. And he almost seemed surprised when he said it that they call something chronic fatigue. No patient is surprised by that. There are 1 million conditions being called chronic fatigue and chronic fatigue syndrome in this country and around the world. We have identified basically through the IOM Report and the PTT report we have identified a disease that the medical community was not really aware of before. That's big news. And if we don't pull it out it's not recognized as big news. So that was one recommendation we had made last time. Is that - does anyone else agree with that?

Woman: I do.

Woman: Okay well it sounds like (Gustavo) and Beth we should maybe words with it and then pass it around for a vote. Does that make sense (unintelligible)?

Man: Is this - Donna is this what you emailed me this morning?

Donna Pearson: No this is a recommendation, it's to separate the distinctive ease acknowledged by the IOM from the broader set of conditions defined by (Secuta) and Oxford and all the other physicians that just call things chronic fatigue based on fatigue. It was a recommendation that was submitted last year and it's it hasn't been adopted it hasn't been really addressed at all. It's in the back of everyone's binder its tab six.

(Dan Cook): This is (Dan Cook).

Woman: Which number?

(Gustavo): I'm about to put it up.

Donna Pearson: It's...

(Dan Cook): It's recommendation number 2.

Donna Pearson: Correct.

Woman: Okay.

(Dan Cook): Donna are you - are we just resubmitting this again for - because the response, we want a better response?

Donna Pearson: I certainly do and I'm...

(Dan Cook): So we don't need to necessarily wordsmith it.

Donna Pearson: No I don't think so.

Woman: Okay.

Donna Pearson: We need to discuss what do we need to do to get if everyone agrees that this is an important what do we need to do to get this to happen?

(Dan Cook): Well the first step is that this committee needs to express strongly that we're not satisfied with the response.

Woman: Now this is - ask (Colin Sharpen). So is sort of a new set of eyes on this? I'm not sure I understand what the outcome is from separating out. I mean I understand it's in terms of terminology it's I am not sure what we're separating.

(Colin Sharpen): So the whole wide world thinks they know what chronic fatigue is.

Woman: Right.

(Colin Sharpen): All these physicians are meant understand what this is. We know that there's this unusual characteristic of exertion and tolerance, that's a big, big deal. And it's being lost, it's even being lost in the new educational materials. When you read some of the updates on some of the, I don't know not Medscape but what are some of the ones that use? I'm losing the there's something that meant students, that doctors refer to frequently on the web.

Woman: Update.

(Colin Sharpen): Update is that one of them?

((Crosstalk))

Group: Up to date.

(Colin Sharpen): Thank you so much.

Woman: Yes.

(Colin Sharpen): So when you look at these things they're not focusing on this extremely unusual and very prominent characteristic of this disease which is that there is exertional intolerance. They're talking about fatigue, they're talking about cognitive, you know, all these other things they don't really understand that one thing. I think that's why the IOM wanted to rename the illness. And unfortunately it didn't go over well. But I think that was their goal, how can we achieve that goal is the question.

Beth Unger: Yes so I'm - I read the part underneath -- this is Beth (Colin Sharp). And I read these things about a new name and a new IPD code, new clinical guidelines and new CDC webpages. That's for activities. Is that what you're asking for? I'm trying to figure out what the ask is.

(Colin Sharpen): It - okay...

Beth Unger: And what, you know, the secretary would say okay we're going to do X.

(Colin Sharpen): So the ask is we want the secretary to recognize that there's this big wastebasket of people with chronic fatigue in this country. We want the

secretary to recognize that we have identified a specific disease that's in that wastebasket, we want to pull it out from the wastebasket and identify it as its own disease. If we discovered multiple sclerosis within its wastebasket, we would pull it out on the chronic fatigue thing. I know we don't have the biomarker and that's primarily our issue, once we have a biomarker it's pulled out I know that. But if we're not going to get one for years at the very least we can pull it out and educate the medical community that we have identified a very specific disease.

Woman: And do we have I think we might have to say something about the CDC's response to this recommendation. Which I guess we're not satisfied with but I think it has to be commented on when we resubmit it.

(Colin Sharpen): This is him. Oh yes I can't see you Sue. So speaking for CDC the new website that they're developing we've already initiated the process as you know is there roundtable input happening in September. And that website to be based on the case definition that was put forward by the IOF in (unintelligible). That leads to some of the request...

Donna Pearson: The problem is that people are, all of these physicians are just assuming that you're talking about the same chronic fatigue wastebasket disease that they've come to misunderstand. And we're saying identify this disease specifically.

Carol Head: How? I mean so what if we said this is FCID. That's not going to work right?

Woman: Or maybe we want an additional statement that this is indeed distinct from Fukuda that, you know, just maybe a couple sentences of explanation.

Man: Without lining -- this is (unintelligible) again -- without lining the criteria -- the diagnostic criteria that was summed up by IOM do that? Would that address it?

Donna Pearson: Can there still be a CDC webpage for chronic fatigue? And then a separate webpage for this disease? If some, you know, do you know what I'm saying?

Carol Head: Yes.

Donna Pearson: You're kind of eliminating the CFS - you're completely eliminating that and now calling it ME/CFS.

Carol Head: We're calling it ME/CFS -- sorry (unintelligible) -- and I do think there is a little bit of confusion and we never called it chronic fatigue okay?

Woman: Yes you did.

Carol Head: No we didn't and there's a couple of things that are conflated here. We at our part of CDC that is response for the webpage does not have control over the ICD coding. The ICD coding is NCHS and all of the information about how the illness should be coding they're looking to the professional community to it's usually the medical professionals that are, make the initiative for changing medical codes not the patient community. And according to them they have not had input from medical professionals about the need to change code. Okay? So keeping aside the issue of coding the question is, is there a, you know, we have a, you know, there's great concern that there was the 1994 research case definition before that there were other case definitions. There's the 2003 definition. What are the roles of these prior definitions? And are we saying that's totally a totally separate thing?

And I think it's not 100% clear that these are totally separate, different conditions. What you can say that if a person meets all of the criteria of these has and the clinical you have the IOM that it fits this criteria and then every case definition that I know love always has this little codicil if people don't fully meet the case definition what do you do then? Or how do you manage them or how do you consider them? And clinically when people present to doctors if they don't absolutely fit every aspect of the case definition but today said it best often they're managed the same way. None are I mean deferred to all the clinicians how they manage this and that's why we had clinicians, we wanted them to be part of the comment period for how to handle this.

But you - we're building upon some education that has been done out there to have people understand chronic fatigue syndrome and actually when I personally became involved with this the study it was sort of a field that was kind of a major step forward that there even was an ITD code at all for it. And so it's to totally say this is something totally different I think would not be helpful and to have two webpages would be really confusing. So I don't see us doing two webpages, ICS doing a webpage that clearly defines this illness as the IOM and give some background on other how other case definitions were used in the past as appropriate. And I'm not single all the way back to Oxford, that were not even going there. But for background on the 94 case definition in the Canadian case definition and, you know, all those modifications.

So clinicians as they read some of them that are interested have read some of the literature. I've had clinicians tell me well, you know, it's helpful to get different views of this illness. There are different aspects and all and all there is more similar about these case definitions then different. And while you could take individual parts of the 94 case definitions and say there's like 70 million ways you could fulfill it in reality if you meet the case definition the

symptoms are so closely interrelated that most often you fit the IOM case definition. You've got the post exertion and MLAs, you've got all the features. So it is a little, it is truly, you know, it possibly could happen but biologically they're linked. And so I think what we're at is a way of trying to explain to clinicians when a patient comes in what to look for. And so I believe that building on the IOM is the best way to move forward and having a separate webpage on something else would be confusing.

Donna Pearson: So I'm not explaining this well and I'm just going to give it one last try and then I'm going to give up. I hope that someone else can step in. And I don't remember everything that we said last time but the gist was that the Sequoia definition was based on fatigue caused by no known somebody help me out here because I can't remember exactly what it was. But as the just was it was unidentified fatigue, that was the underlying concept. And that anyone who had a specific diagnosis other than that should be excluded from being diagnosed. And we're saying we now have...

Carol Head: Yes.

Donna Pearson: ...this should be excluded.

Carol Head: Okay so what the term was, was unexplained fatigue, unexplained fatigue. And going back to, you know, the 1994 case definition was intended as a research case definition which is one of the biggest problems. I mean it's was it was made for research case definition you can't blame and for being a research case definition. Clinically clinicians recognize that many patients had reasons quote unquote for their fatigue that once were fully treated still had chronic fatigue syndrome and they would manage them it didn't matter. You know, but for a researcher that wanted to say well what is specific about this illness the advice was to researchers which is all a case definition is was to try

to exclude those patients because some of the data could be confounded by other illnesses, that's all. And so the IOM is saying we don't care about research right now, we're trying to get the clinical care and so on a practical level you and this is where you have attention because you don't want a physician to say that's what you have. You do have to still consider all the possible causes of fatigue and make sure that any treatable illnesses are identified and appropriately managed. It's not intended to be just called on chronic fatigue syndrome or SCID.

Woman: (Dane).

(Dane Cook): (Dane Cook) So the IOM report the reason that this recommendation came out the way it was in part was due to the IOM report. Basically said if they don't need this then they don't have this so that's what it stated. The best point and yours Donna if the CDC website were to make it clear that this is what the IOM is, this is a clinical case definition. Historically the 1994 case definition was a research case definition would that not satisfy what is we're asking for here.

Woman: I don't know the protocol here but I'm wondering if (Diane) being on our board...

Carol Head: Yes.

Woman: ...could comment.

Carol Head: Yes.

(Diane): As a parent of a patient I have to tell you that the coding is still critical. Because if their pay is recommended and it's recommended for chronic

fatigue as opposed to chronic I think now the coding is for chronic fatigue syndrome is that right? Or is it...

((Crosstalk))

(Diane): What we have had, you know, personal experiences where because chronic fatigue syndrome was so poorly defined when an insurance company refused to pay for whatever and we appealed it and even and I'm under a federal health plan so this is supposed to be like the top level appeal and they go to an independent panel. But what came back to us was that, you know there is a the diagnosis is vague there are no approved treatments. And whatever was recommended was considered experimental even if there was research in the field to support it. So it is the coding is very, very critical and I take your point that CDC doesn't have any control over this. But certainly you should be able to make a recommendation as to when something don't code it chronic fatigue syndrome that 780 whatever it is unless it meets the IOM definition. Is that possible? Does anybody else does that anybody else understand what I (unintelligible).

(Gustavo): Go ahead (Armeus).

(Armeus): MAS here I agree with you the coding is very critical. It's important for a number of reasons including, you know, doing research using the ICD tint coding. And Beth is right we don't have any direct control in influencing how the code is worded. And this is partly...

