CORPORATE COLLUSION?

The UK Medical Research Council has a secret file on Myalgic Encephalomyelitis (ME) that contains records and correspondence since at least 1988; the file is held in the UK Government Archive at Kew and cannot be opened until 2023. This present document is an overview of the misinformation and contradictions about Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) that have pervaded some UK Departments of State and other agencies since 1988. It also considers the involvement of certain UK psychiatrists who have proven vested interests in the propagation of this misinformation that is contrary to world-wide scientific evidence and that for two decades has resulted in the medical abuse of UK patients with ME/CFS.

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CORPORATE COLLUSION ?

An overview of the misinformation about Myalgic Encephalomyelitis / Chronic Fatigue Syndrome arising from vested interests that pervades some UK Departments of State and other Agencies

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Introduction

One particular question in relation to the plight of patients with ME in the UK keeps recurring: who is driving the persistent denial of the evidence that ME is a multi-system biomedical disorder and not a behavioural disorder?

Does responsibility lie with the "Wessely School" psychiatric lobby (a small but influential group of mental health professionals led by Professor Simon Wessely of Kings College Hospital and the Institute of Psychiatry, London), or is it the other way round, with this psychiatric lobby acting as willing front men for covert State control of those with ME/CFS who are openly referred to as the "undeserving sick"? This term was used in 1999 by Wessely School psychiatrist Professor Michael Sharpe:

"*Purchasers and Health Care providers with hard pressed budgets are understandably reluctant to spend money on patients for whom there is controversy about the 'reality' of their condition (and who) are in this sense undeserving of treatment. Those who cannot be fitted into a scheme of objective bodily illness yet refuse to be placed into and accept the stigma of mental illness remain the undeserving sick of our society and our health service"* ("ME: what do we know (real illness or all in the mind)?" Lecture given at the University of Strathclyde, October 1999).

These psychiatrists seem to be clearly in breach of the first tenet of medicine --- first do no harm--- in that by their words and deeds they have wreaked havoc in the lives of ME/CFS patients and their families by their arrogant pursuit of a psychiatric construct of the disorder which ignores the abundant clinical and scientific evidence (widely presented in the international medical and scientific literature) of the organic nature of ME/CFS.

There have been persistent and frequently covert attempts by these psychiatrists to subvert the international classification of this disorder from neurological to behavioural, with destructive consequences for those affected.

To the serious disadvantage of patients, these psychiatrists have propagated untruths and falsehoods about the disorder to the medical, legal, insurance and media communities, as well as to Government Ministers and to Members of Parliament, resulting in the withdrawal and erosion of both social and financial support.

Influenced by these psychiatrists, Government bodies such as the Medical Research Council have continued to propagate the same falsehoods with the result that patients are left without any hope of understanding or of health service provision or delivery, and Government funding into the biomedical aspects of the disorder is non-existent.

This coterie of psychiatrists has proven affiliations with corporate industry and has insidiously infiltrated all the major institutions, directing funding for research into an exclusively psychiatric model of the disorder, focusing on "management strategies" involving psychiatric techniques, even though such techniques have been shown to be at best of no lasting value and at worst to be harmful to patients with ME/CFS.

Nothing eradicates or changes what has been published time and again by Simon Wessely and his associated about those with ME/CFS, or the untold harm that he and his group of mental health professionals have caused to such very sick people.

Wessely School psychiatrists have published many articles denigrating those with ME, repeatedly claiming (whilst producing no supportive evidence) that there is "*secondary gain*" from "*adopting the sick role*", and that once their incapacity has been *"legitimised"* by being given a medical label, patients with ME can then *"manipulate"* those around them to do their bidding, and that legitimising their "*tiredness*" absolves the sufferer from any sense of guilt for being a failure.

These psychiatrists see cognitive behavioural therapy as a brain-washing technique to rid patients of their "aberrant" belief that they are suffering from an organic multi-system disorder.

Wessely is on record as asserting that ME is merely a "*belief*" held by those who think they suffer from it; that ME patients' muscle weakness is "*simulated*"; that efforts are made to over-interpret laboratory findings; that the average doctor will see ME patients are neurotic and will often be disgusted with them; that blaming a virus for the illness conveys advantages by protecting the victim from personal blame; that symptoms are simply normal sensations and are the result of "*body-watching*"; that ME is a "*myth*"; that ME is "*learned helplessness*"; that once validation is granted by a doctor, the ME patient may assume the "*advantages of the sick role -- sympathy, time off work, benefits etc"*; that ME symptoms have no anatomical or physiological basis; that patients' aberrant beliefs are maintaining factors and that patients with ME exert a large and avoidable financial burden on health and social services.

(For individual references, see the December 2003 Briefing Paper for the House of Commons Health Select Committee: The Mental Health Movement: Persecution of Patients? which is available online at
http://www.meactionuk.org.uk/SELECT_CTTEE_FINAL_VERSION.htm).

Wessely rarely visits those who are house or bed-bound and he never considers those who have no-one at all even to speak to, let alone to attempt to "manipulate" to do their bidding, and who are reduced to a bare existence in truly dire circumstances.

He fails to consider that sufferers who have a conviction that they have a physical disorder may not be suffering from "*dysfunctional thinking*" or from "*psychosocial denial*". Indeed, doctors who have set views regardless of the facts may themselves qualify as dysfunctional thinkers.

Powerful minority groups such as the Wessely School should not be allowed to determine public policy without there being some external moderation.

Merely to state that there is "medical disagreement" over ME/CFS is not enough: people in positions of power are misusing that power against sick people and are using it to further their own vested interests, but no-one in authority is listening, at least not until they themselves or their own family join the ranks of the psychiatrically-persecuted, when they too come up against a wall of utter indifference.

Most of what follows is already in the public domain but needs to be reiterated again and again to prevent it from being expediently "buried", a ploy much favoured by New Labour for dealing with unpalatable facts.

Terminology

The obfuscation of terminology by the Wessely School and their repeated misclassification of ME as a mental disorder is a significant component of the current dilemma facing UK patients with ME. Wessely School psychiatrists refer to CFS, ME, CFS/ME and chronic fatigue interchangeably, when there is abundant evidence that they are not the same, as was recognised by the American Medical Association as long ago as 1990 (JAMA 1990: AMA Science News Editor: correction to July 4th Issue).

In the World Health Organisation International Classification of Diseases -- to which the UK is a signatory and is therefore bound by it – myalgic encephalomyelitis (ME) has been classified as a neurological disorder since 1969. In the 1992 revision (ICD-10) chronic fatigue syndrome (CFS) is listed as a synonymous term for ME and both terms are listed in the neurological diseases section at G93.3, hence the disorder is referred to as ME/CFS. Another listed synonym is Postviral Fatigue Syndrome (PVFS).
Other states of on-going or chronic "fatigue" are listed under mental (behavioural) disorders in the psychiatric section at F48.0, a category from which ME/CFS is expressly excluded by the WHO. Those psychiatric states include the out-dated term "neurasthenia", which Wessely insists is identical to "CFS"; he is on record as wishing to reintroduce the concept of neurasthenia (which fell into disuse in the UK over 100 years ago).

Substantial evidence exists that it is the intention of the Wessely School that ME should disappear and that "CFS" will refer to numerous psychiatric states of on-going tiredness or chronic "fatigue", including neurasthenia. Such thinking focuses only on "fatigue" as a component of ME and wholly ignores the published evidence of biomedical abnormalities ie. the significant body of evidence that ME is a complex multi-system organic disease with, for example, evidence of unique pathology in the blood vessels.

Just a single quotation from Simon Wessely encapsulates his belief about ME/CFS: in a paper on "medically unexplained symptoms", Wessely stated: *"Patients with functional somatic symptoms are generally viewed as an unavoidable, untreatable and unattractive burden"* (Patients with medically unexplained symptoms. Alcuin Wilkie Simon Wessely. British Journal of Hospital Medicine 1994:51:8:421-427).

ME/CFS however, is not a functional somatic syndrome.

Classification

The correct classification of a disorder is important.

Accurate classification of a disorder matters because it defines medical understanding of that disorder and leads to correct investigations, treatment and management.

NHS service provision is based upon classification codes and NHS software systems use ICD-10 to encode diagnostic data for use in statistical reporting, thus the correct code impacts upon NHS service provision and upon the delivery of appropriate and necessary medical care: national provision of NHS facilities by commissioning officers may be based on the use by admitting consultant clinicians of the correct ICD code. If no-one with ME/CFS is admitted to hospital under the G93.3 code, it will reinforce the non-provision of appropriate services for such patients, thus perpetuating the vicious circle of NHS neglect.

Further – importantly -- mental disorders are excluded from certain State and medical insurance benefits.

Current Government Policy concerning ME/CFS (based on the beliefs of the Wessely School)

In 2001 the US Centres for Disease Control pointed out that basic laboratory tests are insufficient for ME/CFS patients because it is known that routine screening is normal in 90% of such patients, thus highlighting the need for sub-grouping and for more complex investigations such as immunological assays, nuclear medicine screening and gene expression profiling (Co-Cure RES: NOT: 17th July 2001).

In the UK, however, current and future policy dictates the non-investigation of ME/CFS patients other than by routine screening. It dictates that no special provision or facilities other than psychiatric clinics need be provided for the care of ME/CFS patients; it dictates that no special training for doctors about the disorder is necessary; it dictates the denial of appropriate medical care; it dictates that there is no need for respite care (and commissioning officers are advised accordingly); it dictates that State benefits for those with ME be withdrawn unless patients agree to psychiatric intervention, whereupon (as for all psychiatric disorders) a lower rate of benefit is payable; it approves the use of Court Orders for the compulsory removal from their home of both children and adults with ME under the auspices of the Mental Health Act if patients decline psychiatric intervention, and it dictates that no biomedical research is necessary into the disorder and that such research should not be publicly funded by Government bodies.

The illustrations below provide examples of the Wessely School's many attempts to reclassify ME as a mental disorder. In the meantime, this psychiatric lobby refers to "CFS/ME"; on their own admission this is to patronise patients with ME, asserting that patients prefer the term "ME" because it sounds more serious but that doctors -- with their superior knowledge -- use the term "CFS".

