

My name is Anne Keith and I have been ill with Myalgic Encephalomyelitis, then called Chronic Fatigue Syndrome, since 1991.

I have several specific recommendations to CFSAC.

First, I ask CFSAC to forcefully reject P2P in its entirety. It is not what CFSAC recommended, it does not reflect current scientific knowledge, and it is dangerous “fluff science” that will prolong misconceptions for decades. Patients need and deserve much better.

Some hail the P2P committee’s recommendation of the “retirement” of the Oxford definition as a step in the right direction. Yes, it is, BUT I ask whether recommending the disuse of a definition which has been roundly criticized as inadequate since its initial publication 23 years ago, which has long since been surpassed by science and practice, is a big enough step forward to offset all the errors and omissions of this report. It is beyond question the answer is emphatically, “NO!” The P2P report doesn’t even take the logical step of recommending the re-evaluation or discarding of research based on the definition it finds inadequate! The report moves research right up to, um, 1992. Not good enough, not even close to good enough. Anything less than a state-of-the-art definition, which the P2P committee seems unaware already exists, is unequivocally not good enough.

Second, since P2P completely fails its charge of sorting out research priorities, I ask CFSAC to state (again) and expand upon which research priorities are important. Those future research priorities for M.E. are clear:

- 1) Require all future HHS funded research to use the ICC or CCC definitions to select study participants;
- 2) Separate M.E. from generalized fatigue; if HHS wishes to continue studying “fatigue,” it should use a better defined cohort where confounding factors are known, such as post-radiation cancer patients;
- 3) Fund M.E. studies at the same level per patient as other similarly disabling diseases (MS, lupus, etc.);
- 4) Study the sickest patients (despite the difficulties due to the level of their impairment) since they are the most likely to present the clearest picture of the biology of this illness and are most likely to have consistent biomarkers.

Third, since even a committee of non-experts given little time or input can see that Oxford is a poor definition, I ask CFSAC to ask that the Secretary to require that HHS not only stop all of its uses of the Oxford definition but also stop its dependence on studies using it. This absolutely includes the highly flawed PACE study and the NICE guidelines which resulted from it. CFSAC should request (again) that the CDC toolkit remove all references to PACE, NICE, GET, and CBT.

Fourth, I ask CFSAC to take advantage of the relatively recent changes in the positions of Secretary and Undersecretary to request change be initiated from the top down regarding M.E. CFSAC should recommend to both Secretary Burwell and Acting Undersecretary DeSalvo that they personally speak to CFSAC members and experts in the field regarding the progress, or lack thereof, in this illness since 1982. CFSAC should clearly warn that HHS’s history of mismanagement and misappropriation for M.E.,

ME/CFS, and CFS has caused unnecessary suffering on the scale of the Tuskegee experiment. It is clear that the entrenched bureaucracy, up to and including Director Nancy Lee, have been unreasonably hostile to M.E. sufferers. Patients, experts, and CFSAC itself have sought to change this without success. Unless the Secretary and Undersecretary wish to go down in history as aiding and abetting those who have caused such untold suffering, a change must be made from the top. Those who have opposed progress for decades must be removed from any and all power over M.E. research and treatment and those with open minds must be given authority. Both P2P and IOM must be abandoned and the experts' choice of CCC adopted immediately.

Finally, many in the community are now debating whether participating in CFSAC has any value. They wonder if they, by submitting testimony (written or oral), simply add a veneer of participation to a process designed to thwart all real progress, a process which is entirely show. I must admit, they have a valid point. This committee has heard impassioned pleas, heart-rending personal stories, facts and figures, dry scientific testimony, and everything in between. Nothing has materially changed HHS' mishandling of M.E., ME/CFS, CFS, and "fatiguing illnesses."

I ask myself what public testimony I can offer that will have an impact on HHS' handling of this disease. My answer is, "None." It will take the Secretary and Undersecretary finally putting an end to the medical abuse of M.E. patients before anything changes. The current and past CFSAC recommendations, as well as the years of testimony, provide all that the Secretary and Undersecretary need to initiate the necessary changes. Since the past DFO has shown a complete disregard for law or truth when it comes to reporting CFSAC recommendations, and the current DFO reports to directly to her, my Fifth recommendation to CFSAC is that each and every CFSAC committee member individually sends this committee's findings to the Secretary – perhaps one will actually get through with the Committee's agreed upon wording.

Thank you for your attention and for your service to patients.