(Gustavo): So...

(Armeus): ...all recommendation. We've talked to (Gustavo) about this about the (unintelligible). And what we...

(Gustavo): We - if you don't mind...

(Armeus): ...should (unintelligible)...

(Gustavo): ...interrupting so I reach out to the same person (Donna Picket) who made a presentation to this committee two years ago. Unfortunately she couldn't make it for personal reasons she had just come out of surgery. However she said that nothing have changed since the presentation she made two years ago. That because Beth and correct me if I'm wrong I'm repeating what Beth said earlier than the change have to come from the medical community. And that has not happened yet.

(Armeus): Right but again since there are a lot of new people on the committee and probably even in the audience we could try to bring her back and give even if it's the same presentation on how to the process is done for the ICD...

(Gustavo): I mentioned that to (Jonah)...

(Armeus): ...coding.

(Gustavo): ...and she said she didn't have anybody in her staff senior enough to come in and speak.

(Armeus): For now.

(Gustavo): For this meeting but she was more than willing to come next time.

Carol Head: (Unintelligible) yes...

(Armeus): I think that would be helpful for the committee to understand how this process is...

(Gustavo): Go ahead Doctor (Calhoun).

(Derek Calhoun): So -- this is (Derek Calhoun) -- I agree with you that the coding is very important. But there's a church and state issue. You are going to get the specific coding for chronic fatigue syndrome on my myalgia and encephalomyelitis and the insurance company is still going to turn around and say to you there are no approved therapies and we're not going to cover this. So the problem so in one sense yes we want to be as specific as we can be with our code for many, many reasons. But as far as addressing the issue with the insurance company that's a whole another problem and I will tell you as a clinician we're getting pushback daily from writing samples prescriptions because they don't cover this particular drug. They won't tell us which drugs they will cover and I mean simple things -- Zithromax. So they won't let me write that antibiotic but they will let me write, you know, for doxycycline. And we're there incredibly pushing back enough in terms of everything that we're coding and we're writing on them. But that's a completely separate issue from the coding itself, the coding is necessary for lots of (unintelligible), the logic data and everything else that we want to do with it. We want to be as precise as possible in communicating to the physician what our diagnoses are. But the insurance companies are a whole another battle and that has to be approached differently.

Donna Pearson: And how would we approach that?

(Derek Calhoun): I don't know but if you can find out I'd love to.

Woman: Okay Carol.

Carol Head: Yes if this is a feed for our organization I'd like (unintelligible) (Mary Dimmick) who is also on our board to comment on this.

Woman: Sure -- okay -- yes.

Carol Head: And I - whiles (Mary's) coming forward I just - ...

Woman: Well are we working - okay may I just say something? Are we working towards refining this recommendation or do we - let's think about it we can keep it as it is or we going to refine it before resubmitting it?

Carol Head: I think (Mary)'s comments address that.

Woman: Go ahead.

(Mary Dimmick): So I'm going to speak to really briefly to the ICD I actually presented to the ICD twice to get this changed. The last time that I created a proposal, submitted the proposal, presented to the ICD. The last time (Andy Cogolnac) actually gave the presentation. So they have had medical input, we can go back to them again and will need to. I agree that it's an issue that needs to be addressed but it's just I mean the point that (Donna's) making about the narrative. We need to be clear about what happens to Fukuda patients that don't need IOM. They need to get the insurance cleared up, they need to address the stigma, it seems to me that there's, you know, to the point you made a workgroup could look at all of these issues. Could look at that the recommendations that haven't been satisfactorily met yet and some others like how do we address the stigma? Because in order to change what's going on in the clinical care there is a number of things that need to come together and we can't work through it all at this meeting.

Woman: Yes I mean I'm just trying to be practical because if it wasn't accepted the way it is we should change it, you know, obviously. So...

Donna Pearson: In (unintelligible).

Woman: How do we then implement that? How do we move forward with that?

(Armeus); And yesterday we discussed about recent meeting recommendation number 1 revise if and I would recommend to the committee if you guys are not satisfied with the way number 2 reads we could do it the same.

Woman: Oh okay (Ted).

(Ted Ganiats): The IOB, try to solve it as you said but having two different names SCID and chronic fatigue syndrome. And if you don't have two different names it's hard to differentiate them. Not give two names. And so that's what I would see our number 2 if you could come up with a second name that would help enable people to act on that. The it seems that ICD if they wanted besides the their report that was just given if you have the IOM which we're medical field people making a recommendation that a get its own ICD. I don't know what else what other medical books do we need to have report to them.

Donna Pearson: It just sounds like we might not resolve this, you know, but it's an important issue and just don't know how we proceed. Okay Carol.

Carol Head: So let me offer a recommendation on this. I mean obviously I think there is general agreement that medical education is critically important and it does it has my short presentation laid out there are a number of issues here. What's presented to the public ICD codes, how you go about educating clinicians, so

let me propose that we form a subcommittee of the staff to come back at our next meeting with some recommendations about how to move forward on the broad topic of medical education.

Donna Pearson: Subcommittee you have to help me here Beth or workgroup...

Carol Head: Workgroups are okay.

Donna Pearson: Okay.

Carol Head: Workgroup.

Woman: And workgroups are not necessarily...

Donna Pearson: Keep that in your mind, we'll do that when we talk about future work groups.

Carol Head: Okay.

Donna Pearson: But yes sure let's keep a list.

Woman: And workgroup is not necessarily just committee members.

Carol Head: Right.

Woman: You're welcome to invite others.

Donna Pearson: Sure, see that's your chance folks. Okay Fred.

Fred Friedberg: Yes I just puzzling how you come into a resolution on recommendation to - it there are just so many complexities with a recommendation like that, I just

don't see how it I think this idea of having like a workgroup dedicated to a recommendation to see what really is involved to get it anywhere I think that's really pretty critical. It's very easy for us to say something should be done but getting it done to me a workgroup is what gets it done or at least find out if it's even feasible to get it done. So, you know, I'm all for identifying the illness as it is. You know, I'm certainly on board with those IOM criteria now even if we got something like that adopted on the CD - it creates complications for clinical doctors who are not concerned about whether it necessarily meets a specific set of criteria. They want to help the patient and it's not like if they meet those criteria there told yes you do XY and Z it's not so clear-cut.

You know, it's if we had a biomarker and said yes they meet this criteria then you get drug acts, that something completely different. This is a mess. So the ones who are even willing to see these patients and treat them they use their clinical skills and their intuition they come up with a very individualized treatment plan and they're probably less concerned about three or four symptoms. They put it together in their head and thank God we have at least a few people out there who are willing to take the time with these patients. So what might make us feel good so to speak I'm not sure that that this advances a doctor's ability to treat these patients. That's why I think you need a workgroup to really think through these issues rather than, you know, a yes, no, up or down vote on them.

Woman: Well that's it I mean I think there's probably too much information lumped into this one recommendation -- the way it stands -- and that people have to vary it out maybe make it into two additional recommendations. Because there's ICD 10 is one issue and then distinguishing between the IOM definition and the Fukuda go ahead Donna.

Donna Pearson: I'm certainly in favor of a workgroup but I just want to point out that this recommendation basically came from the IOM. We quoted the IOM and they said the Fukuda definition identifies a larger more heterogeneous group of patients. And that these some of these patients will not fulfill the criteria proposed here. So they clearly stated there is this disease and then there are some patients who have been diagnosed with chronic fatigue syndrome who aren't do not have this disease. And when we were trying to get at was what do we call what happens to those patients. If we've just converted CFS to this disease we still have all these patients that don't meet the criteria. What are they going to be diagnosed with? That's the question. And I do agree that the name of the problem the name has always been the problem and maybe the workgroup will reach out to some of our experts and see if we can get some consensus or something.

Woman: Okay so pretty soon we have to move on to states recommendations.

(Derek Calhoun): Here's one part - if anyone...

Woman: Yes go ahead...

(Derek Calhoun): The thing that I wanted to emphasize is that we do not truly know the biology of this disease. And so what we're probably looking at is a spectrum disorder and clinicians need to have a leeway. You know, clinical medicine is messy it's not like what happens in research situations where you have that people with this six set of criteria their allowed and then that's the end of it the discussion. Okay we just did a relatively simple research project in the office which was a pilot study. I had to go through 125 people to get 30 people for the study. So and yet they're all very similar but these guys are would all meet these criteria.

So we have to allow for clinical judgment to come into play we can't we have to be careful in terms of narrowing this down to such an extent that clinical judgment isn't allowed to be in effect. And while it would be good to have a series of ICD codes so that we could perhaps get a little more specific in terms of what we're doing we truly don't have enough knowledge about biology to say that actually this is a different disease from this as opposed to a spectrum presentation of the same disease. And so we need to be careful not to try and hamstring are docs. And as I said the other piece of this is it ain't going to fix the insurance problem. The insurance problem is a completely different issue and we want to be as specific as possible. But I don't know if we're ready to be as specific as possible. Because we'd like to be clinically it's a bit of a mess and we need to be able to allow clinical judgment to come into play.

Donna Pearson: Okay would you just clarify you're saying that out of 125 people 30 of them at the IOM criteria? Is that what you're saying...

(Derek Calhoun): No - no.

Donna Pearson: Oh okay.

(Derek Calhoun): For the particular study we were doing the office and in fact 20 of them met it, there were 30 people in the study for tailored control. But we narrow that that's what it takes even though okay so it's two different worlds between research and being a clinician. And...

Woman: So it sounds like we have another working group in the making which will discuss (unintelligible). Now did - was there another recommendation from May that you wanted to bring up?

Donna Pearson: The only other one was we haven't really gotten the a response we we're cautiously optimistic that when the CDC presents their webpage it will have many of the six step recommendations including the very specific details to the item core criteria on there because I know that you want to buy in of the community. You will not get buy in of the community if you just list those four symptoms.

Woman: Okay.

(Gustavo): One quick - I just - I'd be careful I moving forward with perhaps getting rid of completely the Fukuda definition only because that's the definition that has been used in research primarily. And so if you eliminate it's completely then they would be this joint this lack of link. What (Hilly) show that Stanford we took a number of patients a significant number of patients and we applied the three definitions the Fukuda the Canadian, and (Sed) and there was a very high level of concordance between (Sed) and Canadian. And in fact with Fukuda as long as you specify what what's in the Fukuda. And Fukuda is the fatigue for six months that causes all this issues...

Woman: And including.

