

Public Comment
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December 2013 CFSAC testimony

Good afternoon. Thank you for giving me the time to address you today.

I will address just two of the many issues that ME patients face – the failure to focus on the disease patients actually have and HHS' approach to engaging ME stakeholders.

At the last CFSAC, Dr. Unger questioned the nature of post-exertional malaise and even questioned its significance as a hallmark symptom when she rhetorically asking "If a patient doesn't have [PEM], wouldn't you still manage them as a "CFS" patient?"

When I heard that, I wanted to scream. This single statement highlights what is so rotten with HHS policy and initiatives on this disease. From the earliest response to Incline Village patients to HHS' actions today, HHS has either utterly misunderstood or willfully ignored the neuroimmune disease with it's hallmark PEM that patients actually have and instead focused on an illogical clinical entity centered around the concept of medically unexplained chronic fatigue.

It is not just that single comment of Dr. Unger's. Look at the CDC's claims that the Canadian Consensus Criteria, Fukuda and Oxford criteria describe the same set of patients and should be treated with the same set of treatments - even though those treatments cause harm to those patients with PEM. Look at CDC's reclassifying CFS to be a subtype of the symptom of chronic fatigue, in direct opposition to the World Health Organization's classification of CFS as a neurological disease.

And look at HHS' IOM initiative and the muddiness in describing what disease these new criteria are intended to cover. Will these criteria be specific to the neuroimmune disease characterized by post-exertional malaise and described by the Canadian Consensus Criteria and the ME International Consensus Criteria? Or will these criteria describe the set of diverse conditions described by the overly broad CFS criteria, with ME included as a subgroup? Apparently, according to Dr. Lee and IOM's Kate Meck, that has not been decided yet, which is quite stunning given that this is a million dollar contract and the panel is due to be announced. But I was much more concerned when in response to my question, Dr. Lee never said that the new criteria are intended to be specific to ME. Instead, she emphasized the establishment of a subgroup for ME or maybe ME as part of a spectrum of illnesses. She also said that for the sake of primary care physicians, it was better to start broad and define subgroups.

All of this is wrong. ME, with its post-exertional malaise, is not and should never have been stuffed into the overly broad and biologically unrelated group of medically unexplained fatiguing illnesses. Fifty of our leading disease experts have told you this and called on you to adopt the Canadian Consensus Criteria because it better describes the disease that patients have. Countless patients have told you the same thing.

HHS needs to immediately and explicitly acknowledge that ME with its hallmark PEM is a separate disease from the medically unexplained fatiguing illnesses that are described by Fukuda and Oxford. HHS needs to immediately put up a black box warning against exercise for these patients as suggested at the last CFSAC. HHS needs to follow the lead of experts and point clinicians to the CCC. And HHS needs to require that all research use the CCC.

But HHS won't do any of these things. Which brings me to my second point - HHS' engagement with the ME community.

Let's look at the most recent example – the IOM contract. This contract is a microcosm of what is wrong with HHS' approach to engaging with the ME community. There is no doubt where the disease experts stand on the definition. Fifty of them have told you to adopt the CCC. There is no doubt on what the CFSAC recommendation said. There is no doubt where the patients stand. You have received petitions and letters in support of the experts and in opposition to the IOM contract. And it's clear that HHS needs this stakeholder input – just look at the confusion that its approach to definitions and medical guidance has caused in the broader medical community.

So what does HHS do? It rejects the recommendation of disease experts and its own CFSAC and overwhelming patient opposition. It defines its own initiatives - unilaterally with no input from the ME community – to create its own criteria for some vaguely specified condition. It insists on using the same broader medical community that has so mistreated patients because of their confusion on the nature of this disease.

Need more evidence of an engagement model gone drastically wrong? Let's look at the allegations of intimidation at the last CFSAC meeting. On June 12, a joint group of organizations and advocates asked the General Counsel to investigate. He turned it over to Dr. Koh, who after two unanswered reminders, finally stated on October 31 that a) the concerns of the members will be taken into consideration b) the designated federal official has the authority to engage in private conversations that may include discussions on the roles and responsibilities.

This is a blow off answer that says nothing about the allegations of intimidation that we asked to have investigated. Frankly, the original allegations and this response show an utter disregard for the ME community and the CFSAC members.

What about the plan that NIH has developed to guide research? Can we get a chance to look at that and provide input? We've asked and been told no. And why? Because the plan may change. Of course the plan may change. That's the nature of plans. But it is unconscionable to not share this plan with the key stakeholders – the patients – and get their input.

And then there is this CFSAC meeting. Yes, web-based approaches to meetings are used across industries to manage costs. But you have chosen to do it when there are critical issues on the table that require face-to-face contact. The action speaks volumes about your unwillingness to engage this community.

And it goes on and on and on. Minimal information. One-way communication. We are often told "Nothing about me without me." But the HHS' real approach to this disease is "Everything about ME without ME."

And I wont even get into the NIH funding levels.

Patients are beyond angry with HHS and justifiably so. For thirty years, HHS has willfully refused to make a serious, urgent commitment specifically to the neuroimmune disease that patients actually have. HHS has willfully failed to transparently and collaboratively engage the very people that are most affected by its actions. And HHS shows no signs of having changed. It would be insanity for us to continue to have faith in HHS' actions.