Professor Simon Wessely: Questions and Answers

THE GROUP ON SCIENTIFIC RESEARCH INTO MYALGIC ENCEPHALOMYELITIS

Disturbing discrepancies in statements made by Professor Simon Wessely in relation to ME/CFS: some questions and answers of which the Gibson Parliamentary Inquiry needs to be aware

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In April 2002, Professor Simon Wessely kindly agreed to answer some questions put to him by various members of the UK ME community; the questions and answers were electronically published on 10th April 2002 on an ME internet group.

Extracts from these same questions and from Professor Wessely's same answers are taken from the document concerned and reproduced here for the benefit of the Gibson Parliamentary Inquiry

Members of the Inquiry need to be aware of how Wessely's stated views about ME/CFS vary depending upon his audience (ie. how his views expressed to patients differ markedly from his views expressed to Government bodies and to healthcare professionals as expressed in his published papers) and how such dichotomy continues to ignore the scientific biomedical evidence, thereby fostering the confusion about the disorder that currently prevails within the medical profession.

It is the case that Professor Wessely's answers do not accord with the evidence.

Question : Why have you totally overlooked those who are severely ill with ME?

Wessely's answer: "I haven't. I see them regularly, including on DVs *(domiciliary visits)*. We have also published a paper on in-patient rehabilitation of severely afflicted (bed bound) patients from days when I had beds. Our OPD *(Out Patient Department)* population is also severe, as can be seen from the published figures".

Comment: Wessely School authors exclude those with severe ME from their studies. No published study by Wessely has been found that includes people severely affected by ME/CFS who have been seen on DVs.

DVs are regularly refused for those with ME/CFS, no matter how necessary (on the grounds that home visits "condone" the patients' "aberrant belief" that they are physically sick, one NHS Consultant writing to a GP who made such a request: "This places me in a difficult position as if I do a DV then I am condoning his (own) management of his condition. I do not feel a DV is appropriate").

It is a matter of record that the most severely affected (ie. those requiring DVs) are excluded from study in the UK and the Report of 2002 to the Chief Medical Officer noted this, as did the Systematic Review (2001) carried out by the Centre for Reviews and Dissemination at York University that informed the CMO's Working Group report: ("In some studies participants were only eligible if they could physically get to the clinic. Those unable to walk or to get out of bed were automatically excluded, so it is not possible to assess whether [behavioural therapy] would be effective or even hazardous for a more severely disabled group of people").

Moreover, the severely affected are excluded from the MRC current PACE "CFS/ME" trial (the management of which is directed by Wessely, who is also responsible for randomisation and database design): "Exclusion criteria: subjects unable either to attend hospital reliably or to do therapies" (ref: Trial Identifier: 3.6). The Trial Identifier is clear (at 3.4) that: "CBT (cognitive behavioural therapy) will be based on the illness model of fear avoidance" and that "GET (graded exercise therapy) will be based on the

illness model of both de-conditioning and exercise avoidance", neither of which occurs in authentic ME: studies that specifically set out to demonstrate de-conditioning (for example, Bazelmans et al: Psychological Medicine 2001:31:107-114) and exercise phobia (for example, Gallagher AM et al: Journal of Psychosomatic Research 2005:58:4:367-373) failed to do so.

As US researchers noted in 1999: "Unfortunately, neither the 1988 nor the 1994 case definition identifies the sickest patients because information about symptom severity is not required to make a diagnosis of CFS" (ref: Natural History of Severe Chronic Fatigue Syndrome. NF Hill, BH Natelson et al. Arch Phys Med Rehab 1999:80:1090-1094).

Further, as US researchers pointed out in 2000: "Patients who have been persistently ill for more than ten years have not been described in the literature" (ref: Symptom patterns in long-duration chronic fatigue syndrome. F Friedberg et al. Journal of Psychosomatic Research 2000:48:59-68).

For Wessely to imply that (as undoubtedly the most prolific author on "CFS/ME") he does not exclude the most severely affected from his studies is plainly disingenuous and misleading.

