

I am incorporating by reference the comments that have been submitted by Jerrol Spinhirne, Deborah Warhoff and Gabby Klein (comments attached below) as my Public Comment submitted for review as part of the 1/13/2015 CFSAC meeting.

Sincerely,  
Susan A. Kreutzer

1) Public Comment Submitted by Jerrol Spinhirne.

The utter folly of choosing inexperienced non-experts outside the field to write about a contested disease is shown in the opening statement of the 2014 Pathways to Prevention Workshop (P2P) on "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome" Draft Executive Summary:

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a chronic, complex, multi-faceted condition characterized by extreme fatigue and other symptoms that are not improved by rest. The etiology and pathogenesis remain unknown; there are no laboratory diagnostic tests; and there are no known cures.

In the first place, it is entirely unclear what the P2P draft report is about. It purports to be about a condition "characterized by extreme fatigue." However, the neurological disease myalgic encephalomyelitis (ME) is NOT characterized by extreme fatigue. Unexplained fatigue is the characteristic feature of chronic fatigue syndrome (CFS), not myalgic encephalomyelitis (ME). Classic descriptions of the neurological disease ME [Acheson, 1959; Ramsay, 1986] and the 2011 ME International Consensus Criteria [Carruthers, 2011] do NOT list fatigue as a diagnostic symptom of the disease – let alone as a characteristic feature of the disease. Therefore, the P2P draft report cannot be about ME. However, the novice authors of the report seem to be unaware this fact and wish to include ME as a part of the undefined condition they are referring to as "ME/CFS" that is "characterized by extreme fatigue."

This is the complete 1986 definition of myalgic encephalomyelitis by Dr. A. Melvin Ramsay written after 30 years of carefully observing the disease in hundreds of patients:

A syndrome initiated by a virus infection, commonly in the form of a respiratory or gastrointestinal illness with significant headache, malaise and dizziness sometimes accompanied by lymphadenopathy or rash. Insidious or more dramatic onsets following neurological, cardiac or endocrine disability are also recognised. Characteristic features include:

(1) A multisystem disease, primarily neurological with variable involvement of liver, cardiac and skeletal muscle, lymphoid and endocrine organs. (2) Neurological disturbance – an unpredictable state of central nervous system exhaustion following mental or physical exertion which may be delayed and require several days for recovery; an unique neuro-endocrine profile which differs from depression in that the hypothalamic/pituitary/adrenal response to stress is deficient; dysfunction of the autonomic and sensory nervous systems; cognitive problems. (3) Musculo-skeletal dysfunction in a proportion of patients (related to sensory disturbance or to the late metabolic and auto immune effects of infection). (4) A characteristically chronic relapsing course. [Ramsay, 1986]

Where's the "extreme fatigue" that the inexperienced P2P authors claim characterizes "ME/CFS"? It should be clear that whatever "ME/CFS" is in the P2P draft report, it is not ME. Consistent with Ramsay's classic definition of ME, the 26 highly qualified and experienced professionals who developed the 2011

International Consensus Criteria document, published in the Journal of Internal Medicine, also do NOT include fatigue in the name of the disease or as a criterion for making an ME diagnosis. They state:

Using 'fatigue' as a name of a disease gives it exclusive emphasis and has been the most confusing and misused criterion. No other fatiguing disease has 'chronic fatigue' attached to its name – e.g. cancer/chronic fatigue, multiple sclerosis/chronic fatigue – except ME/CFS. Fatigue in other conditions is usually proportional to effort or duration with a quick recovery and will recur to the same extent with the same effort or duration that same or next day. The pathological low threshold of fatigability of ME described in the following criteria often occurs with minimal physical or mental exertion and with reduced ability to undertake the same activity within the same or several days.

The ICC document states ME is characterized by an abnormal biological response to exertion or exercise that is objectively measurable by the 2-day cardiopulmonary exercise test (CPET). [Carruthers, 2011; VanNess, 2007] According to the ICC, "Pain and fatigue are crucial bioalarm signals that instruct patients to modify what they are doing in order to protect the body and prevent further damage." The fatigue experienced by ME patients is the result of an underlying disease process and cannot be considered as medically unexplained any more than can be the fatigue experienced by cancer and MS patients.

