

**Public Comment**  
**Edmund Jalinske**

First, PANDORA wants to welcome the new voting members of the CFSAC. We are glad to see more people willing to dedicate time to make improvements for the patients. We look forward to seeing what experience, knowledge and resources you bring to this distinguished committee. We also hope you will humbly learn about the disease from the veterans, its history and the government's action and inaction on this disease. Especially, take note of the public testimony as you will find it enlightening and compelling.

**NIH:**

We take this opportunity to also welcome Dr. Susan Maier as the new NIH ex-officio and as the new person who oversees the NIH research on ME/CFS. You have big shoes to fill. Dr. Dennis Mangan was driven, open and inclusive. He demonstrated to us that the DHHS can get things done. Our organization is optimistic on what you will bring to this committee.

We expect that **the unfinished business** that Dr. Mangan had to leave behind will come to fruition under your leadership. The ME/CFS State of the Knowledge workshop in April 2011 remains incomplete as a plan of action was supposed to be part of the program, and it did not happen. We look forward to hearing what the plans are to finish what Dr. Mangan started.

We acknowledge and we are pleased to see that the Special Emphasis Panel (SEP) for CFS at the Center for Scientific Review (CSR) at the NIH is now named correctly and is only for ME/CFS as directed by Congress. A lot of time has been wasted as the improper name affected its purpose, leading to grants that should have been for ME/CFS being used in research for other diseases. As Pat Fero, with the Wisconsin ME/CFS Association, reported to this committee last year, as much as \$18.5 million of ME/CFS research grants went to studies that did not primarily study ME/CFS. **How soon will you refund this money to true ME/CFS research?**

In addition, we would like to know if the NIH has planned any extramural or intramural studies on the promising results of Rituximab. Surely, the possibility of an existing drug making two-thirds of the 1 million American patients able to function, possibly even return to work, is worthy of research. Please let us know what plans you have to fund such research.

In addition, we have not seen the new Special Emphasis Panel Roster or a meeting date for the panel. Have they been appointed, and if not, when will they be appointed? Moreover, will you be issuing an RFA for ME/CFS soon? Maybe one for Rituximab?

Dr. Maier, we would appreciate your finding an opportunity during this CFSAC meeting to answer these questions so all can hear. PANDORA welcomes a meeting with you at any time and would like to continue our communication on these very important issues.

**CDC:**

Our next request is for Dr. Ermias Belay, as the ex-officio from the whole CDC as it relates to CFS. As you know, the Coalition 4 ME/CFS submitted a proposal to the National Center for Health Statistics (NCHS) department of the CDC. Please note that this proposal was solely based on recommendations made by this committee as far back as 2004. The Coalition's proposal was

to reclassify CFS in the ICD-10-CM and ICD-9-CM. We were pleased that the NCHS accepted the proposal for reviewing because the reclassification of CFS in the ICD-10-CM to the neurological chapter where myalgic encephalomyelitis is also located is a positive move. However the NCHS presented their own option that contradicts what this committee of experts recommends.

The NCHS procedure, as stated on their website, was for the decision on this proposal to be made before Jan. 1, 2012. Yet, to date, no decision has been announced. We know the implementation of the ICD-10-CM has been delayed, but that has no bearing on the continued revisions to the ICD-10-CM as they are still holding committee meetings and accepting proposals. Since last November, we have emailed them and left phone messages with no response. Just 10 days ago, PANDORA sent a formal letter to the NCHS director. Do you know why the NCHS has not followed its own rules and announced a decision? If you do not, will you help us find out? We cannot let this issue be placed in limbo.