Question : Why don't you believe in the existence of ME as a distinct neurological entity?

Wessely's answer: "Because there is no compelling evidence to support this. There is no compelling evidence as yet on any specific disease process, neurological or otherwise".

Comment: There is a significant body of compelling published evidence that demonstrates the involvement of the central nervous system, the autonomic nervous system and the peripheral nervous system in the pathogenesis of ME/CFS, as well as compelling evidence of immunological and vascular disruption, most of which Wessely has persistently ignored entirely for almost two decades (for references, please see our Submission of 12th December 2005 to the Gibson Inquiry). It is surely remarkable that Wessely continues to ignore the substantial body of biomedical evidence that already exists and appears to demand a level of absolute scientific certainty for ME/CFS that does not apply in his own discipline of psychiatry, where diagnosis is merely a matter of opinion.

Question: Why do you continue to ignore the International Classification (ICD-10) and why do you classify CFS as a somatoform (mental) disorder when ICD-10 classifies CFS as being a neurological disorder in the same category as ME and PVFS?

Wessely's answer: "I have repeatedly explained in various forms the problems with ICD-10 as a political rather than scientific compromise. And I don't classify CFS as a somatoform disorder".

Comment: This answer is particularly disturbing. The ICD is used in NHS software systems to encode diagnostic data, which is information that is used in resourcing and commissioning the provision and delivery of NHS healthcare.

No-one can deny that the Wessely School has flooded the literature with their view that ME/CFS is a functional (or somatoform) disorder: many Wessely School papers, including Wessely's own, specifically refer to CFS/ME as a somatisation disorder. Well-known examples of his influence that spring immediately to mind include the following:

- (1995) Dr Adrian Furniss from the DLA Advisory Board / BAMS / DSS (where Wessely's status as official adviser is on record in a letter from the DLAAB dated 7th April 1992) provided advice to doctors about ME/CFS that specifically stated "The weight of medical opinion regards this as a psychosomatic disorder (and) the majority of these cases are somatisers"

- (1995) In his paper "Psychiatry in the allergy clinic: the nature and management of patients with non-allergic symptoms", Wessely is explicit: "…..reminiscent of the difficulties encountered in distinguishing between ME, a belief, and CFS, an operationally defined syndrome. (In) somatisation disorder, sufferers have long histories of unhelpful medical and surgical admissions with high rates of disability, yet consume vast amounts of health service resources for little benefit" (ref: LM Howard and S Wessely. Clinical and Experimental Allergy: 1995:25:503-514)

- (1996) The Joint Royal Colleges' Report on CFS (CR54), co-authored by Wessely, states in chapter 7 on page 16 (7.9): "Somatisation disorder: Patients with long histories of multiple somatic symptoms are frequently seen in CFS clinics. In CFS, the greater the number of somatic symptoms, the greater the probability of psychiatric disorder". On page 44: (Summary for commissioners) the report is unequivocal: "In essence, CFS is frequently associated with somatisation symptoms", and on page 45: "The report examines in depth the role of psychiatric disorder in CFS. Studies have consistently shown that over half of those presenting with CFS have affective disorders while a further quarter fulfil criteria for other psychiatric disorders, chiefly anxiety and somatisation disorders (see Glossary)". In the Glossary, "Somatisation" is defined as: "a condition where the patient presents with a physical symptom which is attributed to a physical disease, but is more likely to be associated with depression or anxiety"

- (1999) In "Somatoform Disorders" (ref: Current Opinion in Psychiatry 1999:12:163-168) Wessely specifically implied that ME/CFS is a somatoform disorder, in which patients "may selectively perceive bodily sensations and misinterpret them as pathological"