Why then would the P2P draft report authors include the "ME" part of the term "ME/CFS" that is used apparently to refer to some condition other than ME? The only reason can be because bureaucrats at the Department of Health and Human Services (HHS) told the compliant members of the "unbiased, independent" P2P panel to use the term "ME/CFS" throughout their report and never mind what it means. The only published case definition using the term "ME/CFS" is the 2003 Canadian Consensus Criteria (CCC) document [Carruthers, 2003], but confusingly the P2P draft report uses "ME/CFS" in a broader sense to refer to some nebulous fatigue condition that is never delineated.

The hybrid term "ME/CFS" explicitly embodies what has been the major problem in the field ever since the CDC dispatched two inexperienced, unqualified investigators to the Lake Tahoe region of Nevada in the fall of 1985 in response to one of the many outbreaks of ME in the 20th century – the conflation of the neurological disease ME with a poorly described, socially constructed syndrome based almost entirely on the undefinable, unmeasurable symptom of perceived fatigue.

For 26 years after the CDC mischaracterized ME as a fatigue syndrome in 1988, [Holmes, 1988] all patients with ME in the US have been misdiagnosed as part of the CDC's overly broad chronic fatigue syndrome collection of self-reported symptoms. Simply tacking the term "ME" on to "CFS" using a slash does absolutely nothing to correct this problem. In fact, using "ME/CFS" makes the problem much worse. How can the neurological disease ME ever be separated from the fatigue condition CFS if the two disparate terms are combined in a single term? Of course they can't be separated. This is why HHS now favors the unclassifiable, undefined term "ME/CFS" and has instructed their "unbiased, independent" P2P panel to use "ME/CFS" exclusively in their report to refer to who knows what.

If any of the P2P draft report authors had ever attempted to diagnose a patient with "ME/CFS" and consulted the current US ICD-9-CM, used to code diagnoses for billing and reporting purposes, they would find that the hybrid term "ME/CFS" is not listed. Only the diagnostic term "chronic fatigue syndrome" is listed as 780.71 under "Symptoms, Signs, And Ill-Defined Conditions." "ME/CFS" also has never been listed in the World Health Organization's International Classification of Diseases (ICD). ME, however, has been listed in the WHO ICD as a neurological disease since 1969. Indeed, the hybrid "ME/CFS" diagnostic term can never be legitimately listed in the WHO ICD. It's an unclassifiable chimera

that violates the WHO rule of only using mutually exclusive diagnostic terms that fall within a single category.

Nor will the hybrid term "ME/CFS" be listed in the upcoming US ICD-10-CM, official October 1, 2015. Only the diagnostic terms "chronic fatigue syndrome" in the general symptoms section and "benign myalgic encephalomyelitis" in the neurological diseases section will be listed. How then will a doctor code an "ME/CFS" diagnosis? Because doctors in the US have only been informed about CFS, if informed at all, and know nothing of ME, "ME/CFS" will be coded as the ill-defined condition CFS and not as the neurological disease ME. This fact renders HHS's current use of the term "ME/CFS" hypocritical and nonsensical.

How then is one to interpret such statements in the P2P draft report as, "Patients experience stigma from the diagnosis of ME/CFS, including social isolation and judgment"? How can patients experience stigma from a diagnosis of "ME/CFS" when CFS is the diagnostic term now used by doctors in the US? The draft report is retrospectively calling CFS "ME/CFS." This muddled historical revisionism is the result of the "unbiased, independent" P2P panel allowing itself to be misguided by HHS bureaucrats.

Despite obviously not knowing what "ME/CFS" might be, the P2P draft report authors on page 3 make the breathtaking leap of faith to assure readers that "ME/CFS exists." This is bit like declaring Bigfoot exists despite being unable to come up with a clear description of the creature. However, the confusion of the authors is understandable because their newly acquired knowledge of "ME/CFS" is largely based on a recent Agency for Healthcare Research and Quality (AHRQ) Evidence Report No. 219 "Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome" [Smith, 2014] also written by "unbiased, independent" neophytes in the field.

The Executive Summary of the AHRQ Final Evidence Report on page ES-1 makes the egregious misstatement that of the eight published case definitions considered, "All include persistent fatigue not attributable to a known underlying medical condition, as well as additional clinical signs and symptoms."

