

Gabby Klein

This is to serve as my written comment to the CFSAC January 13<sup>th</sup>, 2015 meeting.

I have written the following letter to Secretary Burwell outlining my opposition to the P2P process for ME/CFS. This is for the public record.

January 6, 2015

Dear Secretary Burwell,

I am a patient suffering from Myalgic Encephalomyelitis and I would like to challenge the validity of the NIH's Pathway to Prevention (P2P); Advancing the research for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

I am writing to you as a citizen of the United States who believes that the actions of HHS have and are hindering proper and equal care as promised by HHS' charge of protecting the health of Americans and providing essential human services, especially for those who are least able to help themselves.

At the Lake Tahoe outbreak of Myalgic Encephalomyelitis (ME) in the 80's, CDC made a decision to hijack this serious neuroimmune disease and to derogate it by renaming it with the vague, undignified name "Chronic Fatigue Syndrome" (CFS). Since then, the NIH and the CDC have continuously and stubbornly made certain that this disease remains buried as a vague "fatiguing syndrome". By their action, they have ensured that progress will be impeded and that the future of this disease remains under strict Government control. This is in contrast from other diseases, where it is the medical expert community that creates criteria.

NIH has historically denied proper funding for good scientific research that is based on the biology of the disease. The majority of the meager funding allotted is mostly for studies with a psychological slant to the disease. The CDC has created a vague criteria stressing "fatigue" as the main and only mandatory symptom, in their 1994 Fukuda Criteria. Since then, they have stubbornly held on to it regardless of the production of newer, more accurately descriptive criteria by the medical ME/CFS experts such as the Canadian Consensus Criteria of 2003 (CCC) and the International Consensus Criteria of 2011 (ICC).

Today, nearly 1 million American men, women, and children, and over 17 million worldwide, suffer from the neuroimmune disease, ME/CFS. The cost to the American economy has been estimated to be in the billions, yet NIH has been spending a mere 5 million dollars a year for researching the disease. This amount does not come close to the amount of funding granted to other equally serious diseases.

The Canadian Consensus Criteria (CCC) of 2003, created by international medical professionals with experience treating and researching the disease, was very well accepted by the international medical community. For the past ten years, much pressure was put on the CDC by ME/CFS stakeholders,

specialists, advocates and patients to adopt the new CCC and to reflect the change on their website. To date, the criteria that appears on the CDC's website and toolkit remains the 1994 Fukuda criteria.

In October 2012, the Chronic Fatigue Syndrome Advisory Committee (CFSAC), made a recommendation to the Secretary of the Department of Health and Human Services (HHS); *CFSAC recommends that you will promptly convene (by 12/31/12 or as soon as possible thereafter) 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 for discussion purposes.*

The Secretary did not heed the advice of HHS' own appointed federal advisory committee members. Instead, HHS chose to spend close to 2 million dollars for two separate ventures: The HHS/IOM contract for clinical criteria and the NIH's P2P for research purposes. These two processes were to employ "unbiased"= non-expert panel members in order to guarantee the perpetuation of Government control of the process.

It is interesting to note that the majority of the ME/CFS community; clinicians, researchers, advocates and patients were in agreement with CFSAC's recommendation of adopting the Canadian Consensus Criteria (CCC) now, and working on improving it. This is evidenced by the letter to the Secretary of HHS that 50 ME/CFS expert clinicians and researchers signed, informing her that they have in consensus, adopted the CCC and were urging HHS to do so as well. This letter was later endorsed by over 170 patient advocates.

Nearly 10,000 signatures on two petitions have called for stopping these processes and adopting the CCC now. Advocates have demonstrated in San Francisco and in Washington, DC to protest the HHS contract with IOM and the process of the P2P which have attracted the media and resulting in press coverage. A vigorous twitter campaign has been ongoing highlighting the protest of the IOM and P2P.

Advocates contacted the media and press and participated in numerous radio, TV, and online interviews and articles about the IOM and P2P issues. Numerous articles and blogs have been written outlining the problems with the two processes and why the majority of stakeholders are protesting both actions. The above mentioned initiatives by advocates, patients, and ME/CFS experts have been and continue to be important to protect the best interests of a million Americans, and 17 million worldwide, who suffer from ME/CFS and to move research and treatment forward.