- (1999) In their paper "Functional Somatic Syndromes: one or many?" (ref: Lancet 1999: 354:936-939) Wessely and Sharpe produced what has become their flagship for "CFS/ME" being a somatisation disorder. In this paper, the authors stated: "We review the concept of functional somatic syndromes. We postulate that the existence of specific somatic syndromes (such as irritable bowel syndrome, premenstrual syndrome, fibromyalgia, non-cardiac chest pain, hyperventilation syndrome, chronic fatigue syndrome, tension headache, atypical facial pain, globus syndrome and multiple chemical sensitivity) is largely an artefact of medical specialisation. These symptoms are associated with unnecessary expenditure of medical resources. Many of these syndromes are dignified by their own formal case definition and body of research. Such patients may have variants of a general functional somatic syndrome. If we accept that functional somatic syndromes are considered together, we open the way to more general strategies and services for their management. We propose an end to the belief that each 'different' syndrome requires its own particular subspecialist"

- (1999) In his lecture on 29th October at the Royal Society of Medicine entitled "Somatisation of Depression", Wessely said: " The core reason why people somatise (is) the stigma of psychiatric disorders. I'm going to use to make this point Chronic Fatigue Syndrome, because I want to show the extremes that people will go to (to avoid a psychiatric label). Somatisation is a common way for people to present with psychological problems"

- (2002) At an International Congress in February 2002 on Somatoform Disorders held at Marburg, Germany (sponsored by the pharmaceutical companies Novartis and Pfizer), Wessely gave the Keynote Lecture entitled "The chronic fatigue syndrome and the 'S' (s*omatoform)* word"; Michael Sharpe gave a lecture entitled "Management of somatoform disorders in primary care" and Trudie Chalder (a former registered mental nurse who works with Wessely, specialising in behavioural therapy; she is now Reader in Psychology) gave a lecture entitled "Treatment of chronic fatigue syndrome"

- (2002) Wessely's belief that ME/CFS is a somatoform disorder had an adverse impact even upon the UK ME Association: in its Research and Scientific Bulletin, issue 9, Winter 2002, the ME Association formally backed the Wessely School belief that ME is a functional somatic syndrome: on page 4 it stated: "How best to conduct research in ME/CFS: these problems are not unique to

CFS. There are a number of these so-called functional *(ie. somatoform)* syndromes and arguments continue as to their hysterical origin"

- (2002) In his contribution to the UNUMProvident Report "Trends in Health and Disability", 2002, Wessely's co-author Professor Michael Sharpe included ME/CFS as a somatoform disorder ("Functional Symptoms and Syndromes: Recent Developments"): "Classification is confusing as there are parallel medical and psychiatric classifications. The psychiatric classifications provide alternative diagnoses for the same patients. The majority will meet criteria for depressive or anxiety disorders and most of the remainder for somatisation disorders"

- (2003) In June 2003 the British Medical Journal carried an item about the ME Association, noting that the Association had "adopted some of the arguments of that section of the medical establishment that believes the condition to be a somatisation disorder"

- (2004) In an Editorial on somatoform disorders in the British Journal of Psychiatry (2004:184:465-467), Wessely's like-minded colleagues Michael Sharpe and Richard Mayou included chronic fatigue syndrome, asserting what ME/CFS sufferers know only too well, namely that a label of somatoform disorder is **"often taken simply to indicate a need to minimise access to medical care"** and stated that such disorders are better considered as a combination of personality disorder and an anxiety / depressive syndrome. It was in this Editorial that they revealed the Wessely School hand and their plans to re-classify CFS (in which they include ME) as "post-somatoform" functional (behavioural) disorders in the next revision of the ICD (ICD-11)

- (2004) In a debate that was reported in the British Journal of Psychiatry (ref: There is only one functional somatic syndrome. Simon Wessely / Peter White. B J Psychiat 2004:185:95-96), Wessely and White revisited Wessely and Sharpe's 1999 Lancet paper (Functional somatic syndromes; one or many?). Wessely remained adamant that there is only one functional somatic syndrome which includes syndromes such as chronic fatigue syndrome and fibromylagia. Wessely said: "Five years later, Sharpe and I stand by our thesis".

