Public Comment
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By Jerrold Spinhirne, S.E. An Illinois-licensed structural engineer unable to practice since 1996 due to the neurological disease myalgic encephalomyelitis, ME

I request the Committee recommend that the Department of Health and Human Services (HHS) end its political manipulation of the case definition and diagnostic criteria for the neurological disease myalgic encephalomyelitis (ICD-10 G93.3, ME) and cancel its contract with the Institute of Medicine (IOM) to redefine the disease clinically. A landmark September 23, 2013 letter by 35 clinical and research experts called for the adoption of the 2003 Canadian Consensus Criteria (CCC) and opposed this harmful and unneeded contract to redefine the disease using inexperienced non-experts. On October 25, these experts were joined by 16 more of their colleagues. http://bit.ly/15npS9B Additionally, over 170 ME and CFS advocates have now signed an open letter in support of the experts' letter. http://bit.ly/17fY4EQ

This attempt by HHS to subvert medical science in favor of a politically controlled, false "consensus" is a violation of President Obama's 2009 Scientific Integrity Memorandum. http://1.usa.gov/c4LScz What other disease since AIDS has been subject to this degree of political interference by HHS? For other major diseases, such an unprecedented consensus of experts in the field would be unchallenged by HHS. However with ME, HHS perversely has chosen to pay the nonprofit IOM $1 million to overrule the genuine expert consensus because the experts' opinion based on science does not suit HHS's political agenda to portray the disease falsely as a fatigue syndrome best medically treated as if it were a mental illness. Please recommend that HHS honor scientific integrity and the Department's mission to protect the nation's health by affirming the expert medical and research community's true consensus.

On September 23, 2013, HHS issued a statement which read:

> *We are pleased to announce that the Institute of Medicine (IOM) will begin conducting a study on Diagnostic Criteria for Myalgic Encephalomyelitis / Chronic Fatigue Syndrome this month. This study grew out of the 2012 CFSAC recommendation to the Secretary to convene a workshop to 'reach a consensus for a case definition useful for research, diagnosis and treatment of ME/CFS.'*

If HHS is proud of what it has done, why was this deal done in a rush and in secret? Why was the IOM selected as a sole source by HHS? Why hasn't the full contract been made public? Who were the architects behind this contract? Why haven't these individuals come forward to explain their decision? The 50 experts and over 170 advocates opposing the contract signed their names to open letters. Why aren't the HHS decision makers who support the contract similarly forthright? Why weren't the voting members of this Committee consulted and allowed to participate in the process – despite claims by HHS that this contract is in support of the CFSAC recommendation? The self-serving "FAQ" that HHS issued on November 15 seems to have left out the most important questions. http://www.hhs.gov/advcomcfs/notices/faqs-iom.html

HHS knows this contract with the IOM to develop new "diagnostic criteria for ME/CFS" is both unnecessary and unconscionable. No doubt, that is why HHS has chosen to have this CFSAC meeting as an audio-only web broadcast which limits patient and advocate visibility and limits public exposure of HHS's shameful tactics. The CFSAC's 2012 recommendation in no way justifies this usurpation of authority by HHS. This contract is not only unnecessary, but will inevitably delay and deny appropriate medical treatment to hundreds of thousands of people with ME in the US and cost billions of dollars in lost productivity. HHS has chosen to use its position of public trust to spread confusion, increase human suffering, and impede scientific understanding the disease ME. This is disgraceful and unethical behavior by a governmental department.

Also on September 23, 2013, 35 experts on the disease, now 50 with 16 additional signers on October 25 and one withdrawal, wrote:

> ***We strongly urge [HHS] to abandon efforts to reach out to groups such as the Institute of Medicine (IOM) that lack the needed expertise to develop "clinical diagnostic criteria" for ME/CFS.*** *Since the expert ME/CFS scientific and medical community has developed and adopted a case definition for research and clinical purposes, this effort is unnecessary and would waste scarce taxpayer funds that would be much better directed toward funding research on this disease.* ***Worse, this effort threatens to move ME/CFS science backward by engaging non-experts in the development of a case definition for a complex disease about which they are not knowledgeable.*** [Emphasis added]
> http://bit.ly/15npS9B

Why haven't these ME experts been listened to, or even been given the courtesy of a response? Outside of these 50 experts, there is simply no other consensus available in the field. These experts have also stated:

> *As leading researchers and clinicians in the field, however, we are in agreement that* ***there is sufficient evidence and experience to adopt the CCC [Canadian Consensus Criteria] now for research and clinical purposes, and that failure to do so will significantly impede research and harm patient care.*** *This step will facilitate our efforts to define the biomarkers, which will be used to further refine the case definition in the future*. [Emphasis added]

An excellent set of diagnostic criteria for the disease already exists in the 2003 CCC. Not only is the IOM contract harmful to the proper medical treatment of ME patients and an impediment to understanding of the disease, but completely unnecessary. In this period of restricted budgets, taxpayers certainly will not be pleased to learn that HHS has wasted their money on developing an unneeded set of diagnostic criteria that ME patients and leading experts do not want and strongly oppose. A petition opposing the HHS/IOM contract and supporting adoption of the CCC now has over 3,000 signatures. http://bit.ly/1c502Mn

In addition, the experts agree the CCC is ready now to serve as the basis of a research definition. This will spare the NIH the resources and expense of developing a completely separate research case definition, again using non-experts, which is now underway in the NIH's Evidence-Based

Methodology Workshop project. **I request the Committee also recommend that the unnecessary NIH Evidence-Based Workshop project be cancelled.**

These attempts to create more unneeded sets of diagnostic and research criteria for the neurological disease myalgic encephalomyelitis by non-experts will be a disaster for already marginalized ME patients. That the inexperienced IOM is unqualified to oversee developing diagnostic criteria can be seen in the inaccurate, psychiatrically biased report on Gulf War illness (GWI) that the IOM issued in January 2013. This report, on what the authors claim should now be called "chronic multisymptom illness" (CMI), reveals a preexisting bias toward ME and CFS:

> *The common thread among the terms is that symptoms experienced by patients cannot be explained as pathologically defined, or organic, disease (Sharpe and Carson, 2001). Such syndromes as irritable bowel syndrome (IBS),* ***chronic fatigue syndrome (CFS), also called myalgic encephalomyelitis,*** *and fibromyalgia often are included in this group of unexplained illnesses, as are chronic unexplained symptoms that do not meet case definitions for* ***IBS, CFS, fibromyalgia, and other functional somatic syndromes*** *that have specified diagnostic criteria.* [Emphasis added] http://bit.ly/VjL3cV (page 22)

A knowledgeable and unbiased committee would not seek to conflate ME with CFS. ME is not an equivalent term for CFS. ME has been listed under "Diseases of the nervous system" by the World Health Organization since 1969 and is now in the tabular listing as ICD-10 G93.3. CFS is listed in the US ICD-9-CM as 780.71 under "Symptoms, Signs, and Ill-Defined Conditions." Clearly, the two terms are not equivalent. Additionally, an overwhelming preponderance of scientific evidence shows neither ME nor CFS is a "functional somatic syndrome." How could HHS possibly consider the IOM to be a neutral, unbiased source of scientific inquiry to develop new diagnostic criteria for "ME/CFS"? The previous IOM report's prejudice and naiveté regarding ME and CFS are there in plain sight.

The IOM claims that as an organization it does not hold positions on the topics that are addressed by its committees or other activities. The IOM also claims the various committees it appoints are independent of one another. However, the IOM will now have control over selecting and charging a new "ME/CFS" committee. Issuing two contradictory reports in little over two years would undoubtably harm the credibility of the IOM's "process" and reduce its chances for receiving future business from government agencies. Will the IOM withdraw its Gulf War illness report if its new committee reaches different conclusions regarding ME and CFS? How can the IOM consider itself without a disqualifying conflict of interest in selecting this new committee? Certainly, control over which members serve on the new "ME/CFS" committee and how they are charged is sufficient to predetermine the nature of the conclusions of the committee's final report.

The CFS section in the IOM's 2013 GWI report (pages 97-100) uncritically accepts the ineffective and unsafe behavioral treatment recommendations of the 2007 UK NICE guidelines for "CFS/ME." These guidelines have been widely criticized for being psychiatrically oriented and lacking appropriate scientific evidence to support their claims. The naive acceptance of the treatment recommendations of the 2007 NICE guidelines for "CFS/ME" shows a shocking lack of scientific rigor and critical judgment by the committee the IOM selected and whose report it approved. Psychotherapy and exercise are inappropriate and unsafe primary treatments for CFS.

It should be clear to any knowledgeable person reading the IOM's 2013 GWI report that by issuing this report, the Institute of Medicine has a disqualifying conflict of interest for undertaking new work regarding ME and CFS as an alleged objective overseer.