**Yet, HHS refused to heed the entire ME/CFS community's voice and forged ahead with the IOM and P2P processes.**

ME expert Dr. Byron Hyde wisely observed in a paper presented in New South Wales in 1998:

*Definitions are not diseases, they are often simply the best descriptions that physicians and researchers can offer, with their always imperfect knowledge, to describe a disease. Good definitions are good because they correspond closely to the disease state being described. It is thus important that those that attempt to define any disease or illness to have long term clinical experience with patients with this illness. **There is simply no place for the bureaucrat in defining illness.** All definition of epidemic or infectious illness must be based upon persistent clinical examination of the afflicted patient, an*

*understanding and exploration of the environmental factors producing that illness, and pathophysiological examination of tissue from those patients. For similar reasons, I believe that the inclusion of psychiatrists in the defining of an epidemic and obviously disease of infectious origin, simply muddies the water for any serious understanding of that disease. [Hyde, 1998. Emphasis added]*

**Historically, diagnostic criteria for diseases are created by the expert medical community, not the Government.**

Dr. Derek Enlander, an expert ME/CFS clinician in NYC, stated in his letter presented at the IOM meeting:

*At present, the Canadian Consensus Criteria are used by a majority of experts who diagnose and treat this disease; they adhere to the concepts defined by Dr. Melvin Ramsay, who helped pioneer research in this disease, in contemporary clinical settings. **Were discussion and debate even necessary, one million dollars could still have been saved--a not insignificant percentage of NIH research funding dollars in this area.** Given the paucity of funds allowed for research and study of what we know as Chronic Fatigue Syndrome, it seems, with all due respect, to be a shameful waste of money.*

It leaves me with the conclusion that HHS' move has been a political one at the expense of the wellbeing of the patient. **HHS actions show that they have something to gain in keeping this disease in the shadows.** They prefer to hold on to an outdated set of criteria which ignores the most important hallmark symptom of the disease; PEM/PENE, post exertional exhaustion. PEM/PENE is the mandatory symptom of the CCC and ICC, thereby distinguishing ME patients from other "fatiguing" illnesses.

NIH decided on using the P2P process for ME/CFS research purposes. The P2P process, as per its website is not to be used for "controversial topics". Since its inception, ME/CFS has been complex and controversial, yet NIH ignored that fact. By using the P2P process for ME/CFS and setting the parameters which they have, the results were doomed for failure. In addition, NIH decided to lump every single criteria ever created for ME/CFS (8) no matter how wrong into the mix, as if they all have the same value. This lumping together has ensured that the results will be meaningless.

To make matters even worse, the p2P was charged with using an "evidence based search" for their report. Dr. Enlander stated: *it seems inevitable that any preference given to the "Evidence Base," may produce a set of loose criteria. In this area, where the 'evidence' has long been grossly distorted, and to date has produced a flawed, inaccurate model of this very serious physical disease, such criteria may well describe other conditions or disease models that are, simply put, not the disease described by Ramsay.*

In addition, the choice of a "jury model" unbiased-inexperienced panel writing the final report has ensured that the result will be at best of very low quality. It is impossible for a panel of non-experts to read an evidence based report, listen in to a 1 ½ day workshop and produce a comprehensive report in 24 hours. This "circus act" is not acceptable to me and to the majority of ME/CFS stakeholders, advocates and patients. My future and the future of 17 million patients worldwide will depend on the nefarious actions of the NIH.

I join multitudes of advocates, patients, caregivers, ME/CFS researchers and clinicians, and other stakeholders, in stating the following:

**We do not need HHS bureaucrats who are not ME/CFS experts to redefine this disease.**

**We do not need more Government-sponsored clinical and/or research definitions for ME/CFS**

**We do not need more Government waste of taxpayer dollars on corrupt initiatives to redefine a disease that has been correctly defined.**

**We do not need more Government misinformation about ME/CFS disseminated to physicians, health insurance carriers, the public, and the press.**

My opposition to IOM and P2P is a complete rejection of these initiatives to redefine ME/CFS. HHS should not consider my letter of opposition as participation or buy-in - because it is not. This is a letter of opposition for the public record.

Sincerely Yours,

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cc: Francis Collins (NIH), Thomas Frieden (CDC)