- For the record, despite the fact that fibromyalgia is formally classified as a distinct entity in the ICD-10 at M79 under Soft Tissue (rheumatism) disorders, Wessely is now claiming that because those with fibromyalgia visited their GP more often before being diagnosed, they, like CFS/ME patients, are suffering from a behavioural disorder: "**Primary care patients who had been diagnosed as having FM reported higher rates of healthcare resource use for at least ten years prior to their diagnosis, which suggests that illness behaviour may play a role**" (ref: The impact of a diagnosis of fibromyalgia on health care resource use by primary care patients in the UK: An observational study based on clinical practice. Hughes G, Wessely S et al. Arthritis Rheum. 2005:54:1:177-183).

- Fibromyalgia is clearly another of Wessely's targets; in 2003 he wrote: "**In terms of future directions for (psychiatric) research, epidemiological studies should benefit from widening the net eg. to include individuals with fibromyalgia as well, whilst narrowing criteria eg. looking at individual dimensions of CFS such as mood disorder**" (ref: Chronic fatigue and depression. Iversen, Amy; Wessely, Simon. Current Opinion in Psychiatry 2003:16:1:17-21. Lippincott Williams & Wilkins Inc.).

- It is a matter of deep concern that patients with fibromyalgia are to be intentionally included in the MRC PACE trials on "CFS/ME", the results of which will then be proclaimed to be referring to those with "CFS/ME" (see attached Appendix containing information that was sent to the MRC but was ignored).

- (2005) Wessely and Sharpe edited chapter 5 in "Somatoform Disorders", volume 9, John Wiley & Sons, pp 414. Chapter 5 is entitled "Chronic Fatigue and Neurasthenia: A Review" and covers such topics as "From Neurasthenia to Chronic Fatigue Syndrome: A Journey, Not a Destination";

"Constructing Chronic Fatigue"; "Chronic Fatigue Syndrome as a Paradigm for Psychosomatic Medicine"; "Functional Somatic Syndromes: Many Names for the Same Thing?"

From just these few illustrations (not only prior to 2002 when he provided his answers, but also since 2002), it can readily be seen that Wessely's statement "I don't classify CFS as a somatoform disorder" does not reflect reality.

Question: Why do you exclusively (use the) term "fatigue" to mean "tiredness", without recognising that (in) ME, "tiredness" is only a symptom way down the list of other more severe symptoms?

Wessely's answer: "The phenonology of fatigue is exceptionally complex, and it means different things to different people. I have always taken the core concept of CFS to be severe physical and mental exhaustion following simple physical and/or mental effort that would not normally cause such symptoms"

Comment: In his published studies of ME/CFS, Wessely has concentrated on his own interpretation of "fatigue", which he equates with "tiredness" (claiming it to be one end of a continuum of "tiredness") and he usually disregards other, more serious and incapacitating, symptoms that are the true core features of ME (see the two Linbury Trust Portfolios: "A Research Portfolio on Chronic Fatigue" (1998), edited by Robin Fox and "New Research Ideas in Chronic Fatigue" (2000) edited by Richard Frackwowiak and Simon Wessely). "Fatigue" bears no relationship to the devastating exhaustion and malaise that is ME. As noted on a website (HIV-negative AIDS?), KLL typifies the response of the ME/CFS community: "It is utterly beyond my realm of comprehension as to how the medical establishment can generically name an entire disease paradigm based on just one symptom".

