

## Comments Submitted to NIH Pathways to Prevention Workshop: Advancing the Research on Myalgic encephalomyelitis/chronic fatigue syndrome

From Billie Moore, Advocacy Chair, New Jersey ME/CFS Association,  
writing for myself, January 5 , 2014

This is the 403-line version of the draft report that I am commenting on.

### Overview

I commend the panel for a number of points made in this report. You were given very little time to review the material you were given by the AHRQ. Considering that those research reports AHRQ sent were incomplete in the extreme because thirty years of good research could not have been compiled and then read by you in such a short time, you managed to gather and show an understanding of this disease and a compassion for its patients and the people who care for them. **On line 32 you make a statement that the vast majority of ME/cfs sufferers have never heard: “ME/CFS exists.”** That fact is supported by lines 65-73. And music to the ears of patients and advocates on lines 92-93: “...*this is not a psychological disease in etiology.*”

The short time frame for your work and the knowledge that was not provided to you from many, many more studies done in the last 30 years in many countries has kept your understanding of ME/cfs from being as comprehensive as it could be, however. There are some omissions/misunderstandings/errors in the report which I and others will cite.

The most obvious and important of these is that all – ALL! - recommendations require infusions of **money** that the NIH has historically been unwilling to provide. There is a screaming need for NIH to vastly increase its funding for this disease to be commensurate with the numbers of patients; the fact that the suffering is intense, life robbing, the cause for many and increasing suicides; the fact that there are no treatments approved by the FDA; and the loss to the U.S. economy from the disease, estimated to be over one billion dollars. **A direct correlation exists between the almost non-existent funding provided by the NIH over the last two decades and the lack of progress made in treatments and causes of ME/cfs.** The report fails entirely to address realistically the issue of funding.

My recommendations for a stronger report, which you have the talent and power to create, will echo many others from the patient and advocate community. They are offered in a spirit of appreciation for what you have learned and with the confidence that you can make this report far more accurate, worthy of being used as a tool to help those suffering from this beyond-imagining dreadful disease, which is worse in effect than many cancers. My own son committed suicide after living in pain, with no life, for 20 years and having NO hope that any treatment was going to be coming along in the foreseeable future. There is still no hope for an approved treatment, 3 ½ years after his

death. (He would be alive today if Ampligen had been approved in 2009, I haven't the slightest doubt, as he fit the Ampligen-responder profile.)

**Comments, line by line; line numbers on left (403-line version)**

2-4. "Extreme fatigue" is not accurate on two counts. "Pathological exhaustion" is a much better term. We need to wash our collective brains with soap and get rid of the F-word - fatigue. It doesn't begin to describe what patients suffer from, and it is subject to disrespect and 30 years of "oh, I'm tired, too," and the idea that patients are psychologically damaged layabouts.

**Second, it is post-exertional collapse that is the hallmark requirement for diagnosing ME/cfs, not fatigue.** This is a required symptom in both the CCC and ICC definitions (as post-exertional malaise – PEM), correctly setting them apart from the more general and overly broad Oxford, Fukuda, and Reeves definitions. See the FDA's Voice of the Patient report for testimony regarding exhaustion vs. PEM (which I call PEC[ollapse]. **Please correct this major error.**

4. **There ARE lab diagnostic tests.** Note the table which I have attached. Listen again to Bob Miller on the P2P video cite tests which an expert physician will use to determine if the patient has ME/cfs.

5. Yes, a majority of patients are women. But a reliable percentage is not known because of a lack of funding for adequately powered epidemiological studies. A very significant proportion of pediatric and adult patients are male, however, so this is not really a "women's disease." The majority of patients who suffer from multiple sclerosis, lupus, and rheumatoid arthritis are women, yet these other diseases are not called "women's diseases."

27. "We critically reviewed the scientific literature...." Sadly, you did not. Not because you did not want to, but because only some portions of the applicable literature were provided to you. Crucial literature in areas such as neurological, immunological, autonomic nervous system, pediatric, and cognitive dysfunction findings were excluded from the evidence review, possibly because the major journals are not indexed. In addition, one of the bias problems that exists with ME/cfs is that the major journals generally will not print research on CFS (not a "real" disease); so, therefore, much valuable and valid research that has been done is lost to clinicians, researchers, and the public simply by not being published in leading journals.

32. "ME/CFS exists." On the one hand, it is very gratifying to read that this panel agrees that what is generally considered to be ME/cfs exists. However, there really is no CFS. It is a false name.