Evidently, the "unbiased, independent" authors of the AHRQ report Executive Summary in their eagerness to make "ME/CFS" all about "persistent fatigue" failed to note that several pages later, the main report states, "All but one of the definitions include persistent fatigue not attributable to a known underlying medical condition, as well as additional clinical signs and symptoms that do not all need to be present to establish the diagnosis." [Smith, 2014, page2, italics added]

Table 2 on page 14 of the AHRQ Evidence Report clearly shows that the one exception that does not use the criterion of fatigue in its case definition is the "International ME Carruthers 2011" case definition in the fourth column from the left. [Carruthers, 2011]

This omission is vitally important because the neurological disease ME is not a fatigue syndrome, nor a part of any fatigue syndrome. Nevertheless, HHS and their Centers for Disease Control (CDC) have failed to recognize the disease and to list ME as an exclusionary diagnosis for inclusion in the CDC's broad chronic fatigue syndrome umbrella diagnostic category.

It can be argued, supported by extensive research, that ME itself is a "known underlying medical condition" to which any fatigue reported by a patient can be attributed. Therefore, ME cannot be considered part of any condition characterized by unexplained fatigue – including ironically HHS's new undefined "ME/CFS" fatigue illness blend.

It has been the long-standing policy of HHS to support the misdiagnosis of ME patients with CFS – a policy that spares the private insurance industry the cost of appropriately medically testing for and treating ME. Keeping ME concealed within CFS, and now "ME/CFS," also spares the Department of Health and Human Services the expense of appropriately funding biomedical research on a major neurological disease. Instead, HHS now gets away with only spending a pittance each year on often social science research of an elusive fatigue condition called CFS.

HHS wishes to avoid at all costs acknowledging their concealment of ME for decades within CFS. Apparently the "unbiased, independent" P2P report authors are happy to oblige HHS by failing to read any further than the Executive Summary of the AHRQ report and using HHS's new undefined, catch-all term "ME/CFS" without question.

The P2P authors naively misrepresent ME in their draft report as a part of a dazzling "complex, multi-faceted condition characterized by extreme fatigue" completely oblivious to the history of ME in the medical literature and its current 2011 ICC case definition. Anyone familiar with the field would have noticed the glaring error on page ES-1 of the AHRQ Evidence Review and pointed it out rather than repeating it.

If the P2P draft report authors had read the 2012 ME International Consensus Primer (IC Primer or ICP) [Carruthers. 2012], they would know better than to parrot the CDC's popular myth that "there are no laboratory diagnostic tests" for the disease. The IC Primer already lists over 30 laboratory tests and imaging studies specifically useful in diagnosing ME, in addition to standard laboratory screening tests.

Despite the P2P draft report's familiar call that more research is needed, it is completely unclear just what it is that needs to be researched. Research on any actual disease has been hampered for decades by use of the overly broad 1994 Fukuda CFS case definition. [Fukuda, 1994] Fukuda CFS research results cannot be applied to any specific patient group or consistently replicated.

The P2P draft report completely fails to address the total lack of funding by the National Institutes of Health (NIH) for any research on the neurological disease ME with subjects selected using specific ME criteria. As the IC Primer states, "There is a current, urgent need for ME research using patients who actually have ME." This urgent need is completely ignored by the authors of the P2P draft report who were charged with identifying "research gaps and future research priorities."

The P2P draft report calls for the 1991 Oxford CFS definition to be "retired." No mention is made, however, of retiring the CDC's 1994 CFS Fukuda definition which has also been impairing progress in the field for over 20 years. Does "retiring" the Oxford definition mean the CDC will remove the 2011 PACE trial, which used the Oxford definition, as a reference in their CFS continuing medical education course? The CDC has used the Oxford-based PACE trial to support their irresponsible recommendation of using exercise as "therapy" to treat CFS.

In fact, "retiring" the Oxford definition means very little in actual practice because Oxford has never been used in NIH-funded CFS research. Will the invalid UK PACE trial be retracted based on the P2P panel's recommendation? It won't be. No doubt, the CDC will continue to use Oxford-based research as a reference whenever it supports the CDC's agenda of recommending primarily behavioral treatments for their chronic fatigue syndrome.