Question: *(ask him)* **how he has the conscience to use such loose diagnostic criteria when collecting his patient samples when it is openly admitted that each study using these criteria creates flawed and meaningless study data using heterogeneous patients groups instead of the scientifically recognised method of using homogeneous patient groups**

Wessely's answer: "I was criticised recently for precisely the opposite – being far too careful in selecting our patients to make sure the result fitted our theories. In all our research, the criteria are explicit and clear. It is also clear that we exclude those with major psychiatric disorders. The patients in our studies have CFS, ME, or whatever we are going to call it"

Comment: Following a meeting in 1990 at Oxford, psychiatrists Simon Wessely, Michael Sharpe and Peter White and their colleagues intentionally broadened the 1988 Holmes et al CFS criteria specifically to include all those with psychiatric "chronic fatigue" and stipulated the exclusion of those with neurological disorders. These criteria became known as the Oxford criteria (A report – chronic fatigue syndrome: guidelines for research. MC Sharpe et al. JRSM 1991:84:118-121). These Oxford criteria removed, by definition, those with authentic Ramsay-defined ME from study, yet the Wessely School psychiatrists continued to refer to whatever "fatigue" syndrome they were studying as "CFS/ME". Whatever fatigue syndrome this may be, it cannot, by definition be authentic ME.

That the intention was indeed to dilute the ME case definition by including those with psychiatric fatigue is confirmed by Wessely School psychiatrist Anthony David, who in 1991 stated about the Oxford criteria: **"British investigators have put forward a less strict operational definition which is essentially chronic (six months or more) severe, disabling fatigue in the absence of neurological signs"** (ref: Postviral fatigue syndrome and psychiatry. BMB 1991:47:4:966-988).

Chronic "fatigue" is not ME/CFS, but it is these Oxford criteria that have been, and continue to be, used by Wessely School psychiatrists who refer to "CFS/ME": the current MRC PACE trials use the Oxford criteria, even though it is almost unheard of for studies to use criteria that have been superceded, as is the case with the Oxford criteria. By using the Oxford criteria, the Wessely School aim of drawing in as many

people as possible is more readily achieved: the MRC CFS/ME Trial Identifier is quite clear that this is the intention: **"We chose these broad criteria in order to enhance recruitment"** (RCT of Cognitive Behavioural Therapy, Graded Exercise and Pacing versus usual medical care for the Chronic Fatigue Syndrome"). To intentionally mix patient populations does not accord with a rigorous scientific process, yet the Wessely School proposal was approved by the MRC, which inevitably raises questions of a pre-determined agenda.

The Oxford criteria have been shown to have no predictive validity and there has never been consensus about them. They are used only in the UK by Wessely School adherents and have never been adopted internationally. This is reflected in the 2003 Report to the New Zealand Ministry of Health, which refers to the "**Anglocentric nature of the research base and consequent omission of relevant research evidence from international studies".** It is internationally recognised (CDC 1994) that the Oxford criteria identify what has been called "idiopathic chronic fatigue" as opposed to authentic ME, whereas stricter criteria identify those with neurological symptoms (sufferers from which, of course, would not be responsive to the Wessely School favoured psychiatric "management" regime).

Conclusion

In relation to the Wessely School's incessant assertions that ME/CFS is a behavioural disorder that should not merit medical investigation, the Inquiry is asked to bear in mind (1) what the CMO's Working Group Report of 2002 said on page 32: "**A physician who does not admit to the reality of the disease can not be supposed to cure it" (William Cullen, 1710 – 1790)"** and (2) what Ghandi said: **"An error can never become true, however many times you repeat it".**

APPENDIX I

Myalgic Encephalomyelitis / Chronic Fatigue Syndrome and Fibromyalgia: additional considerations for the MRC in relation to the PACE trials

Margaret Williams 5th January 2005

Further to previous observations on the clear differences between ME/CFS and fibromyalgia already provided for the MRC's consideration, two additional points may be of relevance.

In 1994, the British Medical Journal published information from Dr Darrel Ho-Yen, a well-known and respected virologist and researcher into ME then at Raigmore Hospital in Scotland, who stated the following: "The distribution and number of tender points in fibromyalgia are different from the chronic fatigue syndrome, **and the management of the two conditions is different. Patients with (ME/CFS) should be advised not to increase their activities gradually until they feel 80% of normal, whereas patients with fibromyalgia may benefit from a regime of increasing activity"** (BMJ 1994:309:1515).