The disease was first called ME in the 1980's and was subsequently changed to CFS, to go along with a very broad definition including depressive and other psychiatric symptoms. The Fukuda definition of 1994 did not improve on prior definitions, and significantly ***did and does not require that post-exertional neuroimmune exhaustion (PENE) be present for a diagnosis of CFS.*** (See the International Consensus Criteria definition.) Fukuda also requires a six-month waiting period before a diagnosis of CFS could be given, a time-requirement ***no other disease requires.*** The Canadian Consensus Criteria, which has been recommended by CFSAC to be adopted, was developed in 2003 by ME/CFS experts.

The term ME/CFS was also developed in the mid-2000's because patients and expert physicians alike recognized that "chronic fatigue syndrome" was a vague, diminishing name with strong overtones of "it's all in your head." The joint name, ME/CFS, is now used by many patients and patient groups and much of the Dept. of Health and Human Services. It is still not correct, however. What has emerged from these decades of misnaming and sloppy defining (prior to the CCC) is confusion and incorrect diagnoses which included those with psychiatric problems.

#### **Four possibilities exist regarding the two terms, ME and CFS:**

1. either these two terms define the same illness; or
2. ME is a subset of CFS; or
3. ME and CFS are two entirely different diseases, or
4. **the term "chronic fatigue syndrome" is a false construct and invalid.**

To address the possibilities listed above I start with #4 and state that "**chronic fatigue syndrome" does not exist.** It is too vague and imprecise a name for a disease with many discrete and measurable symptoms. (See the Table of Biological Abnormalities, Clinical/Lab Tests and Drugs with Potential for Repurposing" which gives an outstanding overview of abnormalities of the disease.) However, because CFS has been in the literature for 25 or more years as a result of the naming in the 1980's and 1990's and definitions mentioned above, it is still being used.

#1 and 3 follow from #4. CFS is a falsely created and defined set of imprecise symptoms; therefore, it is not the same as ME. It is also not a disease that is different from ME. **It is not a disease at all.**

Number 2: If you can consider that #4 is true, it, too, becomes a non-possibility: **ME cannot be a subset of a non-disease.**

Nevertheless, let me address this point. For 25 or so years this disease has been called chronic fatigue syndrome. Very likely the majority of patients who have been diagnosed with CFS as far back as the 1990's meet the ICC definition of ME. (At least three studies have shown that this is the case.\*) **Why were those patients diagnosed with CFS and not ME? Simply because that while their symptoms met the criteria for ME, ME was not being used as a label in the U.S. until the mid-2000's. Their symptoms had not yet been listed and explained properly until the**

**CCC came along; everything was called CFS.** The CCC definition refers to ME as “sometimes called” chronic fatigue syndrome and adopts the combination name, ME/CFS, while the ICC clearly defines ME.

However, what has evolved somehow is the thinking in some quarters that ME is a subset of CFS. No. ME has the more restrictive diagnosis, but that does not make it a subset because Oxford, Fukuda, and Reeves are really not describing anything accurately. **“Chronic fatigue syndrome” is not real. It is a false construct.** It is a vague name that prevents a proper diagnosis of the real disease. ME is a neurologic and immune disease with distinct and measurable abnormalities. **ME is not a subset of this oddity “chronic fatigue syndrome.”**

\*1, Jason, L.A., Brown, A., Evans, M., Sunnquist, M., & Newton, J.L. (2013). Contrasting chronic fatigue syndrome versus MyalgicEncephalomyelitis/chronic fatigue syndrome. *Fatigue: Biomedicine, Health & Behavior*, 1, 168-183.

2, Jason, L.A., Sunnquist, M., Brown, A., Evans, M., and Newton, J.L. (in press).

Are Myalgic Encephalomyelitis and chronic fatigue syndrome different illnesses? A preliminary analysis. *Journal of Health Psychology*.

3. Brown, A. A., Jason, L. A., Evans, M. A., & Flores, S. (2013). Contrasting case definitions: The ME International Consensus Criteria vs. the Fukuda et al. CFS criteria. *North American Journal of Psychology*, 15(1), 103-120.

40-42. Again, the misunderstanding on line 40 that there are no valid diagnostic tests. The criteria do exist. In September 2014, 50 clinicians and researchers reached a consensus on an excellent definition: the Canadian Consensus Criteria definition. The fact is, the NIH will not accept an expert-driven definition. In the meantime, Oxford AND Fukuda are continuing to be used incorrectly as reasonable definitions for ME/cfs in research studies. **This report must recommend that Fukuda be retired from use in research or clinical settings, as well as Oxford.**

51- 54. Yes, yes, and yes; the make up of the population of those with ME/cfs is simply unknown. So many of the sufferers of ME/cfs are not included in ANY studies, particularly homebound and bedbound patients and minority and low-income patients. This must change, but it takes **money** to do the epidemiologic studies.