There is no doubt whatever that Wessely School psychiatrists use the terms "ME", "CFS", "CFS/ME" and "chronic fatigue" interchangeably, asserting that the WHO classifies it as the same disorder in two different sections of the ICD-10, once as a physical disorder (G93.3) and again as a mental disorder (F48.0).

This has been categorically refuted in writing by the WHO and on 11th February 2004 the UK Health Minister (then Lord Warner) was obliged to confirm in writing that the WHO classification of ME/CFS is as a neurological disorder.

This confirmation has had no effect upon the Wessely School and Departments of State to which they are advisors: ME/CFS continues to be listed throughout the NHS as the mental disorder "CFS/ME" (see below), even though the WHO classification renders such a classification factually incorrect.

The reality and nature of ME/CFS

At the launch by the US Centres for Disease Control in November 2006 of its "Toolkit" to promote better awareness of the reality of ME/CFS, Anthony Komaroff, Professor of Medicine at Harvard, said there are over 4,000 papers on the biomedical nature of ME/CFS. This extensive medical literature spans over 60 years. No-one who is aware of this wealth of information can credibly doubt the reality, the validity and the devastation of this organic multi-system disease.

Although the precise cause(s) is yet to be determined, the symptoms of ME/CFS are not "medically unexplained" and it remains beyond reason that the existence of so many

documented abnormalities in people with ME/CFS should simply be disregarded and denied, including the following:

- abnormalities of the central nervous system include abnormalities of brain cognition, brain perfusion, brain metabolism and brain chemistry; there is evidence of low blood flow in multiple areas of the brain; neuro-imaging has revealed lesions in the brain of approximately 80% of those tested and according to the researchers, these lesions are probably caused by inflammation: there is a correlation between the areas involved and the symptoms experienced; abnormalities on SPECT scans provide objective evidence of central nervous system dysfunction; there is evidence of a chronic inflammatory process of the CNS, with oedema or demyelination in 78% of patients tested; there is evidence of a significant and irreversible reduction in grey matter volume (especially in Brodmann's area 9) which is related to physical impairment and may indicate major trauma to the brain (which could also explain the low recovery rate); there is evidence of seizures; a positive Romberg is frequently seen in authentic ME/CFS patients

- abnormalities of the autonomic and peripheral nervous systems: there is evidence of dysautonomia in ME/CFS patients – see, for example, "Standing up for ME" by Spence and Stewart: Biologist 2004:51(2):65-70; according to Goldstein, ME/CFS represents the final common pathway for a multi-factorial disorder causing autonomic dysfunction

- cardiovascular dysfunction: there is evidence of haemodynamic instability and aberrations of cardiovascular reactivity (an expression of autonomic function); there is evidence of diastolic cardiomyopathy; there is evidence of endothelial dysfunction; there is evidence of peripheral vascular dysfunction with low oxygenation levels and poor perfusion and pulsatilities; there is evidence of abnormal heart rate variability and evidence of abnormal orthostasis; there is evidence of abnormally inverted T-waves and of a shortened QT interval, with electrophysiological aberrancy; there is evidence of abnormal oscillating T-waves and of abnormal cardiac wall motion (at rest and on stress); there are indications of dilatation of the left ventricle and of segmental wall motion abnormalities; there is evidence that the left ventricle ejection fraction – at rest and with exercise – is as low as 30%; there is evidence of reduced stroke volume

- respiratory system dysfunction: there is evidence of significant reduction in many lung function parameters including a significant decrease in vital capacity; there is evidence of bronchial hyper-responsiveness

- a disrupted immune system: there is evidence of an unusual and inappropriate immune response: there is evidence of very low levels of NK cell cytotoxicty; there is evidence of low levels of autoantibodies (especially antinuclear and smooth muscle); there is evidence of abnormalities of immunoglobulins, especially SIgA and IgG_3, (the latter having a known linkage with gastrointestinal

tract disorders); there is evidence of circulating immune complexes; there is evidence of a Th1 to Th2 cytokine shift; there is evidence of abnormally diminished levels of intracellular perforin; there is evidence of abnormal levels of interferons and interleukins; there is evidence of increased white blood cell apoptosis, and there is evidence of the indisputable existence of allergies and hypersensitivities and positive mast cells, among many other anomalies, with an adverse reaction to pharmacological substances being virtually pathognomonic

- virological abnormalities: there is evidence of persistent enterovirus RNA in ME/CFS patients; there is evidence of abnormalities in the 2-5 synthetase / RNase L antiviral pathway, with novel evidence of a 37 kDa binding protein not reported in healthy subjects or in other diseases; there is evidence of reverse transcriptase, an enzyme produced by retrovirus activity, with retroviruses being the most powerful producers of interferon; there is evidence of the presence of HHV-6, HHV-8, EBV, CMV, Mycoplasma species, Chlamydia species and Coxsackie virus in the spinal fluid of some ME/CFS patients, the authors commenting that it was surprising to find such a high yield of infectious agents on cell free specimens of spinal fluid that had not been centrifuged

- evidence of muscle pathology: this includes laboratory evidence of delayed muscle recovery from fatiguing exercise and evidence of damage to muscle tissue; there is evidence of impaired aerobic muscle metabolism; there is evidence of impaired oxygen delivery to muscles, with recovery rates for oxygen saturation being 60% lower than in normal controls; there is evidence of prolonged EMG jitter in 80% of ME/CFS patients tested; there is evidence of greater utilisation of energy stores; there is evidence that total body potassium (TBK) is significantly lower in ME/CFS patients (and abnormal potassium handling by muscle in the context of low overall body potassium may contribute to muscle fatigue in ME/CFS); there is evidence that creatine (a sensitive marker of muscle inflammation) is excreted in significant amounts in the urine of ME/CFS patients, as well as choline and glycine; there is evidence of type II fibre predominance, of scattered muscle fibre necrosis and of mitochondrial abnormalities

- neuroendocrine abnormalities: there is evidence of HPA axis dysfunction, with all the concomitant implications; there is evidence of abnormality of adrenal function, with the size of the glands being reduced by 50% in some cases; there is evidence of low pancreatic exocrine function; there is evidence of an abnormal response to buspirone challenge, with a significant increase in prolactin release that is not found in healthy controls or in depressives; there is evidence of abnormal arginine – vasopressin release during standard water-loading test; there is evidence of a profound loss of growth hormone; even when the patient is euthyroid on basic screening, there may be thyroid antibodies and evidence of failure to convert T4 (thyroxine) to T3 (tri-iodothyronine), which in turn is dependant upon the liver enzymes glutathione peroxidase and iodothyronine deiodinase, which are dependant upon adequate selenium in the form of selenocysteine (which may be inactivated by environmental toxins)

- defects in gene expression profiling: there is evidence of reproducible alterations in gene regulation, with an expression profile grouped according to immune, neuronal, mitochondrial and other functions, the neuronal component being associated with CNS hypomyelination

- abnormalities in HLA antigen expression: Teraski from UCLA found evidence that 46% of ME/CFS patients tested were HLA-DR4 positive, suggesting an antigen presentation

- disturbances in oxidative stress levels: there is mounting evidence that oxidative stress and lipid peroxidation contribute to the disease process in ME/CFS: circulating in the bloodstream are free radicals which if not neutralised can cause damage to the cells of the body, a process called oxidative stress: in ME/CFS there is evidence of increased oxidative stress and of a novel finding of increased isoprostanes not seen in any other disorder; these raised levels of isoprostanes precisely correlate with patients' symptoms (isoprostanes being abnormal prostaglandin metabolites that are highly noxious by-products of the abnormal cell membrane metabolism); there is evidence that incremental exercise challenge (as in graded exercise regimes) induces a prolonged and accentuated oxidative stress; there is evidence of low GSH-PX (glutathione peroxidase, an enzyme that is part of the antioxidant pathway: if defective, it causes leakage of magnesium and potassium from cells)

- gastro-intestinal dysfunction: there is evidence of objective changes, with delays in gastric emptying and abnormalities of gut motility; there is evidence of swallowing difficulties and nocturnal diarrhoea; there is evidence going back to 1977 of hepatomegaly, with fatty infiltrates: on administration of the copper response test, there is evidence of post-viral liver impairment -- an increase of at least 200 in the copper level is the expected response, but in some severely affected ME/CFS patients the response is zero; there is evidence of infiltration of splenic sinuses by atypical lymphoid cells, with reduction in white pulp, suggesting a chronic inflammatory process; there is evidence that abdominal pain is due to unilateral segmental neuropathy (Gastrointestinal Manifestations of Chronic Fatigue Syndrome: H Hyman, Thomas Wasser: JCFS 1998:4(1):43-52); Maes et al in Belgium have found significant evidence that people with ME/CFS have increased serum levels of IgA and IgM against the LPS of gram-negative enterobacteria, indicating the presence of an increased gut permeability resulting in the autoimmmunity seen in many ME/CFS patients; this indicates that the symptoms of irritable bowel seen in ME/CFS reflect a disorder of gut permeability rather than psychological stress as most psychiatrists believe (gastro-intestinal problems are a serious concern in ME/CFS, and 70% of the body's immune cells are located in the GI tract)

- reproductive system: there is clinical evidence that some female patients have an autoimmune oophoritis; there is evidence of endometriosis; there is evidence of polycystic ovary syndrome; in men with ME/CFS, prostatitis is not uncommon

- visual dysfunction: there is evidence of latency in accommodation, of reduced range of accommodation and of decreased range of duction (ME patients being down to 60% of the full range of eye mobility); there is evidence of nystagmus; there is evidence of reduced tracking; there is evidence of problems with peripheral vision; there is evidence that the ocular system is very much affected by, and in turn affects, this systemic condition.

The above list is by no means comprehensive but merely gives an overview of documented abnormalities seen in ME/CFS that can be accessed in the literature, as well as in the abstracts and reports of international Clinical and Research Conferences (http://www.meactionuk.org.uk/ME_Exists_-_True_or_False.htm).

The evidence is there, and to deny it is to deny reality. However, it is easier to deny the evidence if the tests necessary to prove these abnormalities are proscribed, as is the case in the UK.