In 1999, Professor Leonard Jason and colleagues published an updated US case definition for (ME)CFS which seems to have received little attention from certain UK psychiatrists who are on record as believing that "CFS/ME" is a psychosocial disorder and who regard the many abnormalities present in the disorder as inconsequential. This 1999 US case definition makes two points of particular and current relevance to the MRC PACE trials:

"If a person with chronic fatigue syndrome specifies a large number of physical problems caused by this illness, these physical problems might also make the person eligible for a diagnosis of somatization disorder, depending upon the accuracy of the diagnostician. Fibromyalgia Syndrome (FMS) and Multiple Chemical Sensitivity (MCS) **represent additional illnesses of interest where issues of diagnostic accuracy are concerned".** (JCFS:1999:5:3-33).

In the interests of evidence-based medicine, those involved with the MRC PACE trials may wish to reflect upon the available evidence, given that long-established elementary rules of procedure demand that those

undertaking research are normally required before proceeding to define the proposed topic and to produce a comprehensive review of the relevant literature: only by so doing can they place themselves in a position to ensure that their own prospective contribution represents a potentially useful and original development of knowledge that is based squarely on the foundations of existing knowledge.

By proposing to proceed as if a substantive body of mainstream knowledge did not exist, those involved lay themselves open to suspicions of ignorance and / or disingenuousness, or even frank intellectual dishonesty.

As has been previously noted, investigators are, of course, always at liberty to take issue with established knowledge, but if they wish to do so legitimately and credibly, they need to provide a reasoned critique of each tenet of established knowledge from which they propose to depart and to provide convincing arguments to show that the proposed research strategy will move understanding and knowledge along and will not simply reinforce existing confusion.

For convenience, information already provided for the MRC PACE trial investigators about the most recognised differences between ME/CFS and FM is reproduced and summarised here:

In respect of the MRC CFS trials, there are known and established differences between FM and ME/CFS and many believe that the FM community and the ME/CFS community have a right to know why patients suffering from both disorders are to be amalgamated in the MRC trials that claim to be studying "CFS/ME".

Likewise, an explanation is required as to why GPs are suddenly to be offered financial incentives to identify and refer people with FM to the new CFS centres specifically so that such patients can be entered into the MRC studies of "CFS".

It is a matter of record that Whiting et al expressly excluded FM studies from the systematic review of the literature that was commissioned by the Policy Research Programme of the Department of Health and carried out by the Centre for Reviews and Dissemination at the University of York for the CMO's Working Group on CFS, the results of the systematic review being intended to underpin the conclusions of that report (namely that cognitive behavioural therapy, including graded exercise regimes, is the management of choice for patients with chronic fatigue syndrome). The systematic review is unequivocal: "Studies including patients with fibromyalgia were not selected for the review"; why, therefore, and on what evidence, was it decided to include patients with FM in the subsequent MRC trials of CBT on a CFS population? (*see* Interventions for the Treatment and Management of Chronic Fatigue Syndrome. Penny Whiting et al. *JAMA 2001:286:11:1360-1368*).

Of foremost significance is the fact that fibromyalgia is classified as a distinct entity in ICD-10 at section M79.0 under Soft Tissue Disorders and it is not permitted for the same condition to be classified to more than one rubric, since ICD categories are mutually exclusive.

The literature itself is quite clear about this distinction, stating that up to 70% of those with ME/CFS have *concurrent* FM, and those who have both FM *and* ME/CFS have worse physical functioning than those who have ME/CFS alone.

