

Submission re: DSM-V and ME/CFS

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Introduction

The 25% ME Group for the Severely Affected is a registered UK charity representing people who are profoundly disabled by Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

Myalgic Encephalomyelitis (ME) has been classified by the World Health Organisation (WHO) as a neurological disorder since 1969. Currently it is listed in the International Classification of Diseases (ICD), chapter 6, under Disorders of Brain at ICD-10 G 93.3. In the 1992 revision of the ICD, the WHO approved the term “Chronic Fatigue Syndrome” (CFS) as a term by which ME may be known. The term CFS is coded only to ME at ICD-10 G93.3, hence the composite term “ME/CFS” is often used to denote the disorder. A synonymous term also sanctioned by the WHO is “postviral fatigue syndrome”.

This submission is a public record of the charity’s concern relating to the forthcoming revision of the American Psychiatric Association (APA)’s Diagnostic and Statistical Manual for Mental Disorders (DSM) and the intention to create a new diagnostic category of “Complex Somatic Symptom Disorder” (CSSD) which would combine existing categories of somatisation disorder, undifferentiated somatoform disorder, hypochondriasis and pain disorder (APA; Justification of Criteria – Somatic Symptoms, 1/29/10).

An influential group of American and European psychiatrists, including British psychiatrists Professors Michael Sharpe, Peter White and Simon Wessely (often referred to as the “Wessely School”: Hansard; Lords, 9th December 1998:1013), together with Francis Creed (since 1997, Professor of Psychological Medicine in the Psychiatry Research Group in the Manchester University School of Medicine; European Editor of the Journal of Psychosomatic Research and a member of the Medical Research Council Advisory Board) does not accept the WHO classification of ME/CFS as a neurological disorder but assert that it is a functional somatic syndrome (ie. a mental disorder).

Although the CSSD literature currently does not specifically mention the terms ME or CFS as proposed inclusions, the existing evidence suggests that the DSM Somatic Symptom Disorder Work Group intends to ensure that ME/CFS will fall within the purview of the new category of CSSD because they believe ME/CFS to be an example of a CSSD (ie. they believe that ME/CFS patients complain of physical symptoms that do not result from underlying physical disease but are the consequence of abnormal illness beliefs, and that the abnormal beliefs are responsible for the perpetuation of the perceived disability). It seems clear that in clinical practice, these psychiatrists would like to see the diagnosis of ME/CFS replaced by a diagnosis of CSSD (ie. a psychiatric classification instead of an organic one) and that they are working diligently to achieve their aim.

However, on 28th June 2001 the Classification, Assessment, Surveys and Terminology (CAS) Measurement and Health Information Systems (MIS) section of the WHO confirmed that it had no plans whatsoever to remove ME from the section on Disorders of Brain and transfer it to a psychiatric classification. The WHO provided further confirmation on 6th August 2002, when it reconfirmed that ME will not be reclassified as a psychiatric disorder and will remain in the neurology section of the ICD, and on 24th March 2003 the WHO confirmed that ME/CFS cannot be known as or included with any mental or behavioural disorder, once again confirming that it will remain classified as a neurological disorder, and that the WHO has no intention of re-classifying it as a psychiatric disorder in any forthcoming revision of the ICD.

In the years following this confirmation, yet more evidence of neurological pathology in ME/CFS has emerged and therefore in order to harmonise with the ICD, the APA needs to ensure that ME/CFS does not

by default fall within the ambit of the proposed diagnostic category of CSSD that will appear in the forthcoming DSM-V.

It is submitted that the proposed diagnostic criteria for CSSD are conceptually flawed because they lack sufficient specificity to be clinically meaningful. They do not define the target population and represent a potential threat to people with a diagnosis of ME/CFS as they are open to misapplication by clinicians who refuse to accept the substantial evidence that ME/CFS is an organic disorder.

Submission

Evidence that the DSM CSSD Work Group believes ME/CFS to be a somatoform disorder

UK Professors Creed and Sharpe are members of the DSM-V Somatic Symptom Disorder Work Group and were members of Conceptual Issues in Somatoform and Similar Disorders Project (CISSD, not to be confused with CSSD) that was launched by Richard Sykes to stimulate dialogue about the taxonomy of functional somatic syndromes, which the CISSD Group asserted included irritable bowel syndrome, Chronic Fatigue Syndrome and fibromyalgia. (Richard Sykes was formerly Director of the ME charity Westcare, now merged with the charity Action for ME, whose brother Sir Hugh Sykes is a non-executive Director of Action for Employment known as A4e, the largest European provider of Welfare to Work programmes that implements a social policy introduced in the UK in 1997 which focuses on specific groups of people claiming benefits, including those on disability benefits). According to Sharpe and Sykes, the CISSD Group's aim was to make the criteria for Somatoform Disorder either *"more inclusive"* or to add a *"lower threshold category"* (Kurt Kroenke, Michael Sharpe, Richard Sykes. Review Article: Revising the Classification of Somatoform Disorders. *Psychosomatics* 2007;48:277-285).

