

CFSAC Testimony of Billie Moore, New Jersey ME/CFS Association, Inc., Advocacy Chair

I am Billie Moore, Advocacy Chair of the New Jersey ME/CFS Assn, Inc.

This year we are seeing progress from the HHS in getting help to patients through various HHS initiatives as a result of the IOM and P2P reports. It is very encouraging that the NIH and CDC have made explicit efforts to involve expert clinicians, researchers and patient advocates in these initiatives. We do appreciate this new focus on the disease, although it is long overdue.

From here on I am going to refer to the disease as ME in keeping with the IOM's recognition that "CFS' ...should no longer be used as the name of this illness." Myalgic Encephalomyelitis is the preferred name of the community because it was the historical name and because of the neurological effects of the disease. The CFS label carries decades of negative baggage – derision and disbelief within the medical profession and the public (which continue to this day), overly broad definitions, and psychogenic theories, all of which harm patients, prevent the funding that drives research, and prevent medical schools from teaching about ME.

"ME/SEID" might in future be acceptable, but only if it includes the CFSAC IOM Workgroup additions to the IOM criteria, as shown in the Recommendations 8, 10, 15 and the Box 1, "Proposed Diagnostic Criteria," p. 12 of the Workgroup's report. Adding these modifiers will distinguish the IOM criteria from Fukuda in addition to making diagnoses by not-expert medical personnel more accurate than using the IOM diagnostic criteria alone. Again, before the HHS adopts new criteria, patients and experts must be consulted.

Naturally, much more needs to be done for patients with this dreadful, life-robbing and sometimes life-ending disease. **Major** money needs to be directed to studies into all aspects of ME - \$250 million in NIH grants would barely make up for the loss of 30 years of appropriate-level research funding of ME (what was called CFS). A minimum of \$100 million should be allotted every year by the NIH. RFA's should be funded to the maximum amount possible, starting as soon as possible.

Equally critical is the need for approved treatments from the FDA. There has been no movement from the FDA toward this end since its 2013 Drug Development Workshop and The Voice of the Patient Report; the Drug Guidance document was not detailed enough to provide real guidance to drug companies. **Continuing passivity from the FDA regarding treatments is unconscionable.** The time has come for the FDA to gather in the companies that make drugs that are being used off label for ME to help those firms find a path to test these drugs for approval for ME. The one drug that is in the pipeline should be given conditional approval. Let hundreds of thousands of other patients nationwide have the opportunity to get their lives back as so many of the test patients for this drug have.

Centers for Excellence affiliated with university medical centers are critically needed for patients. These Centers need to include a clinical component. In addition, there is a critical shortage of ME doctors who recognize the disease as a physical one, not psychological or a “somatoform disorder.” One recommendation to ease the shortage of properly trained doctors is for the NIH to give grants to both expert ME doctors and to doctors who want to specialize in treating ME patients – expert doctors paid for their time training the new specialists and the trainees being paid to learn the specialty.

Finally, I want to urge the HHS to find the funds for CFSAC to give ME two full days of in-person seminars with visual webcast. This audio-only webinar structure is insensitive to the needs of the millions suffering from this terrible disease.

Thank you.