Some illustrations from the literature make these distinctions clear:

1991: in spite of some overlap, FM and ME/CFS do not represent the same syndrome. (Primary fibromyalgia and the chronic fatigue syndrome. AJ Wysenbeek et al *Rheumatology Int 1991:10:227-229*)

1996: "fibromyalgia appears to represent an additional burden of suffering amongst those with (ME)CFS" (Fibromyalgia and Chronic Fatigue Syndrome – similarities and differences. Dedra Buchwald and Deborah Garrity. *Rheum Dis Clin N Am 1996:22:2:219-243*)

1997: levels of somatomedin C are lower in FM patients but higher in ME/CFS patients (Somatomedin C (insulin-like growth factor) levels in patients with CFS. AL Bennett, AL Komaroff et al. *J psychiat Res 1997:31:1:91-96*)

1998**:** "recent studies suggest that (co-existent FM and (ME)CFS) may bode much more poorly for clinical outcome than CFS alone. In contrast to (significantly) elevated CBG (cortisol binding globulin) levels in patients with CFS, no differences were observed in FM patients. Differences in secretion of AVP may explain the divergence of HPA axis function in FM and (ME)CFS" (Evidence for and Pathophysiologic Implications of HPA Axis Dysregulation in FM and CFS. Mark A Demitrack and Leslie J Crofford. *Ann New York Acad Sci 1998:840:684-697*)

1998: there is no evidence for elevated Substance P in patients with ME/CFS, whereas levels are elevated in patients with FM (CFS differs from FM. No evidence for altered Substance P in cerebrospinal fluid of patients with CFS. Evengaard B et al *Pain 1998:78:2:153-155*)

2001: patients with FM are **not** acetylcholine sensitive (Investigation of cutaneous microvascular activity and flare response in patients with fibromyalgia. AW Al-Allaf, F Khan, J Moreland, JJF Belch. *Rheumatology 2001:40:1097-1101*)

2004: patients with ME/CFS **are** acetylcholine sensitive (Acetlycholine mediated vasodilatation in the microcirculation of patients with chronic fatigue syndrome. VA Spence, F Khan, G Kennedy, NC Abbot, JJF Belch *Prostaglandins, Leukotrienes and Essential Fatty Acids 2004:70:403-407*)

2003: endothelin-1 is **raised** in fibromyalgia (Increased plasma endothelin-1 in fibromyalgia syndrome. Pache M, Ochs J et al *Rheumatology 2003:42:493-494*)

2004: endothelin-1 is **normal** in ME/CFS (Plasma endothelin-1 levels in chronic fatigue syndrome. Kennedy G, Spence V, Khan F, Belch JJF *Rheumatology 2004:43:252-253*)

Consultant rheumatologists who have sufficient experience with both syndromes have observed clinically that in FM, the muscle pain is helped by gentle stretching and exercise, whereas in ME/CFS, exercise makes muscle pain worse.

If the Oxford criteria are to be used for the MRC "CFS" trials, on what logic (other than a pre-determined agenda) can patients with FM, a completely separate disorder, be intentionally included from the outset?

Is the MRC entirely content that the PACE trial proposal also states "Those subjects who also meet the criteria for "fibromyalgia" will be included"**, given that FM is classified by the WHO as a quite separate disorder from ME/CFS, with a discrete biomedical profile that is entirely distinct from that found in ME/CFS?**

Importantly, on 3rd June 1998, Baroness Hollis from the then Department of Social Security sent a letter to Lindsay Hoyle MP (reference POS(4) 3817/88) which says "The Government recognises that fibromyalgia syndrome (FMS) is a condition which can cause a wide variety of disabilities from mild to severe. In some cases it can be a very debilitating and distressing condition. People with FMS who need help with personal care, or with getting around because they have difficulty in walking, can claim Disability Living Allowance to help with meeting related expenditure". From this letter, it is clear that Government already recognises fibromyalgia as a distinct entity.

Further, in the CMO's UPDATE of August 2003 (a paper communication from the CMO sent to all doctors in England) entitled "Improving Services for Patients" there is an item called "Fibromyalgia – A Medical Entity". This means that the CMO considers fibromyalgia to be a separate, stand-alone medical entity (and the fact that it is designated a "medical" disorder means that it is not considered to be "psychiatric" disorder).

How can the deliberate inclusion of patients with fibromyalgia in trials that purport to be studying "CFS" not result in skewed and meaningless conclusions when the patients being entered in the PACE trials are, from the outset, not clearly defined?