The 2007 Review discusses *"pseudo-neurological symptoms"*; *misinterpretation of bodily symptoms"*; *"rumination about bodily symptoms"*; *"catastrophizing, ie. fear of bad outcomes despite reassurance"* and *"seeking care from multiple providers for the same symptoms"*, all of which exemplify the Wessely School's description of ME/CFS patients and which form the bedrock of the APA's new category of CSSD.

The DSM classification uses multiple axes (Axis I, referring to psychiatric diagnoses; Axis II, referring to personality disorders, and Axis III, referring to general medical conditions). The 2007 Review discusses whether *"these so-called functional somatic syndromes such as chronic fatigue syndrome would properly be placed on Axis III (but) this can be seen as inconsistent if a patient with the same symptoms seen by a psychiatrist is diagnosed with a somatoform disorder on Axis I"*. An Axis I diagnosis is required in some healthcare systems to justify financial reimbursement to a mental health professional.

Of particular concern is the fact that a diagnosis of somatisation may depend on a *"total symptom count"*, which *"may bypass the methodological difficulties in arbitrating symptom aetiology"*, because there are over 50 recorded symptoms in ME/CFS (The Disease of a Thousand Names. David S Bell. Pollard Publications, New York, 1991). At the Royal Society of Medicine meeting on 28th April 2008 on CFS, Professor Peter White advised that once a CFS patient has more than four symptoms, it was likely that s/he had a psychiatric disorder. Such a belief cannot be objectively verified and is not in accordance with the British Medical Association's advice on complex medical disorders. The Foreword to The British Medical Association Complete Family Health Guide is clear: *"The Guide is based on advice from a panel of medical consultants chosen by the BMA, and their experience provides an unrivalled assurance of quality and reliability"*. Under hyperthyroidism, the BMA consultants list 10 symptoms; under Cushing's syndrome, 11 symptoms are listed; under asthma, 11 symptoms are listed; under chronic kidney failure, 8 symptoms are listed; under AIDS, 13 symptoms are listed.

The unproven beliefs of the psychosocial school have no relevance to complex organic disorders such as ME/CFS.

However, these psychiatrists have variously described the discrete neurological disorder ME/CFS as:

“medically unexplained symptoms” (referred to as MUS):

- *“....MUS. This term is now used in preference to ‘somatisation’...The medical specialities employ shorthand descriptions for particular clusters of MUS, including irritable bowel syndrome, fibromyalgia and chronic fatigue syndrome” (L. Page, S. Wessely, JRSM 2003:96:223-227).*

“somatisation”:

- in relation to ME/CFS patients’ correct belief that there is viral involvement and Wessely’s chapter “Viruses and fatigue: the current status of the chronic fatigue syndrome” in “Biological Factors and Psychiatry” edited by Kurskak E, New York, Plenum, 1991, Wessely’s colleagues emphasise that *“Wessely sees viral attribution as somatisation par excellence”* (Helen Cope, Anthony David, Anthony Mann. Journal of Psychosomatic Research 1994:38:2:89-98). (Note that the correct citation should be “Psychiatry and Biological Factors” and that the editor’s name is Kurstak E).
- Professor Sharpe argues that people with ME/CFS are not ill as a result of any physical disease; he is on record as affirming that ME is *“a pseudo-disease diagnosis”* (Occup Med 1997:47:4:217-227); his view about ME/CFS *“has long been that the issues surrounding (it) are the same as those surrounding acceptance and management of (patients) who suffer conditions that are not dignified by the presence of what we call disease”* (J Psychosom Res 2002:52:6:437-438) and he maintains that patients with ME/CFS choose the *“advantages”* of the *“sick role”* and therefore should not qualify for welfare benefits. It is also his belief that ME/CFS patients are *“the undeserving sick of our society and our health service”* because they *“refuse to be placed into and accept the stigma of mental illness”* (Michael Sharpe; “ME. What do we know – real physical illness or all in the mind?”; lecture given in October 1999 hosted by the University of Strathclyde).

“neurasthenia”:

- *“Neurasthenia remains in the Mental and Behavioural Disorders chapter (of ICD-10) under Other Neurotic Disorders. Neurasthenia would readily suffice for ME”* (A. David, S. Wessely, Lancet 1993:342:1247-1248).

a “functional somatic syndrome”:

- *“....the existence of specific somatic syndromes (in which the authors include ME/CFS) is largely an artefact of medical specialisation....Functional somatic syndromes...are associated with unnecessary expenditure of medical resources”* (S. Wessely, C. Nimnuan, M. Sharpe, Lancet 1999:354:936-939).
- in 2002, Michael Sharpe wrote a paper titled “Functional Symptoms and Syndromes: Recent Developments” (published in “Trends in Health and Disability” by the insurance company UNUMProvident: <http://www.unumprovident.co.uk/NR/rdonlyres/E03B0BCF-EAA0-45B6-95E2-54BEC5C600F8/0/CMOReport2002.pdf>) in which he stated that functional somatic syndromes have been referred to as *“‘hysteria’, ‘abnormal illness behaviour’, ‘somatisation’, ‘somatoform disorders’....Recently, the terms MUS and ‘functional symptoms’ have become popular amongst researchers”*. In his table of *“Common medically defined functional syndromes”* Professor Sharpe included the taxonomically separate disorders Chronic Fatigue Syndrome, fibromyalgia (classified in ICD-10 at M79), irritable bowel syndrome and multiple chemical sensitivity and proposed that *“these conditions be considered together as a ‘general functional somatic syndrome”*. It is of note that the creation of a CSSD category would represent the fulfilment of Professor Sharpe’s proposal.