58. **“Fatigue” is NOT it. Pathological exhaustion is.** Patients suffer equally from indescribable exhaustion plus post-exertional malaise (another misnomer; “malaise” defined as a “slight or general feeling of not feeling well or happy”). The amount of research done to date is woefully inadequate because of lack of funding. Private funding cannot begin to fill this great black hole of need for causes and treatments.

65-73. It is so satisfying to read this paragraph in an NIH report, as I mentioned in my introduction. I can’t think of another disease where the patients are treated like lepers, except leprosy, and you have understood that. What can fix it? Proper, accurate physician education, Centers for Excellence, a Marshall Plan for research into causes

and treatments. **All require money and the willingness of all pertinent agencies of the HHS to change how this disease is viewed, funded, and prioritized.**

74-91. This discussion again shows the need for significantly higher levels of NIH **funding** – in the range of over \$100 million per year at least. MS, with fewer than half the number of patients and nine approved drugs, will get \$115 million in 2014 from the NIH. See attached table: NIH funding by amount of money allocated to each disease.

92-101. This paragraph makes a great but unstated case for retiring not only the Oxford definitions but also the Fukuda and Reeves definitions, all of which allow psychological cases to be included in ME/cfs studies. Researchers and clinicians should use only the CCC or International Consensus Criteria (ICC) definitions in determining whether people have ME/cfs or not. **This report can perform a major service to the patients and to improving study design by forcefully making this recommendation.**

113-114. **CBT and GET are NOT treatments.** CBT at best is an adjunct coping therapy. GET is harmful to patients. Exercise is harmful to patients. Movement is helpful but must be done on a scale commensurate with each patient's condition severity and would rarely be equated with "exercise." The CDC's Toolkit and CME course advocating both CBT and GET as "treatments" have been recommended by CFSAC to be removed from the website. CDC has refused to do this, furthering the false idea that what these people need is to get their heads on right and get out and exercise.

125-129. If new patients, not yet diagnosed, were to be given the CCC and ICC definitions to self diagnose, they could very likely self diagnose themselves as having, or not having, ME/cfs. It is a complex disease, but the patients know what they feel, as do the expert clinicians and researchers. **Endless studies on definitions are NOT needed. They waste years of time!**

130. "Self management." Oh, please. I understand the paragraph and do not disagree with the thrust of it. But the term "self management" in this context has already set off anger and alarm bells in the patient community, as it fears this will be a major recommendation of the P2P report instead of other much more important recommendations. Does one recommend to cancer patients "self management" as a way to improve their health? The real point here is the need for accurate physician education and research so that such trivial and useless ideas as "self management" and "graded exercise" are no longer have any currency. **Please eliminate this paragraph.**

142-150. What you are describing is a lack of accurate physician education in medical schools and CME courses. Please expand your discussions of such educational needs and include specific recommendations for Centers for Excellence and for the funding to bring these programs into being.

157-177. All good points. **But, these answers will not be forthcoming without money from the HHS through NIH and other HHS departments. MUCH MORE**

**MONEY. Funding to be commensurate with the seriousness of the disease (extremely serious), the urgency of the need (couldn't be more urgent), and the number of sufferers – at least one million in the U.S. – and the cost to the U.S. economy in health costs and loss of productivity, estimated to be between \$17 and \$23 billion in 2009.**

179. ME/cfs is not a “condition”; it is a disease as you rightly say in the next line. Please call it that throughout your report (lines, 3, 179).

184-185. Excellent statement. Patients should indeed be at the center of research efforts. Patients and their doctors should be equal partners with the government agencies in determining what studies should be done, what CME and Toolkit content should appear on the CDC's website, etc. CFSAC's last 10 years of recommendations (patient and expert driven) should be adopted, in large measure, by the HHS, yet almost none have been.

202-212. **Please omit this entire paragraph from your report.** This was done! Hundreds, if not thousands, of people in the ME/cfs community joined in support of the 50 experts who recommended that there be no IOM study but rather, that the NIH adopt the CCC definition. See their letter attached. No more definition studies, please! It is a terrible waste of time and public money. And the waste of time translates into more deaths and years of dreadful suffering by patients.