Dr. Unger, in 2011, we sent you a letter welcoming you to your new position and listed some actions we would like to see from the CDC. We are pleased to see you have taken action on five of those points: meeting with organizations, collaborate with experienced researchers and clinicians outside of the CDC (CASA Project), use cohorts from clinical centers that specialize in this disease, create CME courses and work on a medical school curriculum on this disease and focus research on biological pathologies. We also note that you have made some changes on the website that we discussed when we met with you and which has been discussed here at the CFSAC meetings. However, more work must be done. So we ask that you:

- 1- Continue to work with the CFSAC ad hoc committee to improve the CDC website content.
- 2- Let us know when to expect the promised report on the meetings you have had with patient organizations.
- 3- Update the CME courses on the CDC website that are scheduled to expire this summer. Make new ones that reflect what is now known about the disease and get rid of the contradicting physician's tool kit.
- 4- Change the diagnostic criteria to reflect the biological findings and features of the illness of the outbreaks.
- 5- Use your influence to help set up centers of excellence for this disease.
- 6- Request more ME/CFS research funding for your department program at the CDC.

If you can address some of these requests during this meeting, please do so that we can all hear what you have to say about them.

We are very concerned that the CDC website still treats CFS differently than other illnesses. On the page titled, "Improving Health and Quality of Life," the first topic is CBT. It says that CBT has been successful in helping patients with cardiovascular disease, diabetes and cancer. But, CBT is not mentioned or recommended on the CDC website in the information for those diseases. Why is there a double standard? The recommendation to someone with diabetes, if needed, is for "counseling" to help the person cope with receiving that diagnosis.

As is true with any diagnosis, if an ME/CFS patient has comorbid depression and/or anxiety, then CBT or other appropriate treatments should be recommended.

However, the information listed under CBT in the CFS section of the CDC website is actually the type of guidance a person should receive from their physician — that is how to pace their activity to avoid exacerbating the illness. This is just like the lifestyle changes physicians give to someone with diabetes about exercise and diet. A diabetic does not get this information from CBT. It comes from a nurse or physician. We have a mislabeling problem and a double standard. This should be corrected.

We are glad that you used the term *CFS/ME* in your presentation at the September IACFS/ME Conference. But, the current CME course that expires this year has information conflicting the researcher consensus, your statements at the conference and the WHO's ICD-10. The CME course 1:1 Overview says, "The name *myalgic encephalomyelitis* was coined in the 1950s to clarify well-documented outbreaks of disease; however, ME is accompanied by neurological and muscular signs and has a case definition distinct from that of CFS."

What is the impression here? Is ME different because it occurred in outbreaks? Surely the CDC is not dismissing the outbreaks in Incline Village and Lyndonville, as well as others, which meet the Fukuda criteria and are referred to as *CFS*. Surely you are not implying that *CFS* does not occur in outbreaks. Moreover, CDC research also reveals that *CFS* has neurological symptoms and an abnormal response in the basal root ganglia, part of the brain. In addition, muscle pain and stiffness are part of *CFS*. Therefore, we are expecting the next CME course will correct this misleading information that people diagnosed with *CFS* cannot have what is known in other countries as *ME*.

We also note that a new CME video is now on MedScape sponsored by the CDC. We feel this CME is an improvement from what has come from the CDC in the past. However, we have great concerns over some of the content, especially at the end when the discussion turns to "illness behavior" or "behaving like she should be ill or start trying to live up to the diagnosis." The false impression could be given in some of the statements that these patients display "illness behavior" because they want to remain on disability. What an awful and misleading message to give to physicians. How will they then treat the patient who does not "look sick" but is very debilitated, has extreme financial hardships due to being unable to work and who needs and is ineligible for disability benefits? Will the physician suspect the person is just displaying "illness behavior"?

### **Social Security:**

Denying severely disabled ME/CFS patients Social Security disability benefits for months or year, even when they are unable to perform "activities of daily living," is inexcusable. Yet, we still hear accounts of this happening. To meet the Fukuda-defined *CFS*, a person must have at least 50% reduction in function. We know many that are bedridden for years. The April 11, 2012 Social Security press release on the Compassionate Allowances Program included neurological disorders, which ME/CFS is. The purpose of this program is "to ensure that Americans with the most serious disabilities receive their benefit decisions within days instead of months or years." The CDC says that *CFS* is a disease that "can be as disabling as multiple sclerosis, lupus, rheumatoid arthritis, heart disease, end-stage renal disease... and similar chronic conditions."