- *“Functional somatic syndromes....include chronic fatigue syndrome....Perpetuating factors have particular importance in understanding CFS...Physical deconditioning as a consequence of reduced activity may contribute towards greater experience of symptoms”* (Hyong Jin Cho, Simon Wessely, Rev Bras Psiquiatr 2005;27:3).

a “classical psychosomatic disorder”:

- *“Anorexia Nervosa (AN) and chronic fatigue syndrome (CFS) are classical psychosomatic disorders where response to social threat is expressed somatically”* (advertisement for a psychology graduate to work with ME/CFS patients placed by the Institute of Psychiatry; the closing date for applications was 13th July 2007 and the job reference was 07/R68. The post-holder was to work under the direction of Professor Trudie Chalder, a behavioural therapist who, together with Michael Sharpe and Peter White, is one of the Principal Investigators of the MRC PACE Trial).

It is also the belief of these psychiatrists that *“cognitive distortions”* (ie. aberrant or maladaptive illness beliefs) are responsible for the perpetuation of ME/CFS, for example:

“cognitive distortions”:

- *“I will argue that ME is simply a belief, the belief that one has an illness called ME”* (“Microbes, Mental Illness, The Media and ME: The Construction of Disease”; Simon Wessely; 12th May 1994; 9th Eliot Slater Memorial Lecture, Institute of Psychiatry, London).
- *“CFS is dogged by unhelpful and inaccurate illness beliefs...they include fears and beliefs that CFS is caused by a persistent virus infection or immune disorder”* (Anthony J Cleare, Simon C Wessely; Update 1996;14th August: 61).
- *“The clinical problem we address is the assessment and management of the patients with a belief that s/he has an illness such as CFS, CFIDS (chronic fatigue immune dysfunction syndrome, a term used in the US) or ME....The majority of patients seen in specialist clinics typically believe that their symptoms are the result of an organic disease process...Many doctors believe the converse”* (Sharpe M, Chalder T, Wessely S et al. General Hospital Psychiatry 1997;19:3:185-199).
- The MRC PACE Trial Identifier says: *“CBT will be based on the illness model of fear avoidance. There are three essential elements: (a) assessment of illness beliefs and coping strategies, (b) structuring of daily rest, sleep and activity, with a graduated return to normal activity, (c) challenging of unhelpful beliefs about symptoms and activity”* (Section 3.2).
- *“the symptoms and disability are perpetuated predominantly by unhelpful illness beliefs (fears) and coping behaviours (avoidance)”* (MRC PACE Trial CBT Manual for Therapists, page 18).

Since a diagnosis of CSSD requires the presence of somatic symptoms and cognitive distortion, it can be seen that the Wessely School would consider ME/CFS to fall within that proposed diagnostic category.

Dismissive of the WHO classification, the Wessely School asserts: *“Medical authorities are not certain that CFS is exactly the same illness as ME, but until scientific evidence shows that they are different they have decided to treat CFS and ME as if they are one illness”* (<http://pacetrial.org/PCL%20version%2009.pdf>) and instructs doctors involved with the Trial that: *“if a participant calls their illness ME don’t attempt to challenge this, ME or CFS is an appropriate term to use”* (MRC PACE Trial; SSMC manual for participating doctors, page 13).

Thus there can be no dispute that the Wessely School is referring to the specific neurological disorder ME/CFS, and that their unauthorised reclassification is not in accordance with the WHO taxonomy.

Using Professor Wessely's own material, in 2000 the neurological disorder ME/CFS was included in a textbook for General Practitioners entitled "Guide to Mental Health in Primary Care" that was produced by the WHO Collaborating Centre for Mental Health at the Institute of Psychiatry, London. However, on 16th October 2001 the WHO issued a statement repudiating this unauthorised reclassification, confirming in writing: *"Postviral fatigue syndrome remains under diseases of the nervous system as G93.3. Benign myalgic encephalomyelitis is included within this category. Neurasthenia remains under mental and behavioural disorders as F48.0 and fatigue syndrome is included within this category. However, postviral fatigue syndrome is explicitly excluded from F48.0.... It is possible that one of the several WHO Collaborating Centres in the United Kingdom presented a view that is at variance with WHO's position. I understand that the Collaborating Centre concerned has now made changes to the information on its website after speaking with WHO"*.