(Gustavo): And also - well - but mostly that if you have the PEM and the (unintelligible) sleep that are two of the central states criteria and purely central and Canadian. All these differences went away so and what we have done is now to (unintelligible) all this. Because we just want to do the work we just want to understand the disease and we don't want to be spinning the wheel and on the definitions. We just ask the patients to give us all the information to fulfill the three definitions. And we because we're tired of things that are not moving us forward. And sometimes you can get into this any I'm not saying it's not important but it does become a detractor if you stay in that discussion. So

what we had done is just get all the information, fulfill the three definitions, next.

Donna Pearson: And I'm just going to just say because I'm obviously not being clear. I am nothing to get rid of the Fukuda definition and I am not talking about research. I am talking you are all such high-level people here I'm talking about you walk into the doctor and you have fatigue and the diagnose you with chronic fatigue syndrome. They don't even know what Fukuda is I went to a - I tried to find a new doctor in Florida who told me there was no this is a quote. That's a bullshit diagnosis from academics in Boston. And that is a direct quote of this man, I don't see him anymore. But that is a reality and he advertises that he takes care of people with chronic fatigue. And that's what I'm trying to get at. I'm not saying eliminate any of these criteria, I'm saying how do we let the doctors on Main Street know that some people have chronic fatigue for whatever reasons and some people have this disease.

Woman: Well I propose at this time if it's okay with you guys unless you have something else that we move ahead with I guess could take a short break or do you want to just and early if it's not too bad? You want to move ahead (Faye)? You ready? Now I am - I'm going to...

Carol Head: Can I put the recommendations up on...

Woman: Please.

Carol Head: Okay.

Woman: And if you want to send somebody to keep track of if we're wordsmithing anything.

Man: Oh you sent them to me?

Carol Head: Yes (unintelligible).

Man: You'll make some more changes?

((Crosstalk))

Carol Head: It is what we do.

(Derek Calhoun): The first one phase?

Woman: Yes please, does it say HHS recommendations? Yes.

(Derek Calhoun): You have four.

Woman: We're (unintelligible).

(Stacy): Okay so the -- it's (Stacy) that - who's speaking -- for the working group supporting the pediatric needs of educating students. So the charge is up there and I read them earlier. So let's deal with them one at a time. The first one was to evaluate the need of feasibility for a cooperative effort by HHS and DOE to improve physicians awareness in their role in assisting pediatric CFS patients and their families to acquire appropriate special services to the schools. So the first one was in emphasis on how do we get our children that have pediatric CFS services that they need through a 504 plan or through an IEP.

This second charge was to take - to look at the cooperative efforts by HHS and DOE to promote a greater understanding by school nurses of the symptoms of Pediatric CFS. And the accommodations or modifications most likely to support these children in being academically successful. So two completely different charges. We don't - working group participants all thank everyone we did a nice job. All right going - well we had a couple meetings we - it was a messy December let's put it that way. All right so recommendations I wordsmithed these this morning based on comments that I heard people saying. And I don't know if their - I would obviously like some feedback from everyone.

Woman: Do you have any, like, background documents or...

(Stacy): We did not do that.

Woman: References that you relied on or...

(Stacy): That's so...

Woman: Yes I'm just asking because that's often what we do when we send the final letter to the secretary and this is not - and we're not there yet. So that's actually a really good point. The proposal was at this working -- my working group -- continue and that we well you've better I didn't think about it that way until you just said that.

(Stacy): What?

Woman: That the working group continue but this is the direction that we were going to go in. The CDC could coordinate with USDOE Office of Education with

dissemination of information on pediatric MECFS to all parent information centers.

I don't know if the wording - I don't know how to do the wording and I don't know if we should just continue and then come up with a white paper like we've done in the past or what...

Man: We, the federal staff cannot tell you how to do the wording as best we...

((Crosstalk))

Woman: Well you could include some of the material that some of the presenters had earlier perhaps, where it's appropriate.

Woman: Right. I was going to say, I think the presentation that (Carmen) made was really a lot of the background that this infrastructure exists and it's ideal to be utilized by us and MECFS. And so as well as the school nurses. So I don't - I mean we have their presentations. I don't know that there needs to be extensive write up. And it depends on how fine-tuned you want to make it. But I mean I think a recommendation that we coordinate and you try to take advantage of that, is certainly fine.

((Crosstalk))

Man: ...see anything wrong with that working. And if you say - you see a site IOM and there is a great need to do this, (unintelligible) need to have this incorporated. I would - I mean unless other see a need to change any words there, but I don't see anything wrong there in site IOM.

Man: Oh. You went the other way. The only - and this is only a suggestion. I would change US DOE because I think DOE is Department of Energy.

((Crosstalk))

Woman: Now did IOM include - did they have a separate pediatric case that submission? Does the IOM case definition includes pediatrics? No. They have a section on pediatrics on its chapter 6 I believe, in the IOM report. So maybe you should say the pediatric case definition in the IOM report. All right. So where are you in recommendation in the first one? How would you change it (Sue)?

Woman: Information on pediatric patients diagnosed with MECFS who meet the IOM pediatric case criteria for MECFS. So, you know...

Woman: The IOM did not do a pediatric case definition, did they?

Man: I'm just trying to remember whether the concerns about the pediatric cases - the duration of symptoms and that the discussion is to have it be a shorter duration for children than for adults. And I can't remember how that ended up. But there wasn't a separate recommendation and I believe it's because it was thought it would be the same criteria except possibly the duration of fatigue. But I would have to look that up, because it wasn't two separate charts.

Woman: Okay. So wordsmith that again for me, just fix it someone.

Woman: Just leave off, you know, the dissemination of information on patients diagnosed - on pediatric patients diagnosed who meet the IOM case criteria for MECFS in pediatric patients. And then delete diagnosed with MECFS -

for MECFS after case criteria. And I guess we'd want to have a referenced parent information center that would be just one suggestion. We'd have to explain what that is a little bit.

But you don't have to put it in that recommendation. Just have that as part of your background document.

Woman: Okay. (Becky)?

(Becky): So I was just going to say, in keeping with some of the comments we've heard, I would take out the word patients in both one and I guess it's in one and three, and children with or children who meet rather than patients.

Woman: Okay. So pediatric...

Woman: On children instead of pediatric? Better? Could I ask you something? I know this is probably the wrong time to ask, but Faith, did you discuss homeschooling?

Faith Newton: We did not discuss...

Woman: Okay. Okay.

Woman: Thank you.

Man: Faith, I hate to do this to you.

Woman: Wait, wait, wait, wait, wait, wait. Children and adolescents. All right. (Unintelligible).

Man: Any chance we could look at the original wording compared to the new wording, because actually I liked the first wording. It was simple, straightforward and...

Faith Newton: What I can do is save this as, or did I not just screw that up? Yes. It's on my computer actually. If you...

Man: I have it.

Faith Newton: Oh. Do you have it?

Man: The one you sent me?

Faith Newton: No. The one I responded...

((Crosstalk))

Woman: The original wording was the CDC coordinate with the US DOE Office of Education which we'll have to change, on the dissemination of information on pediatric MECFS, to all parent information centers. That was the original wording. Let me read it one more time, slower. And so the original working was that CDC coordinate with the US Office of Education on the dissemination of the information on pediatric MECFS, to all parent information centers.

Woman: I don't like the sentence starting with that CDC. I would start the sentence with HHS recommends that the CDC...

((Crosstalk))

Man: So what should actually go before this is a paragraph or two stating the need and therefore this committee recommends that and then these are the three things that we would recommend. So this is just exactly the summary of so you're going to create a paragraph before that that says here's the need, here's the problem and because of this need and problem, we recommend that. And then these are the three things we're recommending.

Woman: I mean that might be difficult to create on the spot, but just I would make it a complete sentence at least - well, okay.

Woman: But I'm putting it in here as notes from me and then I can do it.

Vicki Whittemore: This is Vicki and I agree with (Gary). I like the wording of the first - the way it was worded originally, because you're disseminating information on MECFS and how it affects children, not information on children and adolescents who are diagnosed. It sounds like that - what that sentence says to me is you're sending information around, about children who've been diagnosed. And that's not what you're doing. You're sending information out about the disease and how it impacts children.

Man: Right.

Woman: That's true.

Woman: That is actually a good point. Does anybody else like the first one, the original one, as well? Group? Okay. All right, so we have to kind of - we have to finalize it because we all gathered together here so we're going to vote on it. So I guess if we do want to put in the introductory paragraph we should?

Woman: No. Yes. Let me set a new slide up. Insert...

Man: So what do we need for a quorum?

Woman: Four.

Woman: Four.

Man: Four of us?

Woman: Yes.

Man: Okay.

Woman: So if you want to - do you want to do a little two sentence introductory paragraph?

Woman: I can but I don't want to do it right now.

((Crosstalk))

Man: You have to do it right now. You have to...

Woman: Oh, I do?

((Crosstalk))

Woman: So let's go back to the first one. That CDC or actually it's going to be HHS recommends, right?

Man: No, CDC.

Woman: I'm sorry. It's - recommends that the CDC coordinate with the US Department of Education on the dissemination of information on pediatric MECFS, to all parent information centers. Does that work?

Man: Yes.

Woman: Okay. So we need one to two sentences prior to this?

Woman: What I was going to say just to offer, you know, a thing - children and adolescents with MECFS frequently require support services and something like that.

Woman: Children and adolescents...

((Crosstalk))

Woman: I'm sorry.

Man: I was just going to say, you had a charge to your working group. Do you think you can just adapt that first point in the charge to...

Woman: Absolutely I can. Oh, that didn't work. Let's not do that. Okay. So we'll change the charge to say what?

Woman: In order to...

Man: In order to improve physicians' awareness or their role in assisting pediatric CFS patients and their families?

Woman: Oh, good. Slow down.

Man: It's the second part of your...

Woman: Is it? All right. I guess MECFS as opposed to just CFS?

Woman: Yes. It needs to be MECFS everywhere that's in there. Okay. In order to improve physician's awareness of their role in assisting pediatric MECFS patients and their families, to acquire appropriate special services to the schools, we recommend, CFSAC recommends. Correct? Maybe put it underneath, like one - I mean that first point is one, before the CFSAC, point number 1 CFSAC recommends. And then you're going to have two other points, two other recommendations?

Woman: We'll see.

Woman: I mean I would put the number 1 before CFSAC? Well...

Woman: Oh I see. Right here on...

Woman: Because you're doing three - you can use that intro sentence for all three recommendations I think.

Vicki Whittemore: Then wouldn't you want it to be - if you're going to start with that, wouldn't it be then to improve - this is Vicki - to improve healthcare providers so that then you have physicians in one recommendation and school nurse in second?

Woman: Do you want me to put healthcare providers or to put physicians and school nurse awareness? Beth, turn on your - and say your name.

Beth Mattey: This is Beth Mattey and I would recommend healthcare providers, because you are talking about physicians, nurse practitioners and school nurses who've got a whole range of health providers.