213-284. “Leveraging existing NIH infrastructure and dollars...” Five million dollars a year to do all that you recommend? Impossible! **Ask for money, over one hundred million dollars to do what you suggest!** You mention cancer. Cancers will receive over a billion dollars from the NIH in the 2014 fiscal year. Cancer survival improves because money has been invested in research into causes and treatments - real money.

287. Please recognize that there are diagnostic tests for ME/cfs. Expert clinicians use them all the time. **Please refrain from saying there are no tests.**

290-302. **NO! No more workshops from the NIH.** These are viewed by patients and advocates for what they are – NIH-make-work projects, doing nothing for patients!

311. YES! Physician education and training is one of the greatest needs that the field of ME/cfs has. Medical schools must be urged by government agencies to add **accurate**, expert-driven (not CDC driven) courses to their curriculums; very few have them now. Do not, however, recommend that agencies of the government structure these courses. They must be created by expert clinicians, researchers, patients, medical educators collectively.

## **My conclusions and recommendations to this panel.**

1. Many very good and potentially very helpful recommendations are made in this report. But, with respect, do you live in fairy land? How are these be implemented without a tremendous increase in public funding? **You do not call for funding for these studies, courses of action, or educational efforts.** They cannot come solely from “public/ private” cooperative efforts. HIV/AIDS was not fought to a draw without a massive infusion of public money. MS patients did not achieve nine FDA-approved drugs without public monies of over \$100,000 a year allocated by the NIH for many years. **Five million dollars a year is all ME/cfs gets from the NIH.** You can’t do three small studies for that amount, much less fund the multitude of good actions this draft recommends. Without a very strong call in this report for far more funding, the report might as well not have been written.

**You must recommend that the NIH vastly increase its allocation of funding for ME/cfs to a level where these recommendations can actually be implemented, particularly bio-medical research into causes and treatments. THE LEVEL MUST BE RAISED TO OVER \$100 MILLION A YEAR! Otherwise, this P2P report along with your sincere and justified recommendations are just so much more government-wasted time and paper.**

2. **Omitted: a comprehensive statement about the pediatric population with ME/cfs and the differences from and similarities to adult patients.** Did you know that while a majority of adult sufferers are women, in the pediatric population there are about as many male as female patients? Why is this? Unknown, because no studies to help illuminate the cause have been done. This population is a forgotten group. Yet they have a terrible time, not only with this mysterious disease, but with school officials and peers and even the courts, who often will simply not believe the young people are truly sick. They need every bit as much help as adults with ME. **Please address this omission in the report.**

3. The emphasis on finding a proper definition, which runs throughout this report, indicates that the panel has not taken seriously the strong request from 50 ME/cfs experts in October 2013 for the HHS to adopt the Canadian Consensus Criteria definition and stop funding more definition studies.

4. **The Fukuda as well as the Oxford definition must be formally and officially retired as definitions to be used in research and clinical settings.** The CCC or ICC definitions, **without the six month waiting period for diagnosis**, should be recommended for adoption by government agencies, medical professionals, medical schools, etc.

5. **Post-exertional collapse** (not malaise) **is a hallmark characteristic of ME/cfs.** More emphasis needs to be given to this fact in describing the disease in this report. And a more accurate term than “fatigue” should be found to better describe the

pathological exhaustion suffered by patients. (Not having the strength to walk or being able to turn over in bed is not fatigue; it is an extreme pathological exhaustion.)

6. **The name “chronic fatigue syndrome” needs to be retired officially**, at least for use by all government agencies. This recommendation will be met with trench-warfare resistance, such as the CDC. But like “consumption” to “tuberculosis,” “chronic fatigue syndrome” can be vastly improved by a far more accurate medical term, “myalgic encephalomyelitis.” And if there is reluctance to adopt ME, call it “Ramsey’s disease.” Dr. Melvin Ramsey was a pioneer in investigating and treating ME. See link: <http://www.name-us.org/DefintionsPages/DefRamsay.htm>

Thank you all for your hard work on this project. Please keep improving the report. It would be wonderful if all of you could remain involved in the efforts of the patient community to address many of these issues. We need your interest, concern, and understanding of the disease and the suffering it inflicts on its million or more sufferers. Please help give them hope that their disease is as important and terrible as cancers, heart disease, etc. The unnecessary deaths and lost lives from ME must stop.

Billie Moore  
NJME/CFSA Advocacy Chair,  
writing for myself