Undaunted, and rejecting the taxonomic principles employed by the WHO, Wessely School psychiatrists then asserted that the WHO had classified the same disorder (ME/CFS) in two places, once in the Neurological Section (ICD-10 G93.3) and also in the Mental and Behavioural Section (ICD-10 F48.0).

Once again, their claims were formally repudiated in writing by the WHO; on 23rd January 2004, Andre L'Hours from the WHO headquarters in Geneva confirmed that: *"According to the taxonomic principles governing ICD-10 it is not permitted for the same condition to be classified to more than one rubric as this would mean that the individual categories and subcategories were no longer mutually exclusive"*.

The Wessely School, however, has continued to ignore the clarification provided by the WHO.

In his presentation at the Royal Society of Medicine's conference on Chronic Fatigue Syndrome on 28th April 2008 Professor Peter White said: *"I'm going to try to define what Chronic Fatigue Syndrome is. By doing so, I'm going to review the ICD-10 criteria for the illness and see if they're helpful. The answer will be, they are not helpful...Does the ICD-10 help us? Unfortunately not; there are at least five ways of classifying CFS using the ICD-10 criteria. What are they? We start off well: myalgic encephalomyelitis is in the neurology chapter of ICD-10...and helpfully, "chronic fatigue syndrome, postviral". So it starts off well. What if the viral illness is not a clear trigger for the illness? Well, you've got alternatives: in the Mental Health Chapter, you've got Neurasthenia..."*.

Despite the fact that eighteen years previously, the American Medical Association confirmed that "chronic fatigue" is not the same as the Chronic Fatigue Syndrome (JAMA press release, 1990, referring to the issue of 4th July 1990), Professor White conflated "chronic fatigue" (ie. ongoing tiredness) with "Chronic Fatigue Syndrome" (ie. a neurological disorder), thus further demonstrating his belief that ME/CFS (ICD-10 G93.3) is the same as psychogenic fatigue (ICD-10 F48.0). He discussed the various somatoform classifications in the ICD-10, before saying: *"the trouble with these diagnoses is, you somehow have to guess that psychological factors have an important role to play in their aetiology"*. He concluded his presentation: *"ICD-10 is not helpful and I would not suggest, as clinicians, you use ICD-10 criteria. They really need sorting out, and they will be in due course, God willing"* ("What is Chronic Fatigue Syndrome and what is ME?"; webcast: <http://rsm.mediaondemand.net/player.aspx?EventID=1291>).

That was a clear instruction to clinicians to disregard the ICD-10 classification of ME/CFS as a neurological disorder.

Diagnostic accuracy is of vital importance in medicine: a person with a specific and complex neuro-immune disorder such as ME/CFS requires very different management and care from a person with an ill-defined state of chronic "tiredness".

It is indisputable that these psychiatrists have subsumed the nosological disorder ME/CFS within a wide range of undifferentiated states of "medically unexplained chronic fatigue" (ie. they have claimed it as a somatisation disorder); that they ignore the pathognomonic feature of ME/CFS that is measurable and reproducible (post-exertional fatigability of muscles accompanied by intense malaise), and that they

disregard the substantial evidence-base of organic pathoaetiology published in peer-reviewed journals, as well as the objective signs and documented symptoms (summarised at <http://www.meactionuk.org.uk/magical-medicine.pdf> pages 98-214), focusing instead on what they regard as the subjective complaint of “fatigue” and on patients’ supposed “*cognitive distortions*”.

They insist that this heterogeneous group of “fatigued” people must be uniformly managed by cognitive behavioural therapy (CBT) and graded (aerobic) exercise therapy (GET). The aim of these psycho-behavioural interventions is to convince patients – including those with ME/CFS -- that they do not suffer from an organic disorder but are simply deconditioned secondary to inactivity, “*symptom focusing*” and “*hypervigilance to normal bodily sensations*” (asserted to be curable by cognitive “restructuring” in order to disabuse ME/CFS patients of the “*aberrant belief*” that they have an on-going physical disease), together with incremental aerobic exercise to strengthen their “deconditioned” muscles. There is no evidence of deconditioning in ME/CFS; on the contrary, as long ago as 2001, Bazelmans et al demonstrated that deconditioning is not a factor in ME/CFS (Psychol Med 2001;31:107-114.) and this was confirmed by Sargent et al the following year (Med Sci Sports Exerc 2002;34:1:51-56).

Notwithstanding, the MRC PACE Trial, designed and executed by Professors White, Sharpe and Wessely, is predicated on their assumption that ME/CFS patients are deconditioned, and upon their belief that the post-exertional incapacitating fatigability of ME/CFS falls within the continuum of normal, everyday “tiredness”. They believe this “tiredness” to be no different in character from the fatigue experienced by otherwise healthy individuals, but that ME/CFS patients respond to it inappropriately by resting too much, focusing on being tired, and by attributing it to a non-existent physical disease process.

The PACE Trial literature states explicitly that ME/CFS can be cured by the application of cognitive behavioural therapy and/or graded exercise therapy; Professor Michael Sharpe has stated “*There is evidence that psychiatric treatment can be curative*” (British Medical Bulletin 1991;47:4:989-1005) and Professor Peter White has asserted “*recovery from CFS is possible following CBT....Significant improvement following CBT is probable and a full recovery is possible*” (Psychother Psychosom 2007;76(3):171-176).