Woman: And school psychologists and...

Beth Mattey: Yes.

Woman: ...I mean I think that there are a whole number of people who could be involved.

Woman: How is everybody with it now? Show of hands. Is everybody looking good with it? Okay.

Beth Mattey: This is Beth Mattey and I...

Woman: Go ahead Beth.

Beth Mattey: ...have a question. Did you want to include an overall statement about a child as part of their normal development, they attend school or something to that affect, or is that kind of understood?

Woman: I think it's understood.

Woman: It should be understood.

Beth Mattey: Okay. All right.

Woman: All right. So that's the first one done. The second one which I hadn't changed which is good - all right, that - we'll change this one again. The CDC and the School Nurses' Association work together to develop a series of webinars on MECFS to be distributed to all school nurses nationwide. I need a little input from Beth and from...

((Crosstalk))

Woman: We're the National Association of School Nurses. Collaborate to develop a series of webinars to our educational programs. You don't want to limit it to webinars.

Woman: That's true.

Woman: There may be other avenues of education.

Woman: Collaborate to develop...

Woman: Education materials.

Woman: Would it be develop and disseminate?

Woman: Right. Yes, thank you.

Woman: And then you can period after MECFS. Delete the rest of it.

Woman: Delete the rest of it?

Woman: National Association of School Nurses is the correct title.

Woman: My mistake. Okay. Collaborate to develop and disseminate educational materials in MECFS. For?

Woman: Well it could be for school nurses, but school nurses could also educate staff. If you had other - if you left it broader like that then you would have toolkits or fact sheets for teachers, handouts and things like that.

Woman: Okay. But for...

Woman: For school nurses to use.

Woman: Or for school personnel.

Woman: Right. Not the parents is what I'm getting at.

Woman: Well, we could.

Woman: We could. But school nurses - that's part of the scope of a school nurse's role.

Woman: So do you want me to add for school personnel at the end of that or do you want me to leave it be? Do you think it's good? Somebody else? (Gary)?

(Gary): As it affects children and adolescents?

Woman: I can't hear you.

(Gary): As it affects children and adolescents? I mean that's an awfully - I mean - I don't know. It's just an incredibly broad mandate. We suddenly turn over education of MECFS on everything, to school nurses and the CDC. It's under - I don't know.

Woman: Yes. As it affects - right. I think that makes sense.

Woman: As it affects that...

Man: You used the term pediatric MECFS on the other one.

Woman: So as it affects children with pediatric...

Man: Children and adolescents.

Woman: Oh. Children with this disease...

((Crosstalk))

Woman: ...you already have that in the sentence on MECFS? I mean...

Woman: It's underneath the other one.

((Crosstalk))

Woman: Is it A or E?

Woman: A.

Woman: Thank you.

((Crosstalk))

Woman: As affects...

Woman: Adolescents with...

Man: Children and adolescents - now go back...

((Crosstalk))

Woman: Yes. That's good enough. Yes. Everybody happy?

Donna Pearson: This is Donna. Is it assumed that we're using information from the (unintelligible) that whole pediatric chapter? Is that the assumption?

Woman: Yes. The assumption (unintelligible) on the adolescent CDC Web site. That information is fine. I don't have any concerns with it. It's been well done and I haven't gotten any complaints. The school nurses don't have any issues with it. A lot of that - actually I worked with Dr. (Unger) when that was done two years ago. So the pediatric Web site for CDC is well done. Last - everybody good? One more recommendation and I don't know how folks - go ahead Beth.

Oh. I see what you're saying. Yes. You know what? I'm just going to add a new slide. Let's see if it'll do it. Oh, okay. I don't know why one's gold and one's not. We won't worry about it. The very last recommendation was that acknowledgment of the serious educational implications of MECFS for children and adolescents suffering from the disease. CFSAC had one physician on the committee to (unintelligible) educator from the US Department of Education, well versed in the provision of special educational services under IDEA and Section 504 of the Civil Rights Act and the Individuals with Disabilities in Education Act.

I don't know how the committee feels about this. I would like to see this group start to focus on pediatric - on children with MECFS and education is a major, major issue, a major issue.

(Gustavo): This is (Gustavo). What I'm hearing is you want an ex-officio from the Department of Education?

Woman: That is what I'm recommending. Yes. I don't know if it's doable or within our purview or not within our purview.

Woman: Had you guys talked about having a - even a pediatrician or a parent?

Woman: We did not get that far in the conversation. But I don't want to make a recommendation that's not feasible, or you know what I mean, that's not - I don't put a recommendation out there that's not within the purview of HHS or that doesn't make sense. But it's actionable? Okay.

Man: I mean we added, as you all know, we're looking for somebody at DOD and we added the (V8). So I will have to work with (Olga) back in the office, our Chief Management Officer, to see how we can - what can we do to do that and probably - if it is done, the charter will have to be revised.

Woman: Does anybody have any changes to the recommendation?

Woman: It sounds a little wordy.

Woman: It is wordy.

Man: I think we need to ask specifically for an ex-officio member.

Woman: Okay. So change - add one position to the CFSAC - ad an ex-officio member? Is it hyphenated?

Man: I've seen it written in many ways.

Woman: Ex-officio member on the committee's roster from an educator from the US Department of Education, and then the rest of it is they do need to be well versed on 504 plans and on IDEA. Where do you want to - (Gary), where do you want to stop it?

(Gary): It's US Department of Education period.

Man: Can you speak into the microphone?

(Gary): Ex-officio US Department of Education period. We further recommend that this individual be well versed in...

Woman: Yes. Because otherwise it's a run on, too much of a run on sentence. And I think it might be repeating itself I think, suffering from the disease. MECFS - children with MECFS - children and adolescents with MECFS and then cut out suffering from the disease. Up on the first - the second line?

Woman: Oh. Yes, sorry.

Man: How about implications of MECFS in children and adolescents comma?

Woman: Well, you know, do you want me to take that out? In children?

Woman: It's a run on in number 1.

Woman: That's the old one. In fact, I'm going to delete the old one. Is everybody okay with that? The original one up here, I'm just going to delete it.

Woman: Do you mean for this to be an educator from - do you want the specificity of an educator from the US Department of Education? I'm not sure that that job title exists in...

Woman: It doesn't, which is why I left it sufficiently vague, so that if the person was versed in 504 and IDEA, then it'll be fine because they'll have the background knowledge.

Woman: Okay. So then you might just want to say an ex-officio member from the US Department of Education, if you're going to specify that.

Woman: Okay. So an ex-officio member from the US Department of Education, and just take the middle part of it out here?

Woman: It's an idea.

Woman: The idea is good.

Woman: I'm not telling.

Woman: I appreciate all suggestions. Now how are we?

Woman: You're good except for a real grammar geek would say that Individuals with Disabilities and Education Act should come before the acronym.

Woman: Oh, yes. It should. Absolutely.

((Crosstalk))

Woman: Are we good? Special education. It's not educational.

Man: You get rid of the word and - provision of special - yes, that and.

Woman: (David)?

Woman: What about first line serious educational implication?

Woman: ...serious educational implication? Either is correct. Unless somebody is - do I have an English person - I think educational fits better. Anybody else? Good? So do we need to take a roll call or do we want...

Woman: Well put them all up there now if you can.

Woman: I can. Oh. I don't know your - all right. Wait a minute. Okay. This is definitely where I need - okay. Can I delete this box? Does somebody know how to do it quickly? I tried that. Oh, there we go. Thank you very much. The problem with this is that we're just going to make it (gold).

Woman: You might have to actually spell out the agency acronym. Right? Centers for Disease Control? I mean you don't have to do that now. I think when you write the letter they always like you to do that, even though they know CDC is Centers for Disease Control.

Woman: Thank you. Any other English folks, wordsmiths? Beth?

Beth Mattey: Well I would like to suggest that perhaps number 3 should be number 1 and have the other two follow that. Is that possible? I mean what do you think of that?

Woman: Does it have to be in a certain order.

Beth Mattey: I mean it would set the stage for the Department of Education.

Woman: I don't think they have to be - do they need to be in a specific order? Okay. I'm not saying much about my secretarial skills, guys. All right, there is three.

Woman: With an extra typo in there. You're going to save it right?

Man: Well I'm going to need it to put it on your Web site.

Woman: That would be good.

Woman: I think it's on my (desk).

Woman: Okay. So when you're done we can vote on them.

Man: No. I mean you guys have to see it to vote on it. No.

Woman: Oh. That's right. I was just making sure it was in two places and didn't get lost.

Man: This one?

Woman: No, you were there. That's correct. That's the correct version. Right? Does everybody want me to read it one more time?

Woman: Why don't you read them and then pause after one and then we'll vote. And then...

Man: And read them slowly so they can be recorded on the audio.

Woman: Okay. All right. So this is statement again. In order to improve healthcare providers' awareness of their role in assisting pediatric MECFS patients and their families, to acquire appropriate special services through the schools one, an acknowledgment of a serious educational implications of MECFS in children and adolescents; CFSAC add an ex-officio member from the US Department of Education.

We further recommend that this individual be well versed in the provision of special education services under Section 504 of the Civil Rights Act and the Individual with Disabilities and Education Act, IDEA. Period. Okay. I didn't get that. Tell me that again, please. In number 2?

Woman: Precedes that.

Donna Pearson: This is Donna. Once you do that, you'll need to change the first sentence to number 1. Just say that an acknowledgment of the serious educational implications, an ex-officio member from the US Department of Education be added to the CFSAC.

Woman: And it would delete CFSAC. Right? An ex-officio member from...

Woman: And there should be an apostrophe after providers in the first sentence, in the introductory sentence. An apostrophe after providers.

Woman: Okay. Yes.

Woman: I would put CFSAC recommends that (follow up) and then place that in front of one, two and three (unintelligible).

Beth Mattey: This is Beth Mattey. Are you ready? The special education - 504, not special education services. So you may want to say the provision of services under the Section 504 of the Civil Rights Act and special education services under the Individuals with Disabilities and Education Act.

Woman: That's a good point. Yes. You're correct. What was the rest of it Beth? In the special education services...

Beth Mattey: Services. But then before Section 504 you can leave it as education services or services.

Woman: Yes. It needs to come out, right?

Woman: Well special education services needs to come out because the education services, that's what you're making your accommodation...

Woman: Correct.

Woman: ...for. So...

Woman: Provision of education services under Section 504 of the Civil and Special Education Services in - no - yes, under the Individuals with Disabilities and Education Act.

Beth Mattey: And, you know, they've changed that title. This is Beth again. It's the Individuals with Disabilities and Education Improvement Act.

Woman: Oh, that's right. They just changed it didn't they? Well - but is it IDEIA now?