One researcher compared it to late-stage AIDS. Certainly, someone in that condition should be fast-tracked in the disability application process. We ask that the Social Security office work with us in finding a standard for severe cases of ME/CFS to be included in the Compassionate Allowances Program. We are also aware of another program titled the Presumptive Disability Program and we would like to discuss both programs with you.

**FDA:**

ME/CFS applications have been shuffled across six different divisions in the FDA, and the only drug in the pipeline for ME/CFS has been effectively buried since 1997. Today, patients only have inadequate symptomatic relief. No treatments or biomarkers have come out of the process. As part of a community wide effort, PANDORA sent a separate letter to Secretary Kathleen Sebelius and FDA officials requesting an FDA stakeholder meeting to discuss the challenges related to drug review and approval and to identify opportunities to accelerate approval. The FDA and ME/CFS stakeholders — including patients — need to work together to ensure that the process delivers the full complement of drugs and biomarkers needed to effectively diagnosis and treat patients.

**AHRQ:**

In 2009, the North Carolina Buncombe County Department of Social Services removed a sick child from his parents based on inaccurate information coming from ignorant physicians. The parents, — more specifically the mother — were accused of “fictitious disorder by proxy.” Yet, the social worker in question did not even know how to spell the correct name of the disorder, which is *factitious disorder by proxy*. Originally they were referring to it as *Munchausen by proxy*, a term that is no longer used in the U.S. The child actually suffered from ME/CFS. The child was finally reunited with his parents almost a year later after a lengthy and costly court process sustained by tax-payers and by the family that is now financially ruined and left with emotional scars that may never heal. How can a child recover from such an ordeal? During the time that PANDORA was assisting this family, the Mountain Area Health Education Center (MAHEC) entered a verbal agreement with PANDORA for an education conference and CME course on ME/CFS, particularly pediatric ME/CFS. However, this promise for a joint project was later withdrawn.

Terry Cordell, MPH and the director of the MAHEC educational program, said, “While I am certainly open to having MAHEC participate in providing a CME course or courses on CFS and pediatric CFS, I think .... it would be wiser for MAHEC to do so independent of an advocacy organization....” We were extremely disappointed and we shared our disappointment, but there was nothing we could do. Their decision was made. However, neither MAHEC nor the AHRQ, who nationally oversees AHEC state programs, have initiated a physician education program for ME/CFS. We are still waiting almost **two and a half years later**.

We shared these concerns with the CDC in May 2011. Dana Brimmer, at the CDC, said she would contact AHRQ concerning this matter. We have not yet heard if MAHEC has taken any action to fill this need. Therefore, we urge the AHRQ to create a national physician education project so that the more than 80% of American ME/CFS patients who do not have a proper diagnosis can start receiving appropriate treatments.

**To all government agencies:**

Finally, as we strive to developing and working with sister organizations in the ME/CFS community, we want to share with you about an informational website sponsored by Phoenix Rising titled the “ME Analysis.” It is a clever use of technology to display the fallacies in both methodology and internal analysis of the Pace Trial (Peter White), in the United Kingdom. The web site is <http://evaluatingpace.phoenixrising.me/home.html>

As you may know by now, PANDORA collaborated with Mary Dimmock on the communitywide letter, the summary of which will be read as her testimony: fix the definition, name and classification problems, fix the FDA process, educate the medical community and provide a fair share of research funding for this terrible disease.

We look forward to hearing the answers to our concerns and questions during the CFSAC meeting. We appreciate the opportunity to address these pressing matters and hope to continue working with you on improving the quality of life of ME/CFS patients.

Thank you