The previous IOM GWI report's psychiatric bias toward the nature of ME and CFS should disqualify the IOM from any further HHS-sanctioned work in this field. Surely HHS realizes a new IOM-administrated report is not likely to contradict significantly what another IOM-administrated report has already put on the record in January of this year. Any new IOM report on "ME/CFS" must be viewed as tainted regardless of the IOM's avowal that this time the organization will try to select a committee without a preexisting bias.

If HHS sincerely wants to make progress with the diagnosis and treatment of the actual disease, they would begin by supporting the CCC. HHS claims they do not "formally endorse" case definitions. However, this claim does not prevent HHS from paying the IOM $1 million to supervise the writing and distribution of a new clinical case definition for "ME/CFS." Evidently, this action is not to be construed as an endorsement of a case definition by HHS. However, HHS knows the scientific-sounding opinions of the "ME/CFS" report will be considered authoritative because the report will issued pursuant to an HHS contract. Also, the CDC under HHS has a boxed summary of the 1994 CFS "International" case definition on the diagnosis page of its CFS "Toolkit." http://www.cdc.gov/cfs/toolkit/diagnosis.html Evidently, HHS does not consider that a "formal endorsement" either. It is clear that HHS is being disingenuous with the claim that they do not endorse case definitions. In reality, there is nothing to prevent HHS from publicly acknowledging that a consensus of the expert research and medical communities has been reached supporting the use of the CCC for diagnosis and research of the disease myalgic encephalomyelitis, ME.

"Chronic fatigue syndrome" (CFS) is a misnomer. The creation of the arbitrary, overly broad diagnostic category CFS in 1988 by the CDC was simply a medical science mistake. Myalgic encephalomyelitis at that time had already been recognized by the World Health Organization for almost 20 years. Presently, the term CFS has lost all meaning because it was never objectively, or specifically, case defined. Consequently, the CFS diagnosis has become a dumping ground for a variety of conditions involving complaints of fatigue. Research on the disease has been greatly impeded because the composition of groups of research subjects labelled CFS varies from study to study.

It's time to begin correcting the tragic errors presided over by HHS. Simply tacking an "ME" onto "CFS" is not going to help. The sole case definition for the term ME/CFS is the CCC. The only justifiable use of ME/CFS is to refer to the disease described the CCC. However, HHS is now incorrectly using "ME/CFS" to refer also to the broad CFS diagnosis and simple chronic fatigue which has nothing to do with ME. Both the name ME and the existing consensus case definition, the CCC developed by ME experts, must be universally adopted. The CCC has been used both clinically and in research, and it is ready for universal adoption now. Devising more sets of diagnostic and research criteria will only waste time and scarce taxpayer dollars and add another layer of confusion.

Also, there is no need for the NIH to waste more resources developing a separate research case definition in its so-called Evidence-Based Methodology Workshop. The CCC has already been operationalized and used in research. A new research case definition controlled by non-experts at the NIH will only further impede progress in ME research, possibly for decades.

HHS has inexplicably refused to accept what ME experts have concluded and even questions the hallmark symptoms of ME. Instead, HHS. primarily through the CDC, has promoted an overly broad view of the disease and conflated it with so-called CFS. This has confounded ME with depression, deconditioning and non-specific chronic fatigue, has severely impeded research, and is the direct cause of the medical skepticism and inappropriate or harmful treatment recommendations to which patients are subjected.

Instead of secretly and unilaterally seeking to redefine a disease that ME experts have already defined, why not sponsor meetings of actual ME experts to build on and refine the consensus definitions, the CCC and the 2011 Myalgic Encephalomyelitis: International Consensus Criteria (ME ICC) as recommended by the expert research and medical community and the CFSAC? This would allow the experts, free of interference from government bureaucrats, to agree on biomarkers, testing, and treatment – all of which those affected by ME sorely need now.

It’s time to do the right thing. HHS should stop defying President Obama’s Open Government Initiative and Scientific Integrity Memorandum. HHS should set up transparent communications with the ME community. HHS should listen to the ME scientific experts. HHS should stop equivocating and call the disease by its one proper, internationally recognized name – myalgic encephalomyelitis, ICD-10 G93.3. HHS should stop politically redefining my disease and instead follow the lead of the top experts on the disease definition and recommend use of the CCC for ME diagnosis and research.