Beth Mattey: It's IDEIA. It was IDEA...

((Crosstalk))

Woman: I don't think (Carmen) corrected it that way. She didn't. So I'm going to leave it be. Okay. I will read it one more time.

Woman: Yes, okay.

Woman: Read it one more time?

Woman: Sure.

Woman: In order to improve healthcare providers' awareness of their role in assisting pediatric MECFS patients and their families, to acquire appropriate special services through the schools CFSAC recommends that number 1, an acknowledgment of the serious educational implications of MECFS in children and adolescents, an ex-officio member from the US Department of Education be added to CFSAC. We further recommend that this individual be well versed in the provision of education services under Section 504 of the Civil Rights Act and the special education services under the Individuals with Disabilities and Education Act.

Are we going to do them individually or all?

Woman: I guess we'll do them individually.

Woman: So okay, let's start from the left over here. Voting members please.

Woman: Voting members.

((Crosstalk))

Man: Isn't there really two reasons not just to improve the healthcare providers, but also to help the Department of Education provider awareness to the role the education community has in assisting in pediatric patient and their families, to acquire appropriate special services through the schools? Isn't it bilateral that you're doing this both to increase the medical side and the education side to produce that end?

Woman: We are. But it's not the Department of Education's job to educate on the medical side. That's not their role. Their role is to educate us on IDEA and 504. So I don't want to put something in there that they can't - that's not feasible for them to do. Does that make sense to everybody? Or am I misinterpreting what you're saying?

(Ted): Yes. This is (Ted) again. Obviously it's not a big deal, because the most important thing is not the whereas's but the therefore's, the one, two and three. But for example, a number 3 you're talking about school nurses. And school nurses are a part of what I would consider part of the Department of Education. And so we are trying to help them - well not part of the Department of Education. But it's part of the education system.

Now I mean I won't make a big deal out of this because it looks like the group is wincing and I don't want to get in the way of progress.

Woman: And I also know what (Carmen), she has from US DOE certain things that she can and cannot do, just like (unintelligible), like Vicki Whittemore does. So I don't want to put something in there that I know that's not feasible for her to (unintelligible).

Beth Mattey: We can come back to it. Well, does anybody else have any comments? I'm sorry. This is Beth Mattey again. And I did check (Carmen)'s notes because I wanted appropriate language for the Section 504. And it says accommodations and services under Section 504, rather than educational services. If you look on page one of her presentation.

Woman: So I just took out the provision of services under Section 504. Correct Beth?

Beth Mattey: No. You would say eligible for accommodations and services.

Woman: Which one - number 1 or number 2 first of all?

Beth Mattey: Number 1. we further recommend that this individual be well versed in the provision of accommodations and services under...

Woman: Eligibility for services.

Beth Mattey: I just want to use the correct language.

Woman: Accommodations and services. Okay. That would make sense. Yes. Because some of them are not - they're not education services. They could literally be the child is provided with a wheelchair coming to and from school. Or special transportation at later in the morning and an early pickup. So...

Woman: Right.

Woman: ...that's such a - it's probably why she wrote it that way.

Woman: And I would say take out education. Just say accommodations and services.

Woman: I'm sorry. I thought I did - there we go. Now?

Woman: Okay. Voting members...

Woman: Voting?

Woman: ...just say your name please.

(Gary): (Gary). I would call to accept the proposal as it's presently written.

Woman: Okay. Donna?

Donna Pearson: Okay. I'll second the motion.

Man: Yes. Approved.

Woman: Any further discussion? Okay. Then we have to go around and do a roll call. Right? Alisa?

Alisa Cox: Alisa. Aye.

(Gary): (Gary). Yes.

Donna Pearson: Donna. Yes.

(Jose Montoya): (Jose). Yes.

(Susan): (Susan). Yes.

Faith Newton: And Faith. Yes. For the second one - CDC coordinate with the US Department of Education on the dissemination of information on pediatric MECFS to all parent information centers.

((Crosstalk))

Woman: I thought we were doing them one by one.

Woman: I thought we were doing them one by one too.

Man: Somebody said to do it one by one. I thought you guys were too.

Woman: Okay. So for the second one?

(Gary): I vote - I would - I vote that we accept the second proposal as worded.

Donna Pearson: Donna. Second.

Woman: Any discussion? Okay, roll call. Alisa?

Alisa Cox: Alisa. Yes.

(Gary): (Gary). Yes.

Donna Pearson: Donna. Yes.

(Jose Montoya): (Jose). Yes.

(Susan): (Susan). Yes.

Faith Newton: And Faith. Yes. And the last one - CDC and the National Association of School Nurses collaborate to develop and disseminate educational materials on MECFS as it affects children and adolescents.

(Gary): (Gary). I move that we accept the wording as presented for the motion.

Donna Pearson: Second. Donna.

Woman: Any discussion? Roll call. Alisa?

Alisa Cox: Alisa. Yes.

(Gary): (Gary). Yes.

Donna Pearson: Donna. Yes.

(Jose Montoya): (Jose). Yes.

(Susan): (Susan). Yes.

Faith Newton: And Faith. Yes. Thank you all very much.

((Crosstalk))

Man: Well done.

Man: I need you to email me that please.

Woman: I will. Let me save it first. Okay. Okay, so we are - so then are we going to continue with your working group? Or what do you...

Man: I thought we needed to discuss the revised recommendation that Donna proposed yesterday, on - for the (ION) diagnostic criteria.

Woman: Only because Faith is up here now. Do you think we'll - just to provide closure. Do you anticipate that we'll continue with your working group?

Woman: That's a good question. Carol?

Carol Head: Well no. And then I hope to add two other items for discussion before we break. One is the...

Woman: Yes.

Carol Head: One is the recommendation about medical education. And I would also like to discuss how we operationalize procedures that may strengthen the impact of this body.

Woman: I think my workgroup would like to continue just to report back to this group what materials have been developed and what's been disseminated, and so that we can look at where we're going with progress.

Carol Head: Oh. I think that's excellent. I just wanted to note that there are several things to discuss in the next hour.

Woman: Oh, I know. I realize that. I wanted to get that out of the way, because after you guys finish your discussion, we're going to go onto other - if there needs to be another working group. Okay. Why don't you go ahead Carol?

Carol Head: Well I would propose - I do not have language drafted, but I would propose, you know, a number of issues that have come up yesterday and today regarding the desperate need for medical education, with clinicians currently and also in medical schools. So I would propose that we form a working group to come back to this body with recommendations on how to affect that.

Woman: Now. Technically, but I guess it could be changed or amended. We usually have two working groups going at a time. So that's why I wanted to see whether Faith was going to continue with hers, and then are we going to continue with the stakeholders group also? Yes? Right? So could it be like a sub working group within that working group? Does that make any sense? Or how - I mean...

Woman: Is there a limitation of the number of working...

((Crosstalk))

Woman: We just kind of adopted the two...

Woman: It's a matter of bandwidth, of people being able to work on...

Woman: Sure.

((Crosstalk))

Man: ...remind you that we are down to six members and - actually seven, I'm sorry and three of them are - their term expires in May and hopefully we'll bring the other five the doctors have mentioned earlier. But if you create a workgroup - too many workgroups like Beth said, we - you guys might be short on members.

Woman: Well and I know there are people in the audience who might be willing to volunteer and help you out. I just want to make sure that you don't have all the work on your shoulders if there's no workgroup that - we don't over, you know, overdo...

Woman: Well let me - I would remind us of the urgency of the health crisis that we have, and therefore I don't understand the fact of constraint to have two workgroups. Now of course, if we don't have...

Woman: That's not why. I just feel that there aren't enough people on these teleconferences.

Woman: And if we don't have people to step up to staff them then that's a different issue. I would...

Woman: That's what I'm referring to. Yes. But, you know, certainly we can solicit volunteers at this meeting. I just - in the past it's been the case that members - you guys have been doing all the work, but members have not been able to for one reason or another, attend both working group teleconference. So I just want to insure that we get covered. I'm all for doing more. I'm, you know, okay. Go ahead if you guys have any - okay, (Gary)?

(Gary): The other thing we had discussed briefly is whether or not we wanted to address approaching the medical boards with adding questions on MECFS and

how we were going to address potentially other state medical boards about the idea of making requirements for physicians to have some CME on this topic. So that was another working group I think we had been - we had talked about also.

Woman: But (Gary), might it make sense to include that in a medical education working group?

(Gary): Yes. Yes. We can do that.

Woman: As a nurse, I have to suggest that you include all providers. I'm sorry.

Woman: Agreed. Agreed.

Woman: Okay. So we have a proposal for medical education working group. Continue the stakeholder working group. Okay. Did we get any feedback from (Dane) about that? Or do you know if he wants to continue it?

Man: He does.

Woman: Okay. People can overlap on more than one working group. Right?

Man: Do we want to lay out the charge of the medical education group?

Woman: Do I want to do what?

Man: Lay out the charge of the medical education group - what is...

Woman: Well you guys have a better idea than I do. So why don't - I'll let one of you do that. Go ahead. Yes. Go ahead and do it. I'm fine with it. You know, I

know it's a new thing. That's the only - I'm just wanting to make sure you have enough members.

Woman: Well I really - specifically need to be here. Clearly it's not the same as drafting this language. But here, help me (Gary) that, you know, recognizing that medical education is a significant problem.

(Gary): There's a deficiency in medical education recognizing that - I don't know who's going to write this.

((Crosstalk))

Man: Improving all healthcare provider knowledge on diagnosis and treatment of MECFS.

Woman: So we're going to put that under new proposed working group. And what has happened in the past, correct me if I'm wrong Beth, is we've circulated - like to people like yourselves who are interested in doing this, have circulated it among all the members, give people like a week or two to get back to you. And then we formalize it. There's medical education - there are two types of medical education at least. There is medical education for providers and then there is medical education like training programs, scholarship training and that also.

But I'm assuming that you are more interested in disseminating information to providers out there in practice, or - okay.

Man: And that includes nurse practitioners, nurses.

Woman: Yes. Okay. So that's definitely a working group, medical education working group. We're going to continue the stakeholders working group. And we're going to continue Faith's group. Any other - and then I don't know if it's appropriate, you tell me. I know that there are some people in the audience who have expressed interest, you know, some of whom who have participated before, like (Mary) and (Terry Wilder) and others. Would this be a time to ask them to join these working groups or solicit...

Woman: I think there can - this can be the first of a couple of calls for members. We can always send something out to the LISTSERV.

Woman: Okay.

Man: So to - I want to have something clear because I'm - somewhat have to figure out the kind of work that I'm going to be doing in the future. We're - you guys are creating three working groups. We're continuing with the children and adolescent phase, the stakeholder and we're adding a third, the medical education.