How can symptoms that clearly indicate significant pathology be so constantly dismissed and sufferers be so constantly denigrated by certain psychiatrists, given the nature of the problems presented? These include not only the watered-down subjective descriptions of "fatigue", sore throat, cognitive impairment and altered sleep patterns, but organic symptoms that ought to be unmissable, even by psychiatrists, for example:

extreme malaise; abdominal pain and diarrhoea; post-exertional exhaustion almost to the point of collapse; inability to stand unsupported for more than a few moments – this is absolutely diagnostic of ME; sometimes too weak to walk (different from deconditioning); inability to walk upstairs or to maintain sustained muscle strength, as in repeated brushing of hair with arms elevated, or inability to carry a shopping bag, or dry oneself after a bath, peel vegetables or prepare a meal; neuromuscular incoordination, not only of fine finger movement with clumsiness and inability to control a pen and to write legibly, but also of the larynx and oesophagus -- a frequent complaint is the need to swallow carefully to avoid choking; oesophageal spasm and pain; dysequilibrium ie. loss of balance; staggering gait (ataxia); bouts of dizziness and frank vertigo; difficulty with voice production, especially if speaking is sustained; aphasia (inability to find the right word); muscle cramps, spasms and twitching; black-outs and seizure-like episodes; spasmodic trembling of arms, legs and hands; episodes of angor animi (brought about by abrupt vasomotor changes that cause the sufferer to have uncontrollable shaking, like a rigor, and to think they are at the point of death) – it is essential to understand the terror that such attacks induce in a patient, and no patient can fake them; photophobia; difficulty focusing and in visual accommodation, with rapid changes in visual acuity; blurred and double vision, with loss of peripheral vision; eye pain; swollen and painful eyelids, with inability to keep eyelid open; tinnitus; hyperacusis, for example the noise of a lawnmower can cause acute distress and nausea; heightened sensory perception (for

example, acute sensitivity to being patted on the back; inability to tolerate lights, noise, echoes, smells, movement and confusion such as found in a shopping mall or supermarket without being reduced to near-collapse); frequency of micturition, including nocturia; peripheral neuropathy; numbness in face; altered sleep patterns, with hypersonmia (in the early stages) and insomnia (in the later stages); alternate sweats and shivers; temperature dysregulation, with intolerance of heat and cold; parasthesias; sleep paralysis; intermittent palindromic nerve pains; tightness of the chest alternating with moist chest; muscle tenderness and myalgia, sometimes burning or vice-like; typically shoulder and pelvic girdle pain, with neck pain and sometimes an inability to hold head up; orthostatic tachycardia; orthostatic hypotension, and symptoms of hypovolaemia, with blood pooling in the legs and feeling faint due to insufficient blood supply to the brain; labile blood pressure; intermittent chest pain akin to myocardial infarct; segmental chest wall pain; subcostal pain; vasculitic spasms, including headaches; cold and discoloured extremities, with secondary Raynaud's; easy bruising; peri-articular bleeds, especially in the fingers; shortness of breath on minimal exertion; the need to sleep upright because of weakness of the intercostal muscles; pancreatic exocrine dysfunction leading to malabsorption; rashes (sometimes vasculitic in nature); flushing of one side of the face; ovarian-uterine dysfunction; prostatitis; hair loss and mouth ulcers that make speaking and eating difficult. The notable point about symptoms in ME/ICD-CFS is their variability. All the above symptoms and more are documented in the literature; they bear little resemblance to "chronic fatigue" or to a "continuum of on-going tiredness".

It is, of course, the Wessely School psychiatrists' view that such multiplicity of symptoms confirms their belief that ME/CFS is a somatoform disorder. If these psychiatrists do not acknowledge and identify such symptoms, they are either not seeing patients with ME/CFS (so therefore should not describe their studies and results as pertaining to those with "ME") or are comprehensively failing in their professional responsibilities towards such patients.

As there is an ever-increasing abundance of evidence of an organic pathoaetiology, how can these psychiatrists profess to remain unconvinced that ME/CFS is an organic disease and insist that it is merely a "mistaken illness belief"?

Wessely School psychiatrists accord lower evidential weight to objective clinical observation than to laboratory measurements, yet now that there is laboratory evidence that ME/CFS is an organic disease, these psychiatrists continue to dismiss or ignore it in the pursuit of their own belief that "CFS/ME" is a functional somatic syndrome that is amenable to behavioural modification techniques.

Two major but under-reported changes in relation to patients with ME/CFS

In an article written in 2001 attention was drawn to two major but under-reported changes that were taking place in the UK. It was written partly in response to Simon Wessely's article (Functional Somatic Syndromes: one or many? Lancet 1999:354:936-939) in which he wrote: "*Functional somatic syndromes (chronic fatigue syndrome, multiple*

chemical sensitivity, fibromyalgia, irritable bowel syndrome and tension headache) are associated with unnecessary expenditure of medical resources. If we accept that functional somatic syndromes are considered together, we open the way for more general strategies for their management".

The article noted that on 19th November 1996 Britain was a signatory to the preliminary draft of the Council of Europe Strasbourg Convention on Human Rights and Biomedicine. This conveyed certain rights on member states who signed the final document. Those conferred rights included provision for drug and other medical trials on human beings which, in certain groups of people, could be carried out without the individual's consent. One of those groups is people who are deemed to be mentally ill. The Convention stipulated that in certain situations, "general interests" will take priority over those of the individual.

The article pointed out that at the same time, reform of the UK Mental Health Act (1983) was under way (Green Paper: Reform of the Mental Health Act 1983: Proposals for Consultation, November 1999). Proposals were drawn so widely that they would give psychiatrists far greater powers to enforce compulsory psychiatric treatment upon both adults and children, including giving psychiatrists powers to drug people (including children against the will of their parents) if they have **"any disability or disorder of mind or brain, whether permanent or temporary**, which results in an impairment of mental functioning". The chilling inclusion of the words **"or brain"** was noted, as this would include people with incurable neurological disorders such as multiple sclerosis, Parkinson Disease and motor neurone disease, the support of whom costs the State considerable amounts of money for no economic return. The article questioned whether or not ME would be included, particularly if the psychiatric lobby were to be successful in reclassifying it as a mental disorder, and quoted from a letter dated 4th May 2000 from the Minister of State at the Department of Health, John Hutton, which did not completely rule this out: *"it is highly unlikely that (CFS/ME) sufferers would qualify for detention under the Act even if it were to be reclassified as a mental rather than a physical disorder".*

The article noted that already in the UK, children and adolescents with ME were being forcibly removed from their parents and placed in psychiatric care, sometimes with the backing of a Court Order.

In April 1999, Dr Nigel Speight, Consultant Paediatrician at the University Hospital of North Durham and an acknowledged expert on ME/CFS, had reported that the frequency of psychiatrists diagnosing Munchausen's Syndrome by Proxy in parents of children with ME/CFS amounted to an epidemic, and this was reported by the ME Association in the Autumn 1999 issue of Perspectives.

On 11th July 2001, the Daily Telegraph published an article which clearly showed that children and adolescents were being forcibly removed from their parents and placed in psychiatric "care", sometimes with the backing of a Court Order (How the law is being

used to force treatment on children – parents of ME sufferers are being victimised by the Children Act. The Countess of Mar; Daily Telegraph, 11th July 2001).

Wessely was first involved in this practice in 1988, just two years after he obtained his MRCPsych, when on 3rd June he wrote about 12 year old Ean Procter: *"I did not perform a physical examination but was told there was no evidence of any physical pathology"*. Ean had lost the ability to speak, which Wessely asserted was *"elective mutatism" (sic).* Wessely wrote: *"I have considerable experience in the subject of 'myalgic encephalomyelitis'. I feel that Ean needs a long period of separation from his parents. For this reason, I support the application made by your department for wardship"*. On 10th June 1988 Wessely provided another report on Ean Procter, in which he wrote: "*I did not order any investigations. Ean cannot be suffering from any primary organic illness, be it myalgic encephalomyelitis or any other. Ean has a primary psychological illness (and) requires skilled rehabilitation to regain lost function. I therefore support the efforts being made to ensure Ean receives appropriate treatment"*. After his signature, Wessely wrote: "Approved under Section 12, Mental Health Act 1983". That same month, without ever having spoken to Ean's parents, social workers supported by psychiatrists, armed with a Court Order that had been specially signed on a Sunday and in the presence of police officers, forcibly removed the sick child from his distraught parents.

Wessely's involvement with the wardship of Ean Procter is incontrovertibly established, yet in a Channel 4 News programme on 26th August 1998 in which the forcible removal of another child with ME/CFS was being discussed, when asked by the presenter Sheena McDonald if there can ever be a case for the coercive approach in situations involving the forcible removal of a child with ME/CFS from the parents, Wessely replied: *"I think it's so rare. I mean, it's never happened to me"*. Wessely's elective amnesia was broadcast on national television for all to see.

The 2001 article wondered if those two momentous changes determined the intended direction of Government policy and asked if this explained why Professor Anthony Pinching, then Deputy Chair of the Chief Medical Officer's Working Group on "CFS/ME", had said on 7th June 2000 at the Sounding Board Event at the Department of Health in London that there was no need for research into "CFS/ME"? (see below for Professor Pinching's published views on "CFS/ME").

The article also asked if those proposed changes explained why, despite compelling international evidence of biomarkers of organic pathoaetiology, Wessely and colleagues appeared to have carte blanche in all matters relating to ME/CFS, and if this likely direction of government policy underlay the directive of denial?

The article concluded by asking if it is the case that "general interests" are already taking priority over those of the individual, and if those "general interests" are economically and commercially determined? (ref: The 1996 Strasbourg Convention on Biomedicine and the reform of the UK Mental Health Act: have they anything to do with the attempt to reclassify ME/CFS as mental illness? available online: http://www.meactionuk.org.uk/Strasbourg.html).

The Mental Health Act 2007 received Royal Assent on 19th July 2007.