Unbelievably, to remedy the current chaos caused the use of multiple case definitions, the P2P draft report authors want to "assemble a team of stakeholders (e.g., patients, clinicians, researchers, federal agencies) to reach consensus on the definition and parameters of ME/CFS." Apparently, the draft report authors are unaware that a consensus of truly independent, expert professionals in the field was reached over 10 years ago in the 2003 Canadian Consensus Criteria (CCC) and updated in 2011 by the International Consensus Criteria (ICC). The ICC have now been used to select subjects with ME for research studies indicating widespread neuroinflammation and immune system abnormalities are associated with the disease. [Nakatomi, 2014; Brenu, 2013]

However, when then HHS Secretary Kathleen Sebelius was offered the opportunity in 2013 of adopting the compromise CCC case definition, as recommended by 50 expert professionals in the field, she summarily rejected the proposal. Instead, HHS is now pursuing a new unneeded redefinition of "ME/CFS" using a contracted Institute of Medicine panel composed mostly of the controllable "unbiased, independent" non-experts favored by HHS bureaucrats.

Nevertheless, the unknowledgeable P2P panel is calling for yet another grand consensus by a "team of stakeholders" and a pie-in-the-sky "national and international research network." It should be clear to anyone that the problem is bad faith at HHS – not the lack of existing excellent consensus diagnostic and treatment guidelines that can also be used for research.

The diagnostic and research criteria for other major diseases are developed by expert professionals in the field and their organizations, without inference from government bureaucrats and agencies. The harm caused by governmental meddling with disease criteria is demonstrated by the unscientific 1994 Fukuda CFS criteria controlled and developed primarily by NIH and CDC bureaucrats with major input from UK psychiatrists. These bureaucrats had personal and institutional agendas which they placed above the public interest. [Straus, undated] For two decades, the overly broad Fukuda CFS criteria have confounded research and led to the medical neglect and mistreatment of patients.

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]

Yet the naive P2P panel is calling for still more governmental interference in medical science by wanting "federal agencies" to be included in choosing yet another set of criteria for a fatigue condition now called "ME/CFS." When will professionals realize the harm caused by governmental interference with science and refuse to take part in such efforts? Currently, the only two contemporary case definitions that reflect the physical reality of the disease were developed by professionals in the field with a minimum of of governmental interference – the 2003 CCC and 2011 ICC.

The unknowledgeable P2P panel from outside the field seems to be unaware that most of the problems the panel has "discovered" have already been addressed by the 2011 ICC and 2012 IC Primer. HHS can begin correcting these problems by recognizing ME as the distinct neurological disease that it is and removing ME from the broader inappropriate CFS category, as called for by the ICC. HHS needs to assume an ancillary role and begin disseminating the IC Primer to doctors so they can make the differential diagnosis of ME, instead of continuing to place ME patients at risk by misdiagnosing them with CFS or some new "ME/CFS" pseudo-diagnosis.

The tools for educating medical professionals about ME already exists in the ICC and IC Primer. The problem is HHS does not want to devote the necessary resources to educating doctors and healthcare professionals on how to recognize, diagnose, and properly treat ME. HHS prefers, instead, to accept the increased disability in the US population and increased yearly cost to the economy caused by medically neglecting and mistreating ME. The HHS leadership has chosen to support the bureaucrats at the CDC's inept CFS program, and their negligent CFS Toolkit collection of dangerous medical misinformation, over the public interest. [CDC, undated]

Why would HHS ever implement any of the grand proposals of the P2P draft report when HHS stubbornly refuses to take even the low-cost, simple step of removing the harmful, inaccurate CFS Toolkit from the CDC website and disseminating the urgently needed IC Primer to healthcare professionals? Doctors now are unaware of the possible permanent harm to their ME patients posed by exercise and overexertion. ME must be recognized and diagnosed early so the patient can be advised to take total rest to limit the risk of permanent severe disability caused by the disease. Pioneer ME doctor A. Melvin Ramsay has noted:

The clinical picture of myalgic encephalomyelitis has much in common with that of multiple sclerosis but, unlike the latter, the disease is not progressive and the prognosis should therefore be relatively good. However, this is largely dependent on the management of the patient in the early stages of the illness. Those who are given complete rest from the onset do well... [Emphasis added]

Doctors have been left totally uninformed about ME by the continued misconduct of HHS bureaucrats. Instead of conducting seminars educating doctors about ME with information that is now readily available, HHS is squandering public money on the obfuscating P2P Workshop and its report which will soon be forgotten. The leadership at HHS has chosen to place their highest priority on protecting the mistakes of their bureaucrats and the profits of the insurance industry, rather than protecting the public health.