Woman: Right.

Man: Okay.

Woman: Okay. Anybody have any further comments? Go ahead Carol.

Carol Head: I could reintroduce the topic. And I truly don't know the appropriate approach for this.

Woman: Yes. I know.

Carol Head: But I do think there are some proposals that could be brought forward that could make - that could help this body move forward more quickly and more effectively. And I don't know how to do it. Some of those suggestions were made in advance of this meeting and, you know, for lots of understandable reasons, didn't come to pass. But what is the best way to make suggestions, the recommendations about it? Does it require a working group?

Woman: So that part of the committee management is our responsibility. But we're always open to suggestions and I like the idea of suggestions rather than, you know, to know about those before instead of the criticisms afterwards. I mean the criticisms afterwards are welcome also. But, you know, if we can be a little proactive. So those are our responsibility as DFO and - but we can also include the Chair in those discussions.

So I would suggest an email request to the DFO and I know you've made that before. And, you know, we'll accommodate what we can.

Woman: Great. Terrific.

Woman: And provide the feedback that we can, to explain why we do what we do.

Woman: And thank you for that guidance on how to proceed. So I'll probably consult with a couple of folks and then put it together in an email to you both. And I appreciate your openness to that.

Donna Pearson: And this is Donna. And I'm wondering if we could have even a simple standard operating procedure document, because we have had how many DFOs, I think four DFOs in two years. And we're rehashing the same issues. And continuing to upset the community and their basic things that we don't

know who knows what. So there are some very basic things, if you just had a document, I think it would address some of them.

Woman: Yes. And some of those, you know, we may not be able to address. And, you know, that's good to know as well. So I agree.

Man: Vicki?

Woman: Vicki?

Vicki Whittemore: So I would just make a comment about the recommendations and, you know, I think the fact that it makes - so it's my experience - I've only been on CFSAC for about what, a year or a little longer maybe, but it seems that my experience anyway is that the recommendations that come forward from working group, very often are not informed from the - by the ex-officios that it's going to affect. And therefore, then many times, are not feasible to implement.

And I think my frustration to be honest with the center of excellence recommendation, is I was on some of those calls and did make those comments and the recommendations came forward anyway. And it just makes it very difficult for us, when we get these recommendations, that we can't implement and we haven't had input directly into the formation of those recommendations.

And I have not looked back at other recommendations that were made that were not implemented, but I know specifically for NIH, that is one of our difficulties. And I would welcome more open discussions like is going to happen with the stakeholder working group, to really work together to figure

out the solution, rather than having a recommendation come forward that then we say sorry, can't do that.

So I mean I think that's part of how this group could work together more effectively and really utilize us as the ex-officios to help the working groups determine what is feasible and what isn't, so that we're all more successful and are coming up with solutions by working together.

Man: So if I read it correctly, you want, in a way if there's a working group created, draft a recommendation that we think is going to affect a certain agency within the department, to make sure then the ex-officio is part of that group?

Vicki Whittemore: Ideally yes. I mean because I think that there is - I think the recommendation - sometimes there are things that are great ideas that just could never be implemented based on financial, logistic, regulations, whatever that if we're part of that conversation, we can help to inform that recommendation and the formation and the discussion in that working group.

Man: Sort of like nothing about us without us?

Beth Mattey: And this is Beth. And I would say as an ex-officio, I have been on a number of workgroups and I am never - I was not clear what exactly my role was. I did, you know, voice my opinion but I certainly wasn't saying absolutely, you know, we couldn't do this, or couldn't do that. And so I - but however we do it, all of these questions that have been brought up, are absolutely essential. And it's not like any of us alone have the magic answer or we'd be doing it, okay? So I think we just, you know, and maybe even rather than - we don't have to make recommendations in order to get things moving forward. Okay?

So I think that you can bring it up. This is a topic that needs discussion. How do we discuss it and move it forward rather than a recommendation that we'd say oh, you failed. We didn't do it. But if we have it as this is our discussion item, this is how we're going to focus and we're going to document what work has been done to address this question, that is a success. And then we don't have a recommendation that isn't moving forward and, you know, answers that aren't satisfactory.

And yet we recognize the problem and we're working to do it. You understand what I'm saying? So I think that would kind of maybe break that cycle.

Woman: Excuse me. What's up there, is that something we're going to...

Woman: That's the next thing I think.

Woman: ...we should talk about? Okay. Let's have two more comments and then let's talk about that.

Woman: I just want to state because I've been actively involved in these working groups and that we completely appreciate all of the help of the ex-officios. And there are sometimes and I can't speak to the centers of excellence groups, but there are sometimes when the ex-officio brings something forward but we know that the community doesn't feel that way about it or we don't feel that that's the best recommendation, so we feel obligated - we're the advisory committee; we're supposed to make a recommendation that we can get behind.

So I think there's a balance there and I completely agree that we should absolutely pay attention and try to make sure that our recommendations are

doable. And the second little piece of standard operating procedure issue, which I've noticed we got a Doodle poll from the DSO's assistant and on more than one occasion when the ex-officio can attend that's when the meeting is held. I think there has to be some kind of a priority - the meeting shouldn't be held without the ex-officio in my opinion. They have to be there at the meeting.

So maybe it's not fair that they're higher up on the priority list, but the fact is that they have a lot of the information that we need.

Woman: (Jose), did you want to say something? Go ahead?

(Jose Montoya): No. I think that the role of the ex-officio is crucial. But I hope at the same time, it's appreciated that there is some level of mode of obligation of this committee that is independent from the other organizations, to present what the committee may see. So yes, there might be financial constraints that do not allow agencies to come out with funding of levels beyond of what they can do. But I don't think that we should be tied to that, because we need to break from the status quo.

I think the status quo for MECFS 35 years will lead to another 35 years with no progress, unless we do something radically different and I think that it's our obligation if we say, you know, possibly the price tattoo roughly the status quo is $250 million a year. I think it's our model obligation to say so even there is not that amount of money identified in those institutions as of yet.

Vicki Whittemore: So this is Vicki. I don't disagree with that at all and I absolutely understand that. I think I just would - I guess where I'm coming from is for us to continually be damned for not carrying out the recommendations when they're recommendations that our agencies cannot carry out. And so I think

we'd just need to have this dialog, better dialog, about what's possible and feasible is I guess what I'm saying. And I absolutely understand that. And I don't think I, as an ex-officio, would ever want to stand in the way from something the community feels very strongly about.

But I would like to have input into if you feel strongly about this thing happening, how can we make that thing happen?

Man: I would like to add two things. One is, we asked NIH for Mars with regard to the centers of excellence and he gave us moon. Thank you. No, truly. I mean the reality of the matter is there are budget constraints all the way around and we can only do what we can do. And you did a great deal. We are $29 million ahead of where we were last year. That's huge. Thank you.

Woman: So is that a half a percent on our 7-1/2?

((Crosstalk))

Man: The second thing that I was - a quick show of hands of people who would be interested in serving on the medical education group?

((Crosstalk))

Woman: And (Gary), how will people from - on the phone contact you?

((Crosstalk))

Man: Once you - let me propose something. Once you come up with the goal of the committee (Gary)...

((Crosstalk))

Man: (Gary), once you identify the task, we can send it via the LISTSERV. And have your name attached to it and they can email you directly.

(Gary): Okay, fine.

Man: And I think you will get more than enough volunteers.

(Gary): Okay. So I'll go through you. And you have...

Man: No. I don't have any - what I'm telling you is that in order for you to get more volunteers, for example, the people on the phone who are probably part of the LISTSERV, once you come up with the task of the workgroup, I can send it out via the LISTSERV with your email attached and saying if you're interested, email Dr. (Kaplan).

(Gary): Got it.

Woman: Okay. Carol, go ahead.

Carol Head: Just quickly, thank you for your comments Vicki and I too am delighted with what occurred with NIH. And really, underneath the comments I made yesterday, was this desire to do exactly what we're talking about now - to have a more fluid, open working group in which we rely on each other for useful information and we respect each other's role and we come to understand each other better, rather than what had been unfortunately sort of the rigid every six month, very formalized approach.

And I just think that hasn't been optimal, so I'm very excited that there's an openness to working together in a different manner.

Fred Friedberg: Yes, I want to just follow up, this is Fred Friedberg. I think Vicki's suggestion is really excellent. Recommendations made in a vacuum, no matter how good they may sound, generally don't go anywhere, and I think that's off of the history of recommendations here. Once we are informed by what's feasible and what's not, then I think you have a more focused, a more realistic recommendation that could be implemented and if Vicki volunteers, to me is very significant.

Because often ex-officios, you know, they're here out of - they just have to be here, but they're not necessarily engaged. That to me is a real step in the right direction. I know Vicki at the conference, answered 45 minutes of pointed questions. Usually that - a federal official will run for cover before that audience and she didn't. So to me, this - (Nancy Lee) - she was really heavily engaged in the workgroup I was involved with, and I know she was a mover and a shaker.

That's who you need to get onboard, to see what really can be done. And if they're involved in the committee and they develop that sense of mission and purpose, then somebody's recommendations are more likely to get off the ground.

Woman: I also want to thank Beth and Vicki for their help in my working group. We didn't meet that many times, but they have been instrumental - it was Vicki's recommendation for (Carmen Sanchez). And I also like to make sure that we do things that are very feasible, which is running things by the ex-officios before we make those recommendations.

Woman: Thank you. I second that.

Woman: Thank you again for your help.

Woman: Okay. Do we want to look at what's up there or are we not there yet? This is all about expediting the review of the IOM criteria.

Woman: For the benefit of the people on the phone, would you mind - or somebody read it?

Woman: Go ahead Donna.

Donna Pearson: So all it is, is it's the recommendation that we already submitted with just a few words added, as requested yesterday. It says initiate the process for review of the IOM diagnostic criteria, so as to occur no later than May 2018. CFSAC be convened in a timely fashion and in no event, later than May 2018, to reexamine and update the IOM diagnostic criteria.

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

Woman: And one suggestion I have for you is that the IOM criteria update the date the IOM criteria. Insert the date before - that you want the IOM - yes, thank you. The 2015 IOM diagnostic criteria so that we're clear which criteria are being updated. I'm sorry. I'm having trouble speaking as well.

Man: So you're asking...

Donna Pearson: So we only have one diagnostic criteria from the IOM, but you think we should put that date in there, in both places, then?

(Beth Collins Sharp): I do, because - and this is (Beth Collins Sharp). I do, because it shows an interval between the time that it was done.

Donna Pearson: So she's asking that you add 2015 to that heading sentence and then also to the end of the first sentence.

Woman: And should we take that into like a real sentence, the first - in other words, not initiate but in order to or - okay. I don't know.