Wessely School control of ME/CFS issues

For over two decades, in their role as advisers to Government Departments, Wessely School psychiatrists have been tirelessly influencing Government Ministers and Departments of State on behalf of their paymasters, known to be Big Pharma and the medical insurance industry, about what they term "medically unexplained" disorders, notably ME/CFS and Gulf War Syndrome, both of which they assert do not exist.

Simon Wessely, Michael Sharpe, Peter White -- and to a lesser extent their colleague Anthony Cleare -- are deeply involved with the medical insurance industry. Written evidence exists showing that claims for "CFS/ME" are inter-referred amongst themselves, and that claimants are coerced into being assessed only by this group of psychiatrists. Claimants are told: "*If you agree to see (Dr) Michael Sharpe, we will agree to be bound by his opinion*", when the insurance company knows full well that Sharpe lectures to insurance companies, business schools and employers, advising that those with ME/CFS seeking payment of benefit under their policies "*should not qualify for such payments*". Is it justice for Sharpe to be paid by insurance companies when he directly or indirectly advises the non-payment of claims for patients with ME/CFS? It was on 17th May 1995 that Wessely, Sharpe and Wessely's colleague, behaviour therapist Trudie Chalder, all spoke at a Business Symposium in London attended by UnumProvident's Dr John LoCascio: information presented included informing attendees that ME/CFS has been called *'the malingerer's excuse*'. Extracts from UnumProvident's "Chronic Fatigue Syndrome Management Plan" are pertinent: "*Diagnosis: Neurosis with a new banner. UNUM stands to lose millions if we do not move quickly to address this increasing problem. Attending physicians (must) work with Unum rehabilitation services in an effort to return the patient / claimant back to maximum functionality with or without symptoms*".

This important issue of vested interests has been repeatedly raised in the House of Commons, most recently in the 2006 Report of the Gibson Inquiry (see below), and Members of the Scottish Parliament have written to Allied Dunbar about their concerns over Michael Sharpe's suitability to give an unbiased view when assessing people with ME/CFS; Sharpe has asked MSPs to withdraw their statements to Allied Dunbar about him.

The Wessely School psychiatric lobby and ME/CFS patients' charities

The ME Association: that Wessely School psychiatrists have sought absolute control of the ME situation is beyond doubt. Almost 20 years ago, Professor (then Dr) Simon Wessely wanted to become Medical Adviser to the ME Association and was recommended for the post by the then Medical Adviser Dr David Smith. Dr Melvin Ramsay's response as President of the ME Association was "over my dead body". Dr David Smith left his position at the ME Association and Dr Charles Shepherd took over as Medical Adviser.

Shepherd brought with him different (but perhaps related) problems in that he is, on his own admission, an active member of HealthWatch, an organisation that has received funding from both Big Pharma and the medical insurance industry. Simon Wessely has had connections with HealthWatch since its inception in 1989; soon after the press launch, he was listed as one of its leading campaigners. In its literature, one of its clearly-stated aims is to oppose "*diagnoses that are misleading or false, or that may encourage unnecessary treatment for non-existent diseases*", and Wessely assiduously teaches that ME is a non-existent disease.

Despite its vehement denials -- including intimidatory letters sent by its lawyers inexplicably refuting its own literature -- HealthWatch (which started life in 1989 as the Quackbusters Campaign Against Health Fraud) has an indisputable and documented track record of opposing alternative and complementary medicine and of promoting pharmaceutical interventions as the best way of ensuring public protection. It is a matter of record that patients with ME/CFS are unable to tolerate pharmaceutical interventions; given the lack of NHS care apart from psychotherapy, they not unnaturally turn to alternative and complementary practitioners in their efforts to find some relief from their distressing symptoms, so Shepherd's role in the ME Association has been controversial.

In particular, it is difficult to understand Shepherd's strong opposition to advanced investigations for those with ME, notably nuclear imaging, immunological assays and testing for RNase L and other anti-viral pathways, all of which provide evidence of the biomedical nature of ME/CFS. On 17th July 2001 Shepherd wrote to the Chief Medical Officer confirming his opposition to such testing. People with ME/CFS have incredibly up-regulated interferon production (that is what the RNase activity literature is all about), so on what evidence does Shepherd (a part time private GP) oppose such testing, when internationally acclaimed ME/CFS experts – clinicians and academics alike – support it?

In his notes of the ME Alliance meeting held on 20th January 2005, Shepherd wrote: "*I'm now going to reorganise what I've written, especially in the 'call for research' section. We decided not to campaign on the issue of finding a diagnostic test*".

Most people hold the view that until there is a diagnostic test for ME/CFS, the plight of those suffering from it will not improve.

Action for ME: the other main UK patients' charity, Action for ME (AfME), has had a chequered history. In September 1993 it changed its name and logo to "Action for ME and Chronic Fatigue". Complaints were made to the Charity Commission and the charity subsequently dropped "Chronic Fatigue". On 24th July 2003, in a statement approved by its Council of Management, the charity announced that it is funded by the Department of Health.

Psychiatrist Michael Sharpe (infamous for his "*undeserving sick*" comment quoted above) is one of its medical advisers, though his name does not appear on the charity literature. It is well-known that in UnumProvident's Chief Medical Officer's Report (Trends in Disability, December 2002) Sharpe wrote: "*Functional symptoms are not going to go away. Privatised doctors will collude with the patient's views that they have a disabling and permanent disease. An increase in insurance claims is to be therefore anticipated. It will be imperative that social policy addresses this problem. This will not be easy. However, there are glimmers of progress. One of the major patient charities, Action for ME, is aligning itself with a more evidence-based approach. If this convergence of rehabilitation-orientated clinicians and a patient's advocacy group is successful, there could be very positive implications for insurers*".

This liaison is encapsulated in the statement by Lord Turnberg (the former Sir Leslie Turnberg, President of The Royal College of Physicians): "*The largest patients' charity, Action for ME, is working closely with Wessely and his colleagues on new research initiatives funded by the MRC and the NHS*" (Hansard [Lords]: 22nd January 2004: Vol 656: No. 27:1186). It was under the auspices of Turnberg that the biased and highly flawed 1996 Joint Royal Colleges' Report CR54 on "CFS" was produced with his full support (see below).

Professor Anthony Pinching is currently AfME's Principal Medical Adviser. He is lead adviser on "CFS/ME" to the Department of Health and was responsible for allocating the £8.5 million grant from Government for the new "CFS" Centres that deliver only psychotherapy. His views on "CFS/ME" were set out in his article in Prescribers' Journal in 2000:40:2:99-106, published when he was Deputy Chair of the Chief Medical Officer's Working Group on "CFS/ME" ("*CFS is not related to on-going exertion"; "the Oxford criteria are too narrow for clinical use"; "over-investigation can [cause patients] to seek abnormal test results to validate their illness"; "complementary therapists sometimes introduce or reinforce unhelpful illness beliefs"; "the essence of treatment is activity management and graded rehabilitation"*).

In March 2001 AfME produced an excellent report, Severely Neglected: M.E. in the UK. This report was the result of a membership survey of 2,338 respondents, making it the biggest survey ever done on ME in the UK. Its confidential Preliminary Report of 28th February 2001 stated: "*graded exercise was reported to be the treatment that had made most people worse*" but in the published version, this was changed to reporting that graded exercise made 50% of respondents worse. This makes it all the more surprising that AfME "*is working closely with Wessely and his colleagues on research initiatives funded by the MRC and the NHS*" when those "initiatives" are based on graded exercise.

AfME's report found that 77% of respondents experienced severe pain because of ME; nearly two out of three had received no advice from their GP on managing the illness; 70% were either never able, or were sometimes too unwell to attend a doctor's clinic; 80% of those who were bedridden by ME reported that a request for a home visit by a doctor had been refused, and that many people did not receive State benefits to which they were clearly entitled and desperately needed in order to survive.

By aligning itself with the Wessely School, who have a 20 year published track record of denigrating patients with ME, AfME has done patients with ME a massive disservice and may well have devalued the charity's own important report.

Michael Sharpe has a similar published track record to that of Wessely: he asserts that in "CFS/ME", personality factors have been shown to perpetuate disability; that no immunological, virological or nuclear imaging tests should be carried out on such patients; that "*the label of CFS avoids the connotations of pseudo-diagnoses such as ME*"; that "*change in belief is an important factor in recovery*"; that psychosocial factors are important in "CFS"; that his own view has long been "*the issues around CFS/ME are the same as those surrounding (patients) who suffer conditions that are not dignified by the presence of what we call disease*".

Peter White, another key member of the Wessely School, misinforms medical students and clinicians about ME/CFS: together with Anthony Clare, Professor of Clinical Psychiatry at Trinity College, Dublin, Peter White contributed the section on Psychological Medicine in the medical textbook that is likely to be on the desk of every GP in the UK as it won the 'Highly Commended' British Medical Association Award (Clinical Medicine: Kumar and Clark, 2004, 5th edition: published by Saunders: ISBN 0 7020 25798). It is promoted as "*one of the most highly respected textbooks of medicine in the world. It is used by medical students and practising doctors, as well as by many other health professionals. It has been translated into several languages*". One of the editors is Parveen Kumar, Professor of Clinical Medical Education at St Bartholomew's and The London, Queen Mary School of Medicine (ie. the same institution as Peter White). The entry for Myalgic Encephalomyelitis directs the reader to the entry for CFS, which in turn directs the reader to Section 21 (Psychological Medicine) where CFS/ME is listed under Functional or Psychosomatic Disorders: Medically Unexplained Symptoms. White and Clare assert that the psychiatric classification of these disorders is "*somatoform disorder*", which the authors state were previously known as " *'all in the mind', imaginary and malingering*".

It is only when dealing with "CFS/ME" (and Gulf War Syndrome) that these psychiatrists are regarded by Government bodies and the medical insurance industry as "experts". These psychiatrists are on record as being actively involved in social engineering via the deliberate creation of "psychosocial" illness. They believe that the biomedical approach to healthcare (ie. that ill-health and disability is directly caused by disease and its pathological processes) is (quote) "*a blind alley*" and that the correct approach is the psychosocial one, in which "aberrant" thoughts, feelings and behaviour can be "modified" by their own brand of cognitive behavioural therapy with graded exercise (CBT/GET), resulting in restoration of health and productivity.

