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PUBLIC COMMENT TO THE DEC. 3-4, 2014 CFSAC MEETING

Here we are again. I remember many years ago this Committee was referred to as the “sneering committee” due to the dismissive and derogatory treatment of patients and advocates by HHS ex-officio members.

It appears nothing has changed. In fact, the situation is worse than ever, with public appointees, including former patient representative Eileen Holderman, intimidated and threatened with eviction; with recommendations twisted and re-written to conform to HHS’ historic agenda for “CFS” as a subset of prolonged fatigue [1]; and with no regard for the disabilities those with ME and CFS have. (Surely the DFO must realize that this webinar and the five day notice period to submit public comments violates Section 508 and Section 504 of the Rehabilitation Act of 1973.)

The current CFSAC membership includes a nurse, an osteopath, and an educator. Two of the doctors practice “integrative medicine” with a focus on mind-body medicine. For the first time since 2003, no lawyer has a seat at your table.

The agenda for this meeting raises more questions than it answers, and leaves the public in the ridiculous position of commenting without knowing what the presentations consist of.

Several make me apprehensive. While the development of Centers of Excellence (CoE) has been recommended by the CFSAC for years, I question how an osteopath with his own “integrative” clinic “that attends not only to patient’s [sic] physical symptoms, but also addresses the root causes of an individual’s pain and illness, including problems of the mind and spirit that may be contributing to the disease process” [2] will do justice to this subject. Will the Kaplan Clinic serve as a model for a CoE? The thought makes me shudder. I don’t think it’s a coincidence that Dr. Kaplan will be presenting, nor that his clinic is reminiscent of the UK’s “CFS” clinics which focus on treatment with harmful Graded Exercise Treatment (GET) and Cognitive Behavioral Therapy (CBT).

Likewise, having a patient registry is a laudable goal and again, one previously recommended by the CFSAC. However, how can one have a patient registry if HHS continues to use the broad, non-specific Fukuda criteria [1] and ignores the Canadian Consensus Definition [3]? How can any researcher or clinician find useful information collected in a biobank composed of patients whose only commonality is the symptom of fatigue? And why is the Solve ME/CFS Initiative (formerly known as the CFIDS Association of America) presenting on this topic? There are other biobanks with stricter inclusion criteria that would be better suited for this purpose.

The P2P Workshop presentation by Robert Miller, a patient and self-appointed “patient advocate” does not inspire confidence either. Thanks to Jeannette Burmeister’s successful FOIA lawsuit, we have seen NIH internal email correspondence and know that Mr. Miller was hand-picked by NIH as the “patient representative” on the P2P

working group panel. If there was a call for volunteers, no one I know of knew about it. I know I speak for many in stating that Robert Miller does not represent the majority of knowledgeable patients and patient advocates.

And let's not forget HHS' ex-officios' most egregious act concerning those supposedly served by the CFSAC.

A clearly-phrased October 2012 CFSAC recommendation to "...convene ... at least one stakeholders' (Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome(CFS) experts, patients, advocates) workshop in consultation with CFSAC members to reach a consensus for a case definition useful for research, diagnosis and treatment of ME/CFS beginning with the 2003 Canadian Consensus Definition [3] for discussion purposes" has been hijacked. Instead, NIH and HHS ignored all patient and patient-oriented stakeholders and developed two redefinition "efforts" (the P2P workshop and the IOM "study"), neither of which comply with the letter or spirit of this recommendation. Rather, the focus of both is "medically unexplained fatigue".

Surely you cannot be blind to the consensus letter from 50 expert researchers and clinicians to the HHS Secretary stating they have adopted the Canadian Consensus Definition [3] and will continue to refine and update it as scientific knowledge advances, including consideration of the 2011 Myalgic Encephalomyelitis International Consensus Criteria [4]? What about the two petitions advocating for the adoption of the CCD and the cancelation of the IOM study, signed by 7,666 stakeholders (as of this writing), the many letters sent to HHS officials against these redefinition efforts, the tweets urging you to stop the P2P?

The disease you should focus on is Myalgic Encephalomyelitis, aka ME. ME is already defined by the Canadian Consensus Criteria [3] as well as the 2011 M.E. International Consensus Criteria [4].

It is a distinct disease officially recognized in the medical literature in the 1950s and classified in the WHO ICD under G93.3 (neurological diseases) since 1969. The Centers for Disease Control and Prevention (CDC) recognized that "ME is accompanied by neurologic and muscular signs and has a case definition different from that of CFS" in its online medical education classes up until mid-2012 [5], and a 2010 CDC-authored, peer-reviewed research study acknowledged that "the physical findings in persons meeting the Canadian [Consensus] definition may signal the presence of a neurologic condition considered exclusionary for CFS". [6] A 2011 study in England found a prevalence of 0.11% using the 2003 CCC, which, assuming a US population of 310 million, would result in about 340,000 ME cases, well below estimates for Fukuda-defined CFS. [7]

Yet HHS' policy toward ME and CFS ignores all this. It appears that Dr. Stephen Straus' ghost still haunts NIH as his attitude toward those labeled with "CFS" continues to prevail at NIH. The internal employee emails regarding the P2P, finally released in all their dismissive and derogatory glory, attest to that.

All HHS employees involved in “CFS” or “ME/CFS” activities clearly need to become knowledgeable in the subject matter they are working on and could do with some sensitivity training. I suggest the ME ICC as mandatory reading and recommend all view the film Voices from the Shadows. <http://voicesfromtheshadowsfilm.co.uk/>

1. Fukuda K, Straus SE, Hickie I et al. Chronic fatigue syndrome: a comprehensive approach to its definition and study. *Ann Intern Med* 1994; 121: 953–9.
2. The Kaplan Clinic website, <http://www.kaplanclinic.com/about-the-kaplan-center/>
3. B. M. Carruthers, A. K. Jain, K. L. De Meirleir, D. L. Peterson, N. G. Klimas, and A. M. Lerner, Myalgic encephalomyelitis/chronic fatigue syndrome: Clinical working case definition, diagnostic and treatments protocols, *Journal of Chronic Fatigue Syndrome*, 11 (2003), 7–115.
4. Carruthers BM, van de Sande MI et al. Myalgic encephalomyelitis: International Consensus Criteria. *J Intern Med* 2011; 270:327–338.
5. CDC-CME: A Primer for Allied Health Professionals, Course 3151, Chapter 1. <https://www.dropbox.com/s/ec4694d7ousuib1/CDC%20Course%203151B.png?dl=0>
6. Switzer WM, Jia H, Hohn O et al. Absence of evidence of Xenotropic Murine Leukemia Virus-related virus infection in persons with chronic fatigue syndrome and healthy controls in the United States. *Retrovirology* 2010 Jul 1;7(1):57
7. Nacul et al. Prevalence of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) in three regions of England: a repeated cross-sectional study in primary care. *BMC Medicine* 2011, 9:91, <http://www.biomedcentral.com/content/pdf/1741-7015-9-91.pdf>