((Crosstalk))

Donna Pearson: It's a heading.

Woman: Okay. Vicki, go ahead.

Vicki Whittemore: Can I ask why you spelled out institutes and centers? Why isn't it just HHS agencies? And I guess the reason I'm asking is...

Donna Pearson: Whatever you think works.

Vicki Whittemore: ...that this would come to NIH director. It would automatically get passed down to the institutes and centers. So I'm not it's a little bit redundant is I guess what I'm saying, and maybe not...

Donna Pearson: Wait. Which should not be there? Just HHS?

Vicki Whittemore: No. Appropriate HHS agencies. I don't think you need institutes, centers.

Donna Pearson: That's fine.

Vicki Whittemore: I don't know if other people agree with that.

Donna Pearson: Is NIH an agency?

Woman: Yes.

Donna Pearson: Okay. And the CDC is an agency?

Man: Yes.

Donna Pearson: Okay.

Man: Yes. I may weigh in, I...

Man: To be more specific we can say (unintelligible).

Woman: Say?

Man: (Unintelligible).

Man: Did you want to go ahead (Ted), I think maybe you were first?

(Ted): Thanks. Yesterday I voiced some concern about May '18 but now I don't, because I wasn't bringing it up to make sure we're all on the same page. This says convene by May '18, not finish by May '18. And if that's the case, then I'm 100% in agreement. The second part is in the last two lines, refine the

criteria for sensitivity and specificity. I don't think that's what we want, because the criteria for sensitivity and specificity is straightforward.

I think what we want is a sensitivity and specificity of the criteria. And so update the sensitivity and specificity of the diagnostic criteria. If that sounds like gobbledygook to people who don't know the epidemiologic terms, you could take it as a friendly amendment.

Man: Yes. Let me just weigh in. These sensitivity and specificity, this is when you get experts to do an analysis. We don't know how much sensitivity and specificity the IOM definition has. It hasn't been - I mean it's been compared to traditional definitions. I guess I'm a little dubious about this whole enterprise, three years after the 2015 IOM definition where we don't even know - the answers to this for the current definition let alone, you know, does it need to be changed.

This requires an evolution of research knowledge that we don't have now. And I would be very surprised by 2018, if we're going to have it. And let's assume we did have it. Our clinicians, the handful that are involved in treating these patients, it seems like not a lot of bang for the buck, you know, that we're going to develop different severity measures. And this to me is kind of over the top ambitious. To me, you can convene a meeting when you have the data that justify convening a meeting, not by some arbitrary date.

I know IOM said every five years. I don't agree with that. I think you convene a meeting when you have data that justify convening a meeting, not just for the sake of it. Otherwise to me it's kind of an empty gesture. So I'm not sure I see the utility in this recommendation or who it's really going to benefit - clinical doctors; researchers? It's not a research definition. I'm not clear on, you know, how - where this will - in some productive manner.

Woman: Well I think as was stated yesterday that it's going to put us on the map again, or reinforce putting us on the map. And maybe hand in hand with the medical education that we're going to be doing that it would be. I mean...

Man: It seems like a fairly hollow or shallow reason. You know, it has good PR value. I'd like to think it's a little more substantive than that. And frankly, I don't see the substance here.

Woman: Well now you (Ted), you were on IOM. Correct? Yes. And what was the rationale provided for, if you'll recall, for reviewing it in five years? I'm just, you know, let's maybe take it from there.

(Ted): I would love to say to you that discussions within the committee are confidential and we can't share.

Woman: Right.

(Ted): However, I could probably give some information that the feeling was that the field is growing fast enough that within five years it might be worth looking into, because there'd likely be change. Now whether or not sufficient evidence - sufficient change has occurred, could be made now or in a year or in two years. I don't know that answer. But it was the feeling that too many things were happening and we didn't want to wait until after it was too late.

Woman: Yes. I mean I'm just trying to see all points of view here. I don't have a problem with it. I mean...

Man: And just to - and Fred wasn't here when we had the original discussion. (Steve) was. But this IOM process began in 2013 and then the review ended in

April of 2014, so we're talking about four years' worth, instead of five years' worth, of evidence. Also, (Nancy Climas) came. She's a member and specifically said that the contract be delayed one year, that there would have been a significant change to the criteria.

I think specifically, patients would like to see the immune piece identified because there's such an important part of this disease and right now the core criteria doesn't talk about that. So I think that's part of it. And then the second thing I'll just say is we've been using the (CUDA) which was supposed to be a temporary research definition for what, 25 - I don't even know how many years. And we certainly don't want that to happen, so we're trying to be proactive about this and move this forward.

Man: The - I was just trying to scan the guideline. One thing that I was able to find was that the single diagnostic criteria worked for adults and kids. The other thing is I believe it said that what is the new report to relook at the diagnostic criteria in five years. And in order to do that, you have to start ahead of that time. And so then the question is are they saying start again in five years or have it completed in five years?

I think you need to go to the experts which I'm not, and decide if enough evidence has occurred in the last few years to warrant looking at this again.

(Beth Collins Sharp): This is (Beth Collins Sharp). That was going to be my point as well, that perhaps in the spirit of what Vicki is saying, if you want to come back with a yes as opposed to probably not, that you would recommend that there would be some sort of assessment of the evidence to see if it's time to do another review. You could say, to do an assessment and if sufficient, go ahead and initiate a review. But I'll leave the rest to you. I'm not going to comment further on that.

I do want to say that sensitivity and specificity refers to diagnostic tests and diagnoses are not always made as a result of tests. So I would recommend taking out the specificity and sensitivity words.

(Gary): This is (Gary). I completely agree with your last comment about removing sensitivity and specificity because I don't know that we're anywhere near there. But I think that the strongest argument for reconvening a meeting is that we have a public health emergency disaster on our hands, with a number of people struggling with this disease and dying from this disease. And so I think that a - kind of a mandatory review of where we're at, at this point in time, sponsored by the government, is a very good thing to do, a very important thing to do.

And so where are we at? Let us identify the gaps. Let us identify what we've accomplished in the five years and what more needs to be accomplished. And again, put it to the forefront. People forget about it quite honestly. They let it, you know, it's not the disease of the week, so it gets mentioned again. It's back in the compositions, it's back in the consciousness of medical community in whole. And it gives another opportunity to make sure we've got a time period in which we're all reviewing the literature and acknowledgment of the seriousness and severity of the illness we're dealing with.

Woman: I mean and to support like some kind of - we can reach like some kind of agreement here, first of all, should we remove sensitivity and specificity and change the wording to assessment so that we can - I'm trying to think of the right word, so that we can at least come to the middle and then make some kind of a decision about this?

Woman: ...can simply be diagnostic criteria. Just take out the specificity and sensitivity words.

Woman: And then we can - go ahead.

Drew Helmer: This is Drew Helmer. I was just going to suggest, you know, maybe if you make the recommendation just a little bit broader and allow for - and still include the diagnostic criteria because I think that's the piece that people are most excited about. Perhaps also say evaluation and management because there may be more evidence about treatment options by 2018 or something. That way you'll give the secretary a little more leeway in terms of saying yes, let's do this, and there's going to be more value in this IOM report perhaps.

Woman: So what did you just say to refine the diagnostic criteria and management?

Drew Helmer: Yes. Perhaps diagnosis and management of MECFS.

Woman: Oh, compromise. That's the word I'm trying - so if we can reach a compromise and then vote on it, then maybe - go ahead (Jose).

(Jose Montoya): I second Dr. (Helmer)'s proposal that yes, go to the diagnostic criteria. There is a chance that nothing will change. The 2015 IOM review, approximately 9000 articles after they have, you know, a larger number and they set it in 9000. And by April 2013 they finished the revision. But I think they would be more helpful if there was a group of highly, a well selected group of experts that evaluates the clinical evaluation and management of CFS. That will include and address the issues of conditions that in patients you have to exercise, because you have been conditioned and all of these adverse recommendations.

So there is a body of knowledge out there in the brains of a handful of clinicians who, and I'm not counting myself on them, who really know this disease that really that expertise is there, but it's in a group of people who have seen this disease and have learned because they are highly skilled, outstanding physicians. And at the same time, they have learned in the hard way, in dealing with this illness. And then too, you are one of them.

So I think that if that can be compiled in a document to recoup all of this wisdom that is out there in what to do, what not to do, in clinical evaluation and management, that would be a huge step forward.

Woman: So in other words, add to the original chart, to the IOM, to broaden it and does that make sense Vicki or anyone else?

Vicki Whittemore: Yes. I was going to echo what they both said, what (Gary) and Drew both said too, and (Jose). I think to really use it as a way to assess a broader, where are we at; where are the gaps; where are the opportunities, would be really useful. Unless the goal is really to just focus on the diagnostic criteria. But I think the broader assessment would be really, really helpful.

(Jose Montoya): And by the way, (Jose Montoya), having this body of knowledge compiled carefully screened, making sure that we're not including things that are for profit, because a lot of things in MECFS, are used for pure profit with no real benefit. But having this also could help the future - these kind of clinical trials. Because as I said earlier, you know, a draw that could be promising, maybe obscured the benefit, because if you don't pay attention to the nuances and the uniqueness of the unit, so that could also help for future research as well.

Man: So are we asking diagnostic criteria and clinical management?

(Jose Montoya): As clinical evaluation and management.

Woman: Do you want to just stay diagnosis instead of diagnostic criteria or...

Donna Pearson: So where the word - this is Donna Pearson. So where the word says to reexamine, we can say instead, to - oh shoot, I've lost it. To assess - I was going to say to assess the newer literature. I don't know if you'd want to say newer, but to assess the scientific literature, in order to update the diagnostic criteria and (Jose), help me out. I'm sorry.

Man: Could I just suggest you don't restrict them to the literature and that's, you know, coming from a researcher. But I think there are a lot of things to be learned that haven't been published yet.

Woman: We might be able to do it by just - at May 2018 and go right to consider and incorporate. Because that's really what you're doing. You've kind of jumped over just the diagnostic criteria and just convened too, consider and incorporate new evidence to refine the diagnostic criteria. Right. Yes.

((Crosstalk))

Man: I feel Faith now when she was trying to do this. When you have five people speaking at you. So Beth, what are we doing?

Woman: And Beth wanted to sort of caveat.

Beth: So I think it's the really important statement. And I feel that this is a statement you really want to make. Do you want to recognize in some way the NIH funding, which will be relatively new or midway through to which someone

might say well, if we wait three years it's going to change again? Right? So why not wait for those data?