Such a retrograde belief is fallacious, as the regime in question has been shown to be ineffective and even the proponents of the regime are themselves on record as acknowledging that (i) it is not remotely curative (ii) modest gains may be transient and even illusory (iii) these interventions are not the answer to "CFS/ME" (iv) patients have a tendency to relapse and (v) evidence from randomised trials is no guarantee of treatment success.

For more information see www.meactionuk.org.uk/Concerns_re_NICE_Draft.pdf and for a detailed review of Wessely School indoctrination of State agencies, and the impact of this on social and welfare policy, see
www.meactionuk.org.uk/Proof_Positive.htm .

A 52 page booklet (Quotable Quotes about ME/CFS) containing referenced illustrations from the published works of Wessely, Sharpe and White on "CFS/ME" is available from the charity Invest in ME (01603 – 701980).

Wessely School views about ME/CFS are at odds with the view expressed by Dr Mark Loveless, Head of the AIDS and CFS Clinic at Oregon Health Services University, USA, who at a Congressional Briefing in 1995 said that an ME/CFS patient "*feels effectively the same every day as an AIDS patients feels two weeks before death*" – the only difference being that ME/CFS symptoms can go on for decades.

It seems that AfME may be unaware that American ME/CFS experts have concerns about Wessely's approach: Professor Charles Lapp from the Hunter-Hopkins Centre, Charlotte, North Carolina, is on record as saying: "*In my opinion, cognitive behavioural therapy is widely maligned because of the British approach, which presumes that (ME)CFS has no organic basis and is therefore contradictory to current science. (The UK) type of CBT assumes that somatic symptoms are perpetuated by errant illness beliefs and maladaptive coping*". Professor Nancy Klimas from the University of Miami is on record as saying: "*I don't take the British view that CBT is the one thing you can do to effectively treat (ME)CFS*". Dr David Bell from New York is on record as saying: "*I don't refer (ME/CFS patients) to outside CBT therapy*". Dr Daniel Peterson, Medical Director of the Whittmore Peterson Neuro-Immune Institute, Nevada, is on record as saying: "*Sending patients to therapists who don't understand (ME)CFS isn't something I'd comfortably do*". These quotations can be found in CFIDS Chronicle, Spring 2006.

At the ME Research UK international research conference held in May 2007 in Edinburgh, UK, Dr Ellie Stein, herself a psychiatrist, went on record about the MRC trials (see below) with which AfME has aligned itself: "*It's quite hard to watch millions of pounds being spent on a study that will tell us nothing*". Stein also said: "*I would never in my practice use the Wessely model of cognitive therapy. I find it disrespectful to try to convince somebody they don't have an illness that they clearly have*". Stein was supported by Professor Nancy Klimas, who said: "*To dismiss people as not being real – that's just rude*".

When promoting its (subsequently postponed) "Research Summit" in combination with the Medical Research Council in 2006, AfME made an extraordinary claim about its Research Summit being -- as far as AfME knew -- the first time that neurologists, immunologists, pain and sleep disorder specialists and others would be working together to explore innovative ways of tackling ME. This seemed to show remarkable ignorance of the many previous international medical conferences and workshops on ME(CFS) with the same aim -- known to number at least 24 -- that have been held over the last 18 years. Why would AfME (whose duty upon which its charitable status depends is to represent the best interests of its members) be unaware of this substantial body of existing knowledge about the disorder from which its members suffer? AfME, which started life as the ME Action Campaign, has had 20 years to get its act together but seems signally to have failed, not least by joining forces with the MRC, which categorises ME/CFS as a mental health disorder (see below in the section on the MRC). For a list of those conferences of which AfME seemed to be unaware, see
http://www.meactionuk.org.uk/Incessant_belief.htm

Unlike the ME Association, AfME has not held an Annual General Meeting at which members have voting rights since 1996.

Also unlike the ME Association (whose Ramsay Society Research Fund supports research), AfME decided not to fund-raise for research into ME; given that its members have no voting rights, on whose mandate was this decided?

Equally, given the charity's founding mission (and mindful of its obligation to the Charity Commission, which requires a charity to be accountable, to be transparent, to provide reliable information to stakeholders that is free from bias, and to focus on stakeholders' legitimate needs), why did its last Chief Executive Officer, Chris Clark, sign up to the Government policy set out in the NHS Plus Policy Document that is so damaging for those with ME (see below) when AfME refers to itself as "*one of the main national ME charities*"?

On 30th April 2007 Sir Peter Spencer KCB was appointed the new Chief Executive Officer of AfME. He was to give a talk on 3rd September 2007 in London; his talk was to be open to everyone, not just AfME members, and the flyer said: "*We want this to be a constructive two-way process – your views matter!*". Why not restore voting rights to its members so that all of them can make their views known?

AfME's support of the "CFS" clinics

On 1st August 2007 Sir Peter's assistant wrote on his behalf: "*Action for ME continues to support the M.E. specialist services set up by the NHS in 2004*". A substantial body of evidence has been collated by Paul Davis of Research into ME (RiME) documenting the dismay, dissatisfaction and deep concern of ME/CFS patients about these "CFS" Centres. On 10th April 2007 Paul Davis wrote to AfME about the CFS Centres: "*Last summer AfME launched a campaign to save the NHS "CFS/ME" Clinics. In AfME's 8th August*

2006 flyer you wrote '…there is overwhelming support from service users…'. Such a statement surely needs to be qualified by evidence. Can we see the evidence please? RiME has presented a contrasting view at recent All Party Parliamentary Group on ME meetings. There is a difference between our respective views – RiME's is backed up by pages of evidence. Twelve pages are enclosed for your attention. This letter will be put in the public domain. We look forward to hearing from you". The letter seems to have been ignored by AfME because five months later, RiME has received neither acknowledgment nor response. It is disturbing that AfME seems to disregard this first-hand evidence (see www.erythos.com/RiME).

There is evidence that the "treatments" offered by the Government-funded new centres are psychiatrically biased and that the clinics appear to make no distinction between those with ME/CFS and those with other chronic fatigue states. Severely affected patients are not being catered for. One patient has described being put on gym machines and ending up in bed for several months – in a letter to the patient's GP, psychiatrist Peter White from St Bartholomew's Hospital, London, wrote that symptoms were the result of deconditioning, that fear and anxiety prevented the patient from exercising and that psychological factors contributed to the illness. It is reported that in the Greater Manchester area, a psychiatrist unknown to that area has come from nowhere and been made Head of the new "CFS/ME" service, with sufferers being told during cognitive behavioural therapy (CBT) sessions that they have a 'fear of activity' and 'motivation problems'.

It has to be said that some people in the ME community do support the continuance of these Centres. At the recent Invest in ME International Conference held in London on 1st-2nd May 2007, the issue of these psychotherapy Centres arose; they were criticised by one speaker on the basis that they cannot possibly help those with complex neurological disease to recover, and the only management regime -- as distinct from treatment – that they offer could be potentially dangerous for some people with ME/CFS. However, one or two attendees believed that the Centres were better than nothing at all, and that the Centres should be supported by the ME/CFS community on the grounds that if patients do not attend these Centres, they will forfeit their entitlement to State and insurance benefits. When the Countess of Mar became aware of such a view, she was reported to have remarked that if this state of affairs is true, it is illegal.

Lady Mar was therefore asked directly if she had said this, and by email on 11th May 2007 she replied: *"During the Committee Stage of the Welfare Reform Bill – debates from Clause 9 onwards in the Lord -- I managed to extract from the Minister statements to the effect that people with CFS/ME would not be forced to do CBT/GET in order to continue to get their benefits"*. That debate is recorded in Hansard (Lords) on 28th February 2007, column GC198:

Countess of Mar: "If a group of people refuses graded exercise and cognitive behaviour therapy, on the basis either that they are afraid or that they know it will not help them, will they be penalised?"

Lord McKenzie of Luton (Parliamentary Under-Secretary, Department for Work and Pensions; Labour Peer): "there is no requirement for individuals to carry out any specific type of activity or treatment. That cannot be sanctioned".

AfME is involved in a forthcoming Collaborative Conference on 4th and 5th October 2007 in Milton Keynes on the implementation of the NICE Guideline on "CFS/ME" that was published on 22nd August 2007 (which promotes cognitive behavioural therapy and graded exercise for those with mild to moderate "CFS/ME"). The letter of 1st August 2007 on behalf of Sir Peter Spencer said about the Collaborative Conference: *"I will of course be stressing our view that this is essentially a physical illness"*. Does the WHO classify ME as "essentially" a physical illness? Many organic diseases, including multiple sclerosis and cancer, give rise to psychological distress but this does not mean they are "essentially" physical disorders – they <u>are</u> physical disorders, which by their very serious nature may give rise to psychological symptoms, just as may occur in ME/CFS.

Speakers at the Collaborative Conference are almost all members of the psychiatric lobby. On 12th July 2007 at the All Party Parliamentary Group on ME, Sir Peter said he did not understand why people are objecting to the choice of speakers.

Is it perhaps the case that Sir Peter has difficulty in understanding key issues? When on 12th December 2006 he appeared in his previous position as Chief of Defence Procurement before the House of Commons Defence Select Committee, Sir Peter did not excel himself in the Oral Evidence Session, as Questions 45 - 60; Questions 101 - 111 and Question 125 seem to demonstrate, for example:

Q46. Mr Jones (Kevan Jones MP): *"You actually let a contract to Alvis Vickers"*. Sir Peter Spencer: *"I have no recollection"*.

Q47. Mr Jones: *"You are wrong because it did take place"*.

Q52. Mr Jones: *"Can I say, Sir Peter, I find it absolutely remarkable that you can come here today in charge of this programme and say that you did not know about (it). I know about it; industry knows well about it"*.

Q56. Mr Jones: *"A minute ago you told us you did not know about it. Now you are trying to describe what went on"*.

Q59. Mr Jones: *"Sir Peter, that is not true. If you are sitting here today and telling us that this was just part of this entire process, that is not the case. It's no good coming here trying to wriggle out of it"*.