From their prolific publications about ME/CFS, it is clear that the UK Wessely School, and indeed its American and Continental counterparts, have no interest in what has been described by a leading US Professor of Psychology who specialises in ME/CFS as “*diagnostic accuracy*” (Jason L et al. JCFS 1999;5:3-33).

The AMA proposed category of CSSD for DSM-V

The APA states about the proposed CSSD category: “*The hallmark of this disorder is disproportionate or maladaptive response to somatic symptoms...In severe cases (patients) may adopt a sick role...Some patients feel that their medical assessment and treatment have been inadequate...The symptoms may or may not be associated with a known medical condition...The symptoms sometimes represent normal bodily sensations...or discomfort that does not generally signify serious disease...or are incompatible with known pathophysiology (e.g. seeing double with one eye closed)*”.

For the avoidance of doubt, seeing double with one eye closed is not incompatible with known pathophysiology; it is known as monocular diplopia: a false image occurs if, through misalignment, the image falls on the periphery of the retina; it may also be attributable to axial lens opacities, to pterygium (thickening of the conjunctiva over the cornea), or to xerophthalmia (dry eye). It is discouraging to learn that the psychiatrists charged with the task of accurately describing the proposed category of CSSD ascribe recognised ocular pathology to “*cognitive distortion*”.

For a diagnosis of CSSD to be made, there must be not only “*somatic symptoms*” (criterion A) but also “*cognitive distortions (criterion B)*”.

Although the predictive validity of most of the new diagnostic proposals has not yet been investigated, the Work Group proposes that to meet criteria for CSSD (a category designed to be the “interface” between medicine and psychiatry), a person must satisfy the conditions described by criteria A, B and C:

- A. *“Somatic symptoms: multiple somatic symptoms that are distressing, or one severe symptom*
- B. *Misattributions, excessive concern or preoccupation with symptoms and illness: at least two of the following are required: (1) high level of health-related anxiety (2) normal bodily symptoms are viewed as threatening or harmful (3) a tendency to assume the worst about their health (catastrophizing) (4) belief in the medical seriousness of their symptoms despite evidence to the contrary (5) health concerns assume a central role in their lives*
- C. *Chronicity: although any one symptom may not be continuously present, the state of being symptomatic is chronic and persistent (at least six months)”.*

These criteria represent a template for the Wessely School’s assumptions and assertions about the nature of ME/CFS, as can be verified by comparing them with the 1991 Oxford criteria for CFS, whose lead author was Michael Sharpe (JRSM 1991:84:118-121) and with the Wessely School’s many claims that ME/CFS is perpetuated by patients’ *“aberrant illness beliefs”*.

Criteria A and C are so wide and non-specific that they have little clinical utility. These two criteria (physical symptoms and chronicity) could apply to anyone with any long-term disease, for example, renal failure or multiple sclerosis, thus in practice a diagnosis of CSSD becomes contingent upon a person satisfying only criterion B.

In relation to criterion B (misattribution of symptoms), it is the Wessely School psychiatrists, not patients themselves, who misattribute the physical symptoms of ME/CFS by persistently ignoring the biomedical evidence which explains them.

Given the central importance of criterion B (of which two of its sub-criteria must be met for a diagnosis of CSSD), it can be seen that the text requires substantial revision because sub-criteria B (1), B (2) and B (3) are essentially synonymous (ie. they re-state the same issue), thereby leading to potential over-diagnosis of CSSD.

In relation to sub-criterion B (1), diagnostic accuracy is particularly important. It is true that health-related anxiety might well be a feature of some ME/CFS patients and this is hardly surprising given the severity of symptoms which afflict a significant percentage of patients. There is extensive evidence of HPA-axis under-activity in many patients and this will inevitably impact on the output from the adrenal and thyroid glands leading to an exaggerated stress response and the likelihood of anxiety related signs. Appropriate medical management of patients’ signs and symptoms would predictably reduce such anxieties, so they should not be regarded as evidence of either primary or co-morbid CSSD.

The difference between high levels of health-related anxiety in ME/CFS and, for example, patients with general medical disorders such as cancer, is that whilst the latter will be under the expert care of an oncologist, the former have no such specialist on whom to rely. Whilst it may be helpful for psychiatrists to offer secondary support in any serious illness if necessary, the experience of ME/CFS patients with liaison psychiatry is entirely negative because Wessely School psychiatrists avoid engaging with the underlying medical disorder. Once psychiatrists are involved, other medical specialists disengage with the ME/CFS patient; the psychiatrists establish a monopoly and over-claim a primary psychosomatic disorder. They dismiss patients’ concerns, thereby affording bodies such as the MRC no incentive to seek a cure, so priorities become re-arranged.