Man: Let me share something else from the VA side. Yes. So for - the VA has been mandated by congress to do biannual reports on the health of Gulf War veterans because of the concerns about Gulf War illness. And I share that with the committee and I guess the public, because, you know, I think it's the IOM recommended that this be reviewed within five years. And people feel there's some momentum going here that there are varying standards of frequency for some of these reviews.

Woman: Go ahead. So I think, just thinking through this, if this recommendation went forward, likely what would happen is that it would come to probably CDC and NIH to organize a workshop conference. And organizing a large conference in a year or less so that this would happen in May 2018, is possible but might be difficult. So, you know, I think that it's a tough...

Woman: It's really tough. And I keep looking at this - yesterday I wrote it out in the fiscal year. And, you know, our monies are, you know, designated through September. So - and in some places already '18 is already on the books. So in that case you know you should be saying get this on the books, get this in your budget. And on the other hand, people are going to say but we don't know what our budget is, you know.

Woman: So just to make another comment in a kind of a different way, so the centers will be funded in September 2017 so to have a conference where we bring together or whatever - however we convene them, to bring together all of these people to talk about what they're doing, what additional gaps and opportunities there might be, for additional people to work together with the centers, might be an opportune thing.

I think we just have to think through how this would happen. And are we thinking about a conference? Are we talking about bringing a group of people together to write a document?

Woman: It sounds like we don't have to have a full thing like we had with the IOM. But like you said before, an assessment might be okay. But yes, go ahead. Carol?

Carol Head: Carol Head - two thoughts. First, the NIH research is certainly critical and probably sort of the kingpin. And at the same time, there's a lot - there is other research going on. I mean we just heard Fred describe the research that's already completed that was presented at CFSAC. And we're talking about now (IACFSME). We're talking about this being a year and a half from now. We're funding research that will have results within a year and a couple of other projects.

And we know, you know, there are folks in Norway. And so there is other research going on. The field really, you know, is nowhere near where it should be but absolutely there will be new information to explore them. So - and then the second point is I think this leaves very open how this might be done. I get that it would be a burden on NIH and/or CDC now, but the best way to get it into budget somewhere within HHS, is to talk about it now.

And maybe it is some sort of I don't know the right words, but mini IOM. If IOM costs a million there is $250,000 that is pulled from a budget. It's the director of the NIH. I mean I don't know the sources of the funding. But again, if we go back to the fact that this is a public - an urgent public health crisis. If we look at it through that lens then surely we can find the resources to do this.

Man: If I may, the next conference, (IACFSME) is in 2018. That language is to throw out the suggestion if we plan and pay for IACFS not federal, it's already on our books. We don't have a date. We don't have a location. But that's when it's going to happen. And I know we've had synergies with (Nancy Climas)'s group, with (Jose Montoya) at Stanford and previous meetings that really worked out - anyway, one group attracts another group. And you have people who are already going there so it's kind of like you don't even have to look to someone to put it on the books. Well you do have to do that.

But I'm telling you right now, that's when we're having our conference. And perhaps that's one way to facilitate getting this off the ground. And I do like that it's a broader mandate here. That to me is I think better.

Man: But I want to go back to what Beth mentioned. We are in fiscal year '17 which ends in September. And then we start '18 in October. A lot of the activities and many of the federal agencies are planning to in '18, it's already - their budget is being drafted. If this is to be done in May '18, this needs to be the agency's funding no later than October '17, to start the '18 year.

Woman: And when I brought that up I didn't mean to dissuade you. it's just a reminder of the realities. And again, go back to the - make the recommendation you want to, because sometimes it's a statement. What we're trying to do I think in the spirit of the day, is to put a paragraph on so that you can see clearly, you know, what might be ahead.

(Ted): Okay. This is (Ted). There's always a danger when you make a ridiculous request. On the other hand, there are positive things that come out. And I think you should go for May '18. I mean the secretary is going to do what the

secretary wants to do. He/she has that power and if we say by 2020 why don't you give it a thought, that's not the same message as do it by May '18 and they can say well, I can do it by September '18. And we aren't the authority.

I kind of like unless the people who have had more experience, say boy the secretary's really not going to like that, since you don't know who the secretary is going to be, it's hard to know. The other thing though which is perhaps more important, is there's words in there that really change the method. If you're going to consider and incorporate new evidence, in my experience that's not a consensus conference that's going to be able to be performed at a single meeting.

That is implying a lengthy and expensive process. Now that has advantages and lord knows I have done a lot of them and I like it. But perhaps this is the quick and dirty - perhaps we want to eliminate the word new evidence and say to consider a diagnostic criteria and clinical evaluation, and that will allow for new evidence to be considered if that's what the secretary wants. But this would be suggesting that new evidence and that means a literature review and the time to do that and synthesizing it.

And it means that you don't have only experts at the table because you need clinical content and the epidemiologist and the methodologist. I mean it changes things a lot. So I just - I think we need to think about what we want the process to be when we're...

Woman: Omit for instance?

(Ted): Well no. I'm saying that by adding it, it changes the - to me, adding it changes the process but I - that's just how I would do it.

Woman: I mean it sounds like we're coming around to wanting to do something, and so we should try to make it work. And, you know, you are seasoned at this, so I certainly, you know, and anybody else who has some suggestions in the last ten minutes, it would be helpful to get that done.

((Crosstalk))

Beth Unger: Yes. This is Beth Unger. And, you know, again rather than rush to make a recommendation right now, perhaps a charge would be that - and I hate to say this because I'm one of them, but ex-officios get together and come back with okay, this is a problem that you presented. This is one way we could approach it. And discuss it at the next committee meeting. I mean there again, I don't think we have to have a recommendation to make us jump.

You know, we hear you. I would have said this all along. We - I come to this meeting to get input on what are the important issues. And I always come back with an action list with things that we incorporate. I make sure that the program is aware of the thoughts of the community and of the other ex-officios. And I mean I think, you know, this came up several times in our meeting, that we have to have a way to come to grips with treatment.

And it's not going to be a literature review. It's got to be expert opinion. What is the best, most efficient way to do that so that it is both acceptable and, you know, passes, you know, the criteria so that all of the professional organizations will buy into it, etc., etc. And I think it's not a simple answer. And so I would say the only caveat on this is don't expect us to come back with a perfect answer next time, but I think expect us to come back with something that we could discuss further.

Man: I agree with Beth and I would - it will be somehow important to have the IOM methodology incorporated and output backed up by the IOM. I'm just going to give you an example briefly, the MECFS patients - a kid from Stanford, we gave him the antivirus and he got better. He was happy. He relapsed again, did not well with the treatment that we gave him. And then (Peter Roe) from Johns Hopkins and also a professor of (unintelligible) at Stanford, are working in certain patients with MECFS.

I don't want this to be taken that it's happening in everybody. There is an actual anatomical link in the spina fluid. And that gives the certain - besides the MECFS symptoms, a certain profile of more pronounced symptoms. This kid, my patient, went to the evaluation, the link was identified, it takes a blood patch that is placed right there in the (dura) and the symptoms two weeks later were dramatically improved. So this is an example where I would have just continued trying to find something for him that would not have been effective.

And there are other patients out there who have had this (link) like other patients out there whose (link)s have not even been suspected. So I'm referring to these kinds of patients' phenotype profiles that in a conference - not a conference, in an IOM procedure, having it all put together. And there are other examples - (tri test) efficiency; other things that are part of the phenotypes and I have others, but no time for that, that would be very important for clinicians as they get to know the disease more and better, for them to know.

And that, by the way, will excite clinicians to see these patients. Now they have something that they can connect with better, and treatment recommendations.

Woman: Okay. Beth, go ahead.

(Beth Collins Sharp): This is (Beth Collins Sharp). So I like Beth Unger's idea. I think also though I'm going to make a personal commitment on behalf of (Gustavo) and myself, because I hear how important - what I hear is that this is really important to you. And so that while the ex-officios are discussing some potential ideas, that we could use this recommendation which you have worked with very thoughtfully, as an example, the next time when we are introduced to the next Assistant Secretary for Health, that this is the type of issue, this is a great example of the type of issue that this committee is concerned about and wants to discuss and wants to have progress.

And we can see what the reaction is. So if you agree that ex-officios then could take this up next, then in any case, whatever you decide, we can take this forward as an example of the thought that this committee is representing. Does that seem fair?

Woman: So I just want you to clarify, you're saying we wouldn't submit this to the secretary, you would just take this with an understanding and discuss it?

(Beth Collins Sharp): If you take up Beth Unger's suggestion that the ex-officios work on this next, then we would take it anyway, to the Assistant Secretary for Health and then to the secretary as an example, and see what their reaction might be.

Woman: And can we expect you not really to impose a deadline, because it sounds unfriendly. But can we expect an answer like in six weeks? Is that realistic? Or...

((Crosstalk))

Woman: We're going to have an acting - I'm thinking of the permanent Assistant Secretary for Health, so that the timeline would be...

Man: Dr. DeSalvo said May.

Woman: May? Yes. Thank you. I'm only asking because we kind of put a little cap on the timeline here.

Woman: Oh, good point.

Donna Pearson: So I'll just point out that as Carol has indicated, we have a very low success rate. This is actually an outstanding recommendation. You could actually bring the recommendation that we made last year along with many others, I would hope, because you know that those are all important to us. And maybe that would be a great approach because it does seem like we're hitting our heads against the wall, submitting recommendations and then being disappointed afterwards. If we can all work together to move things, I am all in favor of that.

Woman: Thank you for all of your efforts. It's been I think a very productive meeting. I'm glad we can all work together.

(Ted): I'm not sure I'm allowed to say this so don't quote me.

Man: You've been saying it all along whatever it is.

(Ted): Not knowing who the next secretary is going to be, and not knowing who the next assistant secretary is going to be, we can imagine that probably they'll be physicians or at least a clinician. And therefore, if you would take the normal, they may not understand this disease and it would be very good to have early

conversations so that they understand that this is a disease, it's an epidemic. They may not know about an IOM report.

There's a lot of education that can be done before the next committee meeting and I think that's wonderful. And I didn't say it. Yes?

Man: You're being recorded.

Woman: Say what (Ted)?

Man: So it's a minute after 5:00. Two of you have 7:00 flights - 5:30 would be pushing it to make it to Reagan. It's the charge then that we are going to work on this with the ex-officio and bring it up to whenever there is a debrief with the new secretary and the new (assistant).

Woman: Yes. I think that makes a lot of sense. You know, it's feasible that we should...

Donna Pearson: And I would just add that I would strongly urge you to bring the CFSAC recommendations from the last couple of years and use them to help educate as to the needs.

Man: I think you need to call a motion to end the meeting.

Woman: Okay. I call a motion to end the meeting. Thanks once again for a very successful and interesting meeting.

Man: Second the motion.

Woman: All in favor say aye.

((Crosstalk))

END