Q101. (In response to a question from the Chairman, James Arbuthnot MP): Sir Peter Spencer: *"That is really a question for ministers, I'm afraid"*.

Q104. Mr Jones: *" No, it is not, Chairman"*.

Q105. Mr Jones: *"Why can you not tell us?"*

Q106. Mr Jones: *"Why can you not tell us? If you are prepared to tell industry what your estimate is, why are you not prepared to tell the House of Commons Defence Committee what your estimate is?"*

Q109. Mr Jones: *"I am sorry Chairman, I think that is bang out of order. We have got a civil servant here telling us that he is not prepared to give elected Members of Parliament who scutinise the Ministry of Defence information which he is quite happy to give to outside industry. I think it is disgraceful"*.

Q110. Mr Jones: *"Absolutely disgraceful"*. Sir Peter Spencer: *"No, it is not disgraceful"*.

Q111. Mr Jones: *"It is"*.

Q125. Mr Jones: *"How should we be able to see if you have been successful in delivering this programme if we are not going to get this information (because) you are being as evasive as you are?"*. Sir Peter Spencer: *"I am not being evasive…."*.

Sir Peter's interrogation by the Defence Select Committee can be accessed online at http://www.publications.parliament.uk/pa/cm200607/cmselect/cmdfence/159/6121201.htm

If Sir Peter could seemingly mislead a Select Committee of astute MPs in deference to commercial interests, could he equally mislead sick people in deference to commercial interests?

Promulgators and purveyors of misinformation

Perhaps the responsibility between the Wessely School and the State is mutual: whatever the causal direction, the resulting situation is achieving its aim and is effectively paralysing State-funded scientific progress on ME/CFS, as well as compounding patients' indescribable suffering and leading -- in an ever-increasing number of known cases -- to premature death, documented evidence of which has been presented to the Chief Medical Officer in person.

Using the denial of information as an instrument of power is an exceptionally effective strategy, especially when every avenue of dissemination of (mis) information about ME/CFS has been tightly secured to the extent that nothing but psychiatric propaganda can percolate the otherwise impenetrable information machine of the State.

Apart from Wessely School psychiatrists and adherents themselves, chief amongst the promulgators and purveyors of misinformation about ME/CFS are the Centre for Reviews

and Dissemination at York; the NHS Information Centre (formerly the Information Authority); the National Institute for Health and Clinical Excellence (NICE); the Department of Health; the Department for Work and Pensions (DWP); certain Royal Colleges; the Science Media Centre; NHS Direct; the Medical Research Council (MRC), with whom Action for ME has also joined forces, as well as with the medical insurance industry, and the UK medical journals. Brief examples of their respective roles in the perpetration of misinformation about ME/CFS are included below.

All these bodies seem to have been contaminated by Wessely School misinformation about ME/CFS and to have embraced the Wessely School ideology that ME/CFS is a manifestation of aberrant illness behaviour that can be "modified" by a regime of psychotherapy. It is on record (by Michael Sharpe) that this particular "behavioural modification" regime was formulated by Wessely's own group.

In the PRISMA company literature (a multi-national healthcare company which works with insurance companies by arranging "rehabilitation" programmes for those with CFS/ME), the regime is described as *"a unique treatment programme"* for *"hopeless"* cases, in which it expressly includes those with "CFS".

In his article in the UnumProvident Report Trends in Health and Disability of December 2002, Michael Sharpe stated: *"Funding of rehabilitation by commercial bodies has begun in the UK with organisations such as PRISMA and is likely to continue"*. In the PRISMA Company Information, Simon Wessely is listed as a Corporate Officer. He is a member of the Supervisory Board and in order of seniority, he is higher than the Board of Management. He is listed as a *"world expert"* in the field of *"medically unexplained illnesses, including Chronic Fatigue Syndrome"*.

Consequences of opposing the psychiatric ideology

The consequences of opposing Wessely School ideology can be dire. When in January 2006 an organised peaceful protest was mounted outside a public lecture to be given by Professor Simon Wessely at Gresham College, London, some chilling incidents occurred. One day before the event, strange things had begun to happen. Staff at Gresham College began telling people that Wessely had cancelled his lecture. However, other information indicated that Wessely was secretly going ahead. It was said that Wessely claimed he had reason to believe he would be physically attacked. Total confusion ensued, with people returning home believing that the lecture had been cancelled, when in reality it was going ahead. At the event, the police were present and were photographing everyone present. The protest organisers had learned of Wessely's public appearance only a week before the event but, on the day, they managed to display personal stories of people whose lives had been destroyed by Wessely's ideas: some were harrowing, describing years of suffering, financial hardship, ridicule and abandonment by the NHS, family and friends as a result of Wessely's theories. The protest organisers believed that by ignoring *"the mountains of evidence about the physical causes of these syndromes, (Wessely) and*

his colleagues are personally responsible for suffering on a massive scale", so they had set up a campaign called "Illness Denied" (www.illnessdenied.org.uk). On the day of the protest, the lead protester noticed unusual problems with her mobile phone. She also experienced problems with computer hacking (which in an official attempt to undermine her mental stability were ridiculed but which were later validated by an IT expert). The harassment included a threat placed on the internet directed at her children. She was subsequently arrested, with three police officers, two doctors, two social workers and a community psychiatric nurse arriving at her home unannounced with a warrant for her arrest. She was given no time to pack or to get in touch with a lawyer. She was then detained against her will under Section Two of the Mental Health Act 1983. She was kept on Pond Ward of the Central Middlesex Hospital for 30 days under appalling conditions. While she was under detention, her mother was suddenly taken ill and died a few days later; the protest organiser had to beg to be allowed out and was only permitted to see her mother accompanied by an escort in case she "escaped".

In her "Statement regarding my Detention", the protest organiser wrote: *"I feel that my experience raises very serious issues about the powers that psychiatrists, social workers, and other authorities have in our society to repress others on the basis of their political beliefs. It is now clear that there are enough people out there who do have the courage to face issues even when they are controversial or call into question ideas we take for granted – that we live in a democracy, that public health authorities always act in our best interests, that governments are there to protect us, that psychiatrists in the west never diagnose and treat people on the basis of their political beliefs, that the science of medicine is never subordinated to politics or the profit needs of corporate giants. I believe that the recent events will only serve to focus people's minds more than ever on these issues"*. The protest organiser was fortunate to have been supported by informed doctors, scientists, journalists, a peer of the realm and a very sharp, hard-hitting team of solicitors. (For more information, see http://www.lyme-rage.info/elena/statejun06.html).

The UK National Health Service -- Similarities with Russian State Psychiatry?

The above episode seems to have overtones of how Russia used to silence dissidents by giving them a psychiatric diagnosis, a situation that seems not to have disappeared in current times.

In The Daily Telegraph on 13th August 2007, Adrian Blomfield's article "Labelled mad for daring to criticise the Kremlin" told a harrowing tale of "punitive psychiatry" and referred to "state psychiatrists": *"The Daily Telegraph has learnt of dozens of incidents that suggest that Russia's psychiatric system is rapidly becoming as unsavoury as it was in Soviet times"*. Blomfield wrote:*" 'Once again psychiatrists see stubbornness in an individual as a sign of psychosis' said Lyubov Vinogradova, the executive director of the Independent Psychiatrists' Association. 'If a person goes to court against a state institution or writes letters of complaint he is treated as a social danger and is in danger of incarceration'. With a presidential election due next March, 'Everything is ready for a wide scale political abuse of psychiatry' said Mrs Vinogradova"*.

The same day, the following comments appeared on an ME internet group: "*There is some parallel with the treatment of ME patients in the UK: (1) ME patients are given a psychiatric label. (2) As a result, they are regarded as irrational and their opinions are not taken seriously. (3) Effectively they are silenced, since no-one will afford them credibility. Not their GPs, not their MPs, not their employers, and sometimes not their friends. (4) By silencing patients, their opposition is neutered, and psychiatric dominance in ME continues unchallenged. (5) Liaison psychiatrists exult in their success, and bank their loot from the MRC and DWP"* (see http://groups.yahoo.com/group/LocalME/).

As Greg Crowhurst noted in his paper Be a trouble maker: *" 'You can't go after a health care system (that is) under the control of the insurance companies and pharmaceutical corporations. That system is immune' warns Noam Chomsky in his latest book (Interventions; Hamish Hamilton, 2007), yet a radical corporate-led health care system is exactly what New Labour are bringing about in the UK, shadily and with little public consultation. Large companies are being invited to tender for the commissioning function of Primary Care Trusts (PCTs). Private companies will then have control over which treatments patients receive and who receives them. Clinical decision-making will increasingly come under the control of commercial managers and shareholders. That great bane of ME sufferers' lives, the medical insurance industry – which since the mid 1980s has lobbied hard with great success to have ME reclassified as a psychiatric behavioural disturbance, in order to avoid massive pay outs – makes no secret of its intention to take over the UK health market. In 2001, UnumProvident launched New Beginnings, a public-private partnership which has been hugely influential in shaping policy, especially in relation to the DWP's Pathways to Work programme. Illness, according to (Unum's) distorted logic, is a dysfunction of the person; the problem of illness is located in the individual's beliefs and behaviour. New Labour's Welfare Reform Act was passed in May 2007. 'Pathways to Work', based on Unum's behaviourist logic, is to be rolled out across the country by 2008. GPs and Primary Care staff will be offered rewards for getting people back to work. All of this is taking place against a wider picture of social control and state repression: as 'the new rulers of the world' (Pilger 2003), the corporations, aided and abetted by media and government, take over and implement health and social policies consistent with their own strategic and economic interests (Noam Chomsky, Failed States, Penguin 2003). These topics however 'scarcely enter into public discussion and the basic facts are little known'. What can be done? It means a day- to- day dedication to the task. It means incredible courage and determination and above all a complete refusal to compromise on the truth that ME is a physical disease"* (this article was posted on Co-Cure ACT, 14th August 2007; see also http://www.onetree93.freeserve.co.uk/resorces.html).