The primary consideration of "unbiased, independent" P2P draft report is obviously pleasing the HHS bureaucrats who commissioned the report, rather than adding any clarity to the muddled mess created by those very bureaucrats. Any useful suggestions made in the final P2P report will simply be ignored by HHS bureaucrats as they have done for decades. The P2P draft report can hardly be expected to address the main problem currently forestalling any hope of progress in researching, diagnosing, and treating ME – the refusal of HHS to listen to the truly independent, knowledgeable medical and scientific professionals in the field. Instead, HHS continues to enlist controllable non-experts to add more confusion and delay to the field. The P2P draft report itself is a prime example.

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## 2) Public Comment submitted by Deborah Warhoff – co-founder MECFS ALERT

Hard lessons from P2P and Request for a CFSAC member to cease discrimination

There is a terrible, hard lesson to be learned from P2P. That is, members of CFSAC in their recommendations must parse their language with the care they would take for a Supreme Court hearing. Otherwise, their meaning may be distorted by persons with differing motives, and then come back to kick them in the face.

P2P originated with a call by CFSAC for a "consensus" of expert scientists, both clinicians and researchers, and knowledgeable stakeholders such as patients – all of whom have devoted large portions of their lives to furthering understanding of Myalgic Encephalomyelitis. These, CFSAC intended, would review and revise the ICC as necessary in order to achieve a more perfect definition.

What resulted instead was that NIH devised P2P as a purported answer to this quest. But instead of bringing knowledge to bear their construct featured persons selected for complete ignorance of the subject matter, histories and consequences. One group selected for ignorance was assigned to review material previewed and selected by another group that had been chosen for ignorance. This vaunted ignorance notwithstanding, however, a fix was in. The allowed universe of material to be considered had been pre-selected to exclude biomedical science and lead the putatively innocent reviewers down a yellowish brick road to a mushy, quasi-bio-psycho-social definition. In addition, choices made by the Oregon VA pre-viewers showed decided influence in said direction from outside coaching not disclosed in any protocol: e.g., the arithmetic ineptitude I cite in MECFS Alert 71.

Another unpleasant lesson: two major tragic flaws were incorporated into P2P via the choice of data that was input for consideration. One was the inclusion of Britain' PACE trial data. This is fraudulent, the procedure having been very extensively modified from the protocol in order to match the disappointing results. This probably would not stand in America. However, it is standing in Britain because Oxbridge man invariably defends Oxbridge man., as Simon Kuper so eloquently explained in his Financial Times essay of last October 24th1.

Second -- and related -- danger lurks in the vague suggestion by the final P2P committee that America work with other countries. This leaves open a huge expanse of quicksand because healthcare in Protestant Northern Europe is very much controlled by psychiatrists who are incarcerating children and grown women – always women, never men--if they do not submit to programs ordered by the psychiatrists. This is contrary to the U.S. constitution and cannot be tolerated by agencies of the U.S. government.

In another matter, I am greatly concerned that CFSAC has taken on a snobbish, age-ist and anti-patient bias in allowing Dr. Kaplan to join the panel. Dr. Kaplan's clinic does not allow Medicare or Medicaid patients. Of necessity this indicates that he cannot have much background in treating true M.E., and that he will not be treating many M.E. patients from whom he might learn in the future.

True M.E. almost invariably leads to unemployment due to disability. If the disabled person can demonstrate sufficient work history and disability he or she will eventually get Social Security disability and, after delay, Medicare. Even those who do not file for disability will eventually age into Medicare. In

addition, M.E. tends to lead to widespread pauperization for those without adequate alternative family income. This can result in enrollment in Medicaid.

Thus, Dr. Kaplan's clinic de facto maintains a policy of not treating true M.E. patients. This is not to begrudge him his affluent suburban clientele. But it does not seem appropriate for a CFSAC member to specialize in a cohort underweight M.E. patients. In line with this, I would urge Dr. Kaplan to immediately open his clinic to Medicare and Medicaid patients. Otherwise, in line with Virginia's centuries-old tradition of gentlemanly behavior, Dr. Kaplan would be expected to resign his seat on CFSAC. --end--

1 Kuper, Simon. "Confessions of a White Oxbridge Male." Financial Times Magazine. London, October 24th, 2014.

3) Public Comment by Gabby Klein. This is to serve as my written comment to the CFSAC January 13th, 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,

Gabby Klein  
Flushing, NY

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