The proposed category of CSSD seeks to expand the role of psychiatry into the territory of general medicine and aims to increase the influence of psychiatrists upon patients with medical disorders: *“There is a paucity of*

epidemiological data on somatization disorder as defined by DSM-IV, and the impression is that this disorder is extremely rare. When different criteria are adopted...one finds very different prevalence estimates" (APA; Justification of Criteria – Somatic Symptoms, 1/29/10). In seeking wider acceptance of psychiatry within medicine in general, ie. by creating an *"interface between medicine and psychiatry"* and by attempting to capture *"somatic symptoms that are below the diagnostic threshold of somatization disorder"* that they believe occur widely in general medical disorders, psychiatrists whose primary interest is *"somatisation"* may misattribute normal responses to serious physical symptoms as a psychosomatic disorder that they consider requires a psychiatric diagnosis and intervention, as has happened in the case of ME/CFS.

Another aspect is that the high level of health-related anxiety in ME/CFS may well be iatrogenic: when patients with a serious medical disorder are denied appropriate investigations and medical support, when they are falsely accused of seeking secondary gain, when a doctor refuses to validate their genuine physical symptoms, when medical support for essential benefits is refused (which may result in destitution) and when there is no care or cure, then it is entirely understandable that the ME/CFS patient will experience high levels of health-related anxiety but – with the correct medical support and intervention – such anxiety can be ameliorated so should not be considered diagnostic of CSSD.

The basic point that is not addressed in sub-criterion B (1) is the direction of causation of the health-related anxiety and no distinction is made between the natural anxiety that accompanies any serious medical disorder and a morbid anxiety.

In relation to sub-criteria B (2) and B (3), the symptoms of ME/CFS are far from *"normal"* bodily sensations. Wessely School psychiatrists often accuse patients with ME/CFS of holding *"catastrophic illness beliefs"*, but they do not address symptoms of ME/CFS other than *"fatigue"*, such as repeated, prolonged vertigo, frequent episodes of incapacitating chest pain of similar intensity to a myocardial infarction, metabolic demand that is insufficiently met by cardiac output, loss of muscle power, or the inability to look after oneself, all of which may rightly be considered catastrophic by the patient. Wessely School psychiatrists exclude such patients from their studies.

In relation to sub-criteria B (4) and B (5), patients with ME/CFS rightly believe in the *"medical seriousness of their symptoms"* because not only does the biomedical research evidence show such a belief to be rational and correct, there is no *"evidence to the contrary"*; furthermore, when ME/CFS patients recurrently experience such serious symptoms, it is entirely reasonable that *"health concerns assume a central role in their lives"* and such entirely reasonable concerns should not be classed as *"cognitive distortion"*.

Many clinicians and scientists accept ME/CFS to be organic, and that patients do not have cognitive distortions

That ME/CFS is a serious medical disorder has long been accepted by informed clinicians and researchers, for example:

- *"(ME/CFS) has an organic basis; it is not a psychiatric illness. Our Surveillance Study does not support the notion that (it) is a psychiatric illness, and in fact, suggests that it has an organic basis"* (Dr Walter Gunn, Principal Investigator of CFS studies at the US Centres for Disease Control: CFIDS Chronicle, February 1992, page 1).
- *"In my experience, ME/CFS is one of the most disabling diseases that I care for, far exceeding HIV disease except for the terminal stages"* (Dr Daniel L Peterson: Introduction to Research and Clinical Conference, Fort Lauderdale, Florida, October 1994; published in JCFS 1995:1:3-4:123-125).
- In 1995, Professor Mark Loveless, Head of the AIDS and ME/CFS Clinic at Oregon Health Sciences University said in his Congressional Briefing that an ME/CFS patient: *"feels effectively the same*

every day as an AIDS patient feels two weeks before death; the only difference is that the symptoms can go on for never-ending decades”.

- *“In comparison with other chronic illnesses such as multiple sclerosis, end-stage renal disease and heart disease, patients with ME/CFS show markedly higher levels of disability”* (Quality of Life and Symptom Severity for Individuals with Chronic Fatigue Syndrome: Findings from a Randomised Clinical Trial. RR Taylor. American Journal of Occupational Therapy 2004:58:35-43).
- CDC researcher Dr William Reeves, then Chief of the ME/CFS research programme, reported that ME/CFS patients *“are more sick and have greater disability than patients with chronic obstructive lung or cardiac disease, and researchers found that the strongest predictor of the development of ME/CFS is the severity of the acute illness at onset, and that psychological factors played no role”* (Press Release: AACFS, 7 October 2004).
- In 2005, Nancy Klimas, Professor of Medicine, Division of Immunology, University of Miami; Co-Director, E.M. Papper Laboratory of Clinical Immunology; Professor of Microbiology and Immunology, University of Miami, and Director of AIDS Research and Co-Director of the AIDS Clinical Research Unit, Miami VA Medical Centre, said in her American Association for CFS Incoming Presidential Address: *“Our patients are terribly ill, misunderstood, and suffer at the hands of a poorly informed medical establishment and society”.*
- On 3rd November 2006, at the National Press Club, Washington DC, the US Centres for Disease Control announced its “CFS Toolkit” to inform not just the US but the whole world about the nature and severity of ME/CFS. At the Press Conference, Dr William Reeves, then Chief of Chronic Viral Diseases Branch at CDC, said: *“We’ve documented, as have others, that the level of impairment in people who suffer from ME/CFS is comparable to multiple sclerosis, AIDS, end-stage renal failure, chronic obstructive pulmonary disease. The disability is equivalent to that of some well-known, very severe medical conditions. We found that ME/CFS follows a pattern of remitting and relapsing symptoms, the symptoms can change over time, and that spontaneous recovery is rare. We found that the best predictor for ME/CFS was intensity of the initial infectious disease. The sicker the patient when s/he first got infected, the more likely they were to have persisting chronic symptoms. There were no other factors, psychological or biological, that held up under thorough analysis”.*
- At the same Press Conference, Professor Nancy Klimas said: *“There is evidence that the patients with this illness experience a level of disability that is equal to that of patients with late-stage AIDS, patients undergoing chemotherapy (and) patients with multiple sclerosis”.*