The role of State authorities in disseminating misinformation about ME/CFS and their collaboration in State-sponsored medical abuse of patients

The bed-rock of misinformation about ME/CFS in the UK lies firmly in the hands of Wessely School psychiatrists. For twenty years they have flooded the medical literature

with their own theories dressed up as fact and seem to have ensnared ill-informed and uncritical editors who in turn seem to have paid little heed to the disturbing evidence of bias that has been shown to pervade the peer-review process.

Wessely School members have also financially supported the promulgation of their own views – for example, the meeting at which the Oxford criteria for "CFS" were conceived was financially supported by psychiatrist Peter White and it will be recalled that Peter White is paid by the medical insurance industry, which happens to hold the same interests.

However, the role of State authorities should not be underestimated. Examples of their complicity are provided below.

1. **The Centre for Reviews and Dissemination**

The Centre for Reviews and Dissemination (CRD) is based at York. It was set up in 1994 to provide the NHS with information on the effectiveness of treatments and the optimum organisation of health care. It works to support NICE, which in turn is funded by and responsible to the Department of Health. The CRD is a sibling of the Cochrane Collaboration, a body set up under the UK directorship of (then) Dr Iain Chalmers (a long-term member of HealthWatch, see above) to compile a meta-analysis of clinical trials. Simon Wessely offered himself to and was accepted by the Cochrane Collaboration to be responsible for entries on "CFS/ME".

The CRD collaborates with health information organisations around the world and is a member of the International Network of Agencies for Health Technology Assessment (INAHTA). The CRD plays an important part in disseminating the contents of Cochrane Reviews to the NHS.

Recently, the Cochrane Collaboration was exposed as being corrupted by money and vested interests (Evidence-Based Medicine and the Cochrane Collaboration on Trial; David Cundiff, MD. Medscape General Medicine: 2007:9: (2):56).

The CRD's various review teams trawl through the literature and then produce "Systematic Reviews" which claim to be grounded on "evidence-based" medicine. The team members are not medically qualified and so they have advisers to assist them. In the case of ME/CFS, those advisers included psychiatrist Simon Wessely (whose own database formed the basis of the CRD's work on "CFS/ME") and Professor Anthony Pinching.

The work of the CRD on "CFS/ME" was cogently exposed as flawed in a major Review in January 2006 by Hooper and Reid. The CRD team's deficiencies include apparent "misinterpretation" of the data; discrepancy in their data; the inadequacy of the chosen evidence-base; failure to address their remit; concealment of adverse clinical events (which may constitute research misconduct); anomalies between the first version and the up-dated version of their Review and the skewing and even deletion of information in

order to cast cognitive behavioural therapy (including graded exercise therapy) in a good light.

The suppression of published findings in a Systematic Review is a particularly serious matter. The lead author was persuaded to change her mind between her 2001 article in the Journal of the American Medical Association (JAMA) and her 2005 up-dated Systematic Review for NICE: the same author has remarkably different approaches to the same data in the two documents concerning the recommended psychiatric management regime favoured by NICE (ie. cognitive behavioural therapy and graded exercise). In 2001, she found methodological inadequacy; study withdrawals with high drop-out rates; unacceptability to patients of the regime in question; the exclusion of severely affected patients from all studies; the reported improvements of the management regime may be illusory, with little lasting benefit, and an acknowledgement that the data had been corrupted. These findings were published in one of the world's most prestigious medical journals (JAMA), yet in her Systematic Review for NICE, the same author disowns her own previous findings on exactly the same data; she excludes the many reports of adverse events and signally fails to address the safety and effectiveness of the recommended interventions (a remit with which she was specifically charged).

The Hooper and Reid Review (Inadequacy of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base) can be found at
http://www.meactionuk.org.uk/FINAL_on_NICE_for_Gibson.html

2. **The NHS Information Authority (now the NHS Information Centre)**

One of the routes of dissemination of information within the NHS used to be via the NHS Information Authority (NHSIA). Contrary to the WHO classification of ME as a neurological disorder, the NHS Information Authority listed chronic fatigue syndrome / myalgic encephalomyelitis as a mental disorder in its Mental Health Minimum Dataset Version 2.0 July 2001 on its website.

The NHSIA was responsible for providing correct information throughout the entire NHS, which is the third largest employer in the world.

From 6th April 2003, for over a year written representations were repeatedly made to the NHSIA by Mrs Connie Nelson from Glasgow, the mother of a son with ME/CFS and a committed campaigner on behalf of the ME/CFS community, asking for the erroneous entry on ME/CFS to be removed from the Mental Health Minimum Dataset.

The paper-trail of these communications is demoralising but typical, with correspondence being passed from a "Helpdesk" to the Data Quality and Training Department, to the Coding and Classification Helpdesk, to the Department of Health, back to an "IFPH" Helpdesk, to a Data Quality and Classification Advisor, to the Dataset Development team, to a Data Quality and Classification Programme Manager. None of these agents

addressed Mrs Nelson's complaint that ME/CFS had been incorrectly classified as a mental disorder by the NHSIA.

Upon receiving confirmation from the NHSIA that "*the source of the coding of Chronic Fatigue Syndrome in the Mental Health Minimum Dataset (MHMDS) Data Manual is the WHO Guidance on Mental Health for Primary Care (and) the MHMDS Data Manual will continue to maintain consistency with the provision of the WHO guidance*", Mrs Nelson provided written evidence to the NHS Information Authority confirming that the disorder is not classified as a mental disorder, whereupon she received the following reply from the NHSIA: "*The nature and specification of the data items, which make up the Mental Health Minimum Dataset (MHMDS), are matters for the Department of Health. The Department's view is that it is appropriate for the MHMDS to continue to maintain consistency with the provisions of the WHO guidance*"

At that point, Mrs Nelson accepted that as an individual she was unlikely to make progress on this issue, so she enlisted the help of Tony Wright MP, then Chair of the All Party Parliamentary Group on ME, who contacted the NHSIA on her behalf.

On 12th September 2003 Steven Harrison, Head of Corporate Affairs and Governance at the NHS Information Authority, replied to Tony Wright MP about Mrs Nelson's complaint that ME/CFS was incorrectly coded by the Information Authority: "*This causes an anomaly with the ICD-10. It is this anomaly that the Authority has been trying to clarify with the Institute of Psychiatry, London. Originally, the Institute was going to republish its adaptation of the WHO Guide to Mental Health in Primary Care in May of this year (ie. 2003) but delayed it because of our querying of this classification in question*".

On 10th December 2003 the NHS Information Authority sent another letter to Tony Wright MP in the following terms: "*The issue associated with Chronic Fatigue Syndrome was that the Mental Health Minimum Dataset: Data Manual Version 2.0, July 2001, produced by the NHS Information Authority, has referenced the WHO Guide to Mental Health in Primary Care which, with permission of the WHO, has been adapted by the UK and produced by the Institute of Psychiatry, London, from the Diagnostic and Management Guidelines for Mental Disorders in Primary Care: ICD-10, chapter 5, Primary Care Version, and in this UK adaptation Chronic Fatigue Syndrome has been assigned the code of F48.0 under the chapter for mental disorders. The point made by your correspondent was that this classification of F48.0 for Chronic Fatigue Syndrome was wrong. Within the UK adaptation, the code for Chronic Fatigue Syndrome has been allocated a code within the mental health and behavioural disorders chapter, which conflicts with the main WHO ICD-10 (mandated for use in the acute sector). I hope that the situation now arrived at, whereby the Code G93.3 will be available for Chronic Fatigue Syndrome in the UK adaptation by the Institute of Psychiatry will prove to be an acceptable situation*".

Upon receipt of this information, Mrs Nelson wrote to Steven Harrison, Head of Corporate Affairs and Governance at the NHS Information Authority, pointing out that

merely making the correct code for ME/CFS "available" in the IoP's revised edition of the Guide to Mental Health in Primary Care failed to address her original complaint, namely the misclassification of "CFS/ME" in the Information Authority's Mental Health Data Manual.

It was not until 19th February 2004 that a formal complaint was submitted to the NHS Information Authority by Dr Charles Shepherd on behalf of the ME Association.

For over a year, the issues of the misclassification of ME/CFS by the NHS Information Authority remained unaddressed.

It was not until 18th March 2004 that Steven Harrison of the NHS Information Authority sent a letter in the following terms: "*I have now been able to investigate your complaint fully. The NHS Information Authority will place a note on our website drawing users' attention to the changes within this Guide introduced in February. The website will be updated with the current information by 24th March 2004*".

The Guide to Mental Health in Primary Care

The NHSIA's confirmation that it had taken a decision not to alter the Data Manual on the grounds that the source of the information was the WHO "Guide to Mental Health in Primary Care" and that the Mental Health Minimum Dataset had to retain consistency with that guidance requires clarification.

The "Guide to Mental Health in Primary Care" was produced in 2000 by the WHO Collaborating Centre for Mental Health at the Institute of Psychiatry; it used Wessely's own material on "CFS/ME" and included ME as a mental (behavioural) disorder. The Guide was funded by the Department of Health.

Despite strenuous complaints and despite the WHO ICD-10 classification being mandatory in the UK, sales of the Guide were allowed to continue unabated until almost 30,000 copies had been sold, thereby allowing misinformation to continue to be widely circulated via the Royal Society of Medicine Press.

Eventually an erratum was promised; despite misclassification being the vehicle for entry into this Guide to Mental Health, the erratum slip made no clear statement that ME/CFS is not classified as a mental disorder but merely informed readers of the correct classification code within the WHO International Classification of Diseases. This would mean nothing to many readers. The title of the second edition was changed to "Guide to Mental and Neurological Health" but did not clarify which disorder is mental or neurological in nature, so the fact that ME/CFS remains within a Guide to Mental Health will continue to mislead.

The Department of Health claimed – erroneously – that this was a World Health Organisation problem and declined to intervene.

Confusion arose because the WHO Collaborating Centre at the Institute of Psychiatry was legitimately able to use the WHO logo on the Guide, so people were misled into believing it was an authorised WHO Guide when such was not the case: it was not the WHO itself but the WHO Collaborating Centre at the IoP which had reclassified ME as a mental disorder, based on Wessely's own beliefs. In September 2001 the WHO headquarters in Geneva issued a statement repudiating the unofficial reclassification of ME/CFS by the UK Collaborating Centre.