Symptoms of ME/CFS have long been demonstrated to result from dysfunction of the immune, neurological, endocrine, cardiovascular, respiratory, gastrointestinal and musculo-skeletal systems, as reviewed by Jason et al:

“ME/CFS is one of the more complex illnesses involving multiple systems within the body....This debilitating illness can affect the immune, neuroendocrine, autonomic and neurologic systems. Abnormal biological findings...have included aberrant ion transport and ion channel activity, cortisol deficiency, sympathetic nervous system hyperactivity, EEG spike waves, left ventricular dysfunction in the heart, low natural killer cell cytotoxicity, and a shift from Th1 to Th2 cytokines....Van Houdenhove (et al, 2009) suggest that at an early stage of the illness, a switch takes place from HPA axis hyper- to hypo-functioning, and this observation is supported by some animal and human data. When the HPA axis becomes downregulated, there is not an effective Th1 response to attack viral infections (and) the immune system may cause inflammation (explaining elevated antinuclear antibody levels). The patient with ME/CFS now has ineffective protection from viruses, intracellular bacteria, and inflammation...In response to postural stress, 81% of patients with ME/CFS and no controls experienced ejection fraction decreases (and) those who had greater

ejection decreases experienced more severe ME/CFS symptoms...The resulting low circulatory state may make it difficult for patients to meet the demands of everyday activity....Streeten and Bell (2000) found that the majority of patients with ME/CFS had striking decreases in circulating blood volume...Additionally, it appears that the blood vessels in patients with ME/CFS are constricted dramatically....lowered cortisol production during and following exercise may be implicated in the cardiac dysfunction seen in many patients” (LA Jason et al. Journal of Behavioural and Neuroscience Research 2009:7:1-17).

Given the substantial evidence of organic pathology in ME/CFS, it is only possible to attribute the symptoms to somatisation or its proposed replacement category of CSSD by failing to heed the published biomedical literature.

The refusal of the psycho-social school of psychiatrists to acknowledge the existence of the biomedical evidence does not constitute lack of evidence of the organic nature of ME/CFS.

For patients with ME/CFS not to be concerned about such a serious, multi-system organic disorder would be inappropriate; indeed, in the past, psychiatrists argued that indifference to physical symptoms indicated a psychosomatic disorder (*“la belle indifference”*, defined in the DSM-IV description of conversion disorder/hysteria as being an apparent lack of concern shown by some patients towards their symptoms. Jon Stone, Michael Sharpe et al; Brit J Psychiat 2006:188:204-209).

However, CSSD sub-criterion B (5) posits the opposite, namely, that concern about physical symptoms is indicative of a psychosomatic disorder. This is not only contradictory but *reductio ad absurdum* (an absurdity when followed to its logical conclusion) and leaves ME/CFS patients in diagnostic quicksand because any attempt to articulate the serious, organic reality of their symptoms only traps them further in the grip of the poorly designed CSSD construct.

The APA should be troubled by the beliefs of the Wessely School and other CSSD Work Group members

There are many published international concerns about well-known psychiatrists’ lack of scientific exactitude in relation to ME/CFS, with urgent calls for accuracy in diagnosis, for example:

- in 1997 US expert Professor Leonard Jason (a psychologist) expressed concern: *“Many physicians minimised the seriousness of this disorder and interpreted the syndrome as being equivalent to a psychiatric disorder. These attitudes had negative consequences. It is crucial for CFS research to move beyond fuzzy recapitulation of the neurasthenia concept and to differentiate CFS from other disorders”* (Jason L et al. American Psychologist 1997:52:9:973-983).
- Dr Alan Gurwitt, a US psychiatrist who does not subscribe to the Wessely School beliefs about ME/CFS, has repeatedly expressed his dismay and frustration; for example on 23rd January 2003 he noted about these psychiatrists: *“They often fail to distinguish between ‘chronic fatigue’ and ‘chronic fatigue syndrome’. The former is a fairly common symptom in medical clinics that does have a high linkage to already-present psychological problems. The latter is a specific medical condition. Their sloppiness has led to all kinds of trouble and misunderstandings”* (<http://www.masscfids.org/resource-library/3-research/162-on-the-morbid-fascination-with-psychiatric-morbidity>).
- in 2006 Professor Mark Demitrack (a psychiatrist) encapsulated the problem that Wessely School psychiatrists (and those they influence) decline to address. **He noted the entanglement of physical symptoms and behavioural symptoms, and the various studies by certain psychiatrists purporting to show that the likelihood of psychiatric disorder increased with the number of physical symptoms. In relation to ME/CFS, he noted that dismissing it as a somatoform disorder was inappropriate: “The observation of specific protracted fatigue and the absence of substantial**

psychiatric comorbidity argues convincingly that this is an inappropriate and overly simplistic way of approaching this puzzling condition". Demitrack concluded: "In the face of accumulating evidence, there is an increasing realisation that a unitary disease model for this condition has been a theoretical and practical impediment to real progress towards effective therapeutics for ME/CFS. Many treatment studies have, unfortunately, neglected to thoroughly consider the significance of patient selection (and) symptom measurement" (Pharmacogenomics 2006;7(3):521-528).

- in 2007, referring to ME/CFS, fibromyalgia and irritable bowel syndrome, Jason et al pointed out that *"measurement that fails to capture the unique characteristics of these illnesses might inaccurately conclude that only distress and unwellness characterise these illnesses, thus inappropriately supporting a unitary hypothetical construct called functional somatic syndrome"* (JCFS 2007;14(4):85-103).

Because of the Wessely School's continued use of their own much-criticised "Oxford" criteria for CFS, British psychiatric studies of people with ME/CFS have repeatedly failed to address the issue of how to accurately characterise the disease. Referring to the MRC PACE Trial which uses the superseded Oxford criteria, Professor Michael Sharpe specifically stated at the Edinburgh International Science Festival in April 2004: *"We want broadness and heterogeneity in the trial"*. However, in a keynote lecture at the ME Research UK international research conference held on 25th May 2007 in Edinburgh, Canadian psychiatrist Dr Eleanor Stein criticised the Oxford criteria, which she said *"could describe almost anybody. I do not believe that studies which use the Oxford criteria can be generalised to patients with ME/CFS"*.

A key issue is that whilst cognitive behaviour therapy and graded exercise therapy may be of some benefit to those with somatoform disorders, there is abundant evidence that directive CBT aimed at disabusing patients of their correct belief that they are physically sick and incremental aerobic exercise aimed at reversing deconditioning are contra-indicated in ME/CFS (<http://www.meactionuk.org.uk/magical-medicine.htm> pages 88-92; 111-210).

The APA also needs to consider that, whilst those with somatoform disorders are not prohibited from donating blood, people in the UK with ME have been **permanently** excluded from donating blood since at least 1989 (Guidelines for the Blood Transfusion Service in the UK, 1989: 5.4; 5.42; 5.43; 5.44; 5.410). This was upheld by the Parliamentary Under Secretary of State, The Lord Warner, who confirmed in writing on 11th February 2004 in a letter to the Countess of Mar that people with ME/CFS are not permitted to be blood donors. Lord Warner was unambiguous: *"The National Blood Service guidelines on donor selection on ME refer to those on Post Viral Fatigue Syndrome. The Guidance is: defer from blood donation until recovery. The underlying logic is that this condition is possibly viral and therefore the NBS cannot accept the risk of possible transmission by blood. Since the condition is very variable and sometimes prolonged, it could become a lifetime ban in any particular case"*.

There is international concern that the proposed diagnostic category of CSSD as it is currently defined will be used to incorrectly diagnose ME/CFS patients with a psychiatric disorder.

It is of note that the draft of the proposed new category of CSSD states: *"Having somatic symptoms of unclear aetiology is not in itself sufficient to make this diagnosis. Some patients, for instance with irritable bowel syndrome or fibromyalgia would not necessarily qualify for a somatic symptoms disorder diagnosis"* (APA Somatic Symptom Disorders, 29th January 2010) but no such assurance is offered with respect to ME/CFS. This needs to be rectified.

Finally, the Report of the UK All Party Parliamentary Group on ME ("Inquiry into NHS Service Provision for ME/CFS", March 2010, page 15) is unequivocal: *"diagnosing the illness as psychosomatic is unprofessional, inept and callous to the patient"*.

To avoid what would rightly be perceived as a damaging and regressive development, the American

Psychiatric Association must take this opportunity to uphold diagnostic precision and ensure that the neuro-immune disorder ME/CFS is named as an explicit exclusion from the proposed category of CSSD in accordance with the WHO classification.

Without this clarification, the forthcoming DSM-V will signal a willingness by the APA to endorse an approach that ignores medical science.

Failure to uphold diagnostic accuracy will lead to misdiagnosis (leading to potential viral transmission of ME/CFS through blood products), inappropriate treatment and further loss of confidence in the scientific integrity of the psychiatric profession.