The ME community had been informed by Matt Smart, Executive Assistant to the Dean of Psychiatry at the IoP that "*The second edition of the Guide (to Mental Health) due for publication in December 2003, has been in preparation for the past 12 months. CFS has been retained. The entry is a consensus section including both the ICD-10 mental health entry (neurasthenia) and the ICD-10 neurology entry (ME)*".

This demonstrated that when they were compelled to accept the WHO ruling that the correct classification for ME/CFS was in the neurological section of ICD-10, Wessely School psychiatrists simply maintained that the WHO ICD-10 itself had classified the same disorder (ME/CFS) in two different places, once in the Neurological Section (G93.3) and again in the Mental (Behavioural) Section (F48.0).

Once again, the claims made by the Wessely School were repudiated by the WHO: on 23rd January 2004 the WHO confirmed: "*According to the taxonomic principles governing ICD-10, it is not permitted for the same condition to be classified to more than one rubric*".
The matter was raised in Parliament on 22nd January 2004, where Earl Howe noted the suggestion that Professor Wessely had "*effectively hijacked the WHO logo to give credence to his own view of ME as a mental illness*" (Hansard [Lords] 23rd January 2004:Vol 656: No 7:1192).

It seemed that nothing would halt the Wessely School juggernaut's determination to eradicate ME and to classify CFS as a mental disorder, which left the ME/CFS community with a serious problem in that ME/CFS remained incorrectly listed as a mental disorder throughout the NHS Information Authority.

The Mental Health Minimum Dataset "*is a nationally defined framework of data on adult mental health patients. All providers of specialist mental health services for adults are mandated to collect the MHMDS*". This seems to mean that all NHS staff have no option but to regard ME/CFS as a mental disorder.

Things became even more complicated in that on 1st April 2005, the NHS Information Authority ceased operation. Some of its work was being continued by the NHS Connecting for Health and some by the Health and Social Care Information Centre (telephone number 0845-300-6016).

On 13th August 2007 a request was lodged with the Information Centre to see if the NHS Information Authority had kept its promise and removed ME/CFS from the Mental Health Minimum Dataset. Previously the public could check for themselves but -- despite New Labour's lip-service to transparency in government – this facility has been removed and access is now only available to NHS staff by using a password. The inquirer was subjected to a barrage of questions which seemed an extraordinary response to a simple request for information: what is your full name (ie. not just the first fore-name); what organisation do you work for; why are you asking for this information; what do you want this information for; what is the particular reason for wanting this information; what journal are you writing for, and more. It seemed ironic that the logo of the channel through which the enquiry had to be made (the Information Centre for Health and Social Care) carries the words "*Knowledge for Care*".

The answer was received on 17th August 2007: "CFS/ME" is still on the Mental Health Minimum Dataset and has definitely not been removed. There are no plans to remove it. This confirmation came from the Higher Information Analyst on the Mental Health team at the Information Centre for Health and Social Care, who was specifically asked if there were any plans to remove it. The inquirer was informed that this information is 100% correct.

A follow-up enquiry to the NHS Information Authority Contact Centre Team at Leeds (ref: IC-05055-TTF2) resulted in the following information on 23rd August 2007: "*The ICD-10 for CFS/ME (G93.3) is correct. It is not specific to the Mental Health Minimum Dataset. The scope of the MHMDS (affects) adults over the age of 18 who are in contact with and / or receiving specialist secondary health care service and are, or thought to be, suffering form a mental illness. Patients with a diagnosis of CFS/ME (G93.3) would only be included within the MHMDS if they were already in contact with secondary mental health services. Please note that there are potentially issues relating to the sensitivity of data reporting for ME that may need to be considered when responding to this request*".

The wording of this response seemed to confirm that patients with ME/CFS who either are or have been attending the "CFS/ME" Centres or who have attended any secondary psychiatric clinic (albeit suffering from a classified neurological disorder) have acquired a mental health label, which could and inevitably would have far-reaching effects for the rest of their life.

Electronic Libraries

Not only was the inclusion of ME/CFS as a mental disorder to be found in the "Guide to Mental Health in Primary Care" and in the NHS Mental Health Minimum Dataset – it was also to be found in the NHS National Electronic Library for Mental Health (see http://www.nelmh.org/index.asp), where the "Mental Health in Primary Care" section is supplied by the WHO Collaborating Centre for Research and Training in Mental Health, Institute of Psychiatry, Kings College, London; "*Chronic fatigue syndrome (CFS or*

CFS/ME)" was listed under "Adult Disorders" between Bipolar Disorder and Chronic mixed anxiety and depression".

The NHS National Electronic Library for Mental Health has now become The Mental Health Specialist Library (http://www.library.nhs.uk/mentalhealth/).

3. **The National Institute for Health and Clinical Excellence (NICE)**

The National Institute for Health and Clinical Excellence (NICE) was set up in 1999 and is funded by the Department of Health, to whom it is accountable. It is not therefore "independent" of the machinery of State.

Its "consultation" processes are, according to Christopher Booker, merely an empty exercise: the Government and its bodies pretend to "consult" those affected by their actions, then carry on doing exactly what they intended in the first place. In other words, the "consultation" period is a farce, as the Government is not remotely interested in looking at the evidence (Sunday Telegraph, 20th June 2004).

As noted by Peter Kemp, topics for the Institute's work programme are selected by the Department of Health, but once a topic has been referred, the development and communication of the subsequent advice is entirely the responsibility of the Institute.

As Kemp noted: *"This seems to suggest that NICE can be told what to do. This does not sound like independence in the true sense of the word. The remit is so heavily loaded that I believe a truly independent institute would reject it out of hand. The remit is effectively telling NICE what to recommend; ie. 'management of adjustment and coping' and 'rehabilitation strategies'. NICE have been told what to recommend for people with CFS/ME and judging from their draft guideline, have complied"* (ME/CFS and FM Information Exchange Forum, 21st November 2006).

It was on 23rd February 2004 that the Department of Health and the Welsh Assembly formally requested NICE to prepare a clinical and service guideline for "CFS/ME". The remit was:

"*To prepare for the NHS in England and Wales, guidance on the assessment, diagnosis, management of adjustment and coping, symptom management, and the use of rehabilitative strategies geared towards optimising function and achieving greater independence for adults and children of (sic) CFS/ME"*.

On 29th September 2006 NICE issued a draft Guideline on "CFS/ME" for consultation. There were many serious problems with the draft Guideline, starting with incorrect and confusing information about the way in which responses to the consultation Questionnaire should be submitted. The problems of terminology and classification were not addressed; some Guideline Development Group members had a published track record of supporting the psychosocial model of "CFS/ME" favoured by the Wessely

School; in clear contravention of the AGREE Instrument (see below), the vested interests of Guideline Development Group members were not declared (including the fact that one GDG member had spent 15 years working for the medical insurance industry and was Chief Medical Officer for a major medical insurance company); due to the narrow confines of the remit, there was a failure to heed the biomedical evidence that disproved the psychosocial model of ME/CFS; the names of the advisers to the Guideline Development Group were withheld (but were later confirmed by Carole Forbes, Systematic Review Project Manager at the CRD, to be the same people who had advised the Systematic Review team at the CRD, which included Simon Wessely, Anthony Pinching and Chris Clark from AfME -- from which Clark resigned in March 2006); the Questionnaire contained a series of "misprints" relating to questions 29-61, making a nonsense of responses to those questions and meaning that answers to over one third of the questions were likely to be erroneous; the way in which answers were to be provided was changed in such a subtle way as to make it unlikely that patients with cognitive impairments would notice, thereby potentially achieving results that respondents did not intend; out of an ME/CFS UK population of between 0.2 to 0.4% (ie. up to 240,000 people), only 399 questionnaires were sent out and out of these, only 219 were completed, rendering such a tiny and unrepresentative response easy for NICE to ignore statistically; the Key Questions upon which the questionnaire was based (in order to fit the NICE scope, the scope being the document that set out what the Guideline will cover) seemed designed to preclude anything other than a psychosocial model; NICE relied upon the Systematic Review provided for it by the CRD at York, when that Systematic Review had already been exposed as flawed, even to the extent that it may have contained research misconduct in that it had deleted previously published evidence in order to cast the management regime favoured by the Wessely School in a good light.

Most importantly, NICE failed to conform to the AGREE Instrument (The Appraisal of Guidelines for Research and Evaluation) which requires that NICE is obliged to give equal weight to three main sources of data: "evidence-based" medicine, usually deemed to be random controlled trials (RCTs); the opinion and experience of physicians with expertise in the area, and the opinion and experience of the patient group for whom the Guideline is intended. This did not happen in its draft Guideline on "CFS/ME".

Despite the fact that the UK medical defence unions have advised doctors that exercise regimes (which form part of a cognitive behavioural therapy programme) must be prescribed with just as much caution as pharmacological interventions, it seemed that NICE may have overlooked the implications of this advice: in its Draft Guideline on "CFS/ME", the only recommended management regime was cognitive behavioural therapy (CBT), including graded exercise therapy (GET) and, for the severely affected, "Activity Management".

For further analysis of the draft Guideline, see the 54 page document compiled on behalf of The 25% ME Group for the Severely Affected: "Some Concerns about the National Institute for Health and Clinical Excellence (NICE) Draft Guideline issued on 29th September 2006 on Diagnosis and Management of Chronic Fatigue Syndrome / Myalgic

Encephalomyelitis in Adults and Children" available online at http://www.meactionuk.org.uk/Concerns_re_NICE_Draft.htm

Other cogent criticisms of the draft NICE Guideline included one submitted by a member of the Association of British Neurologists:

"The draft guideline is fundamentally flawed because it presupposes certain interventions (CBT and GET) to be highly effective in CFS/ME for routine clinical use despite lack of adequate evidence. The Guideline is also selective in its review of existing literature and is heavily influenced by (the) psychiatric view of the condition. Indeed, it almost seems that a select group of psychiatrists with a polarised view of this complex condition is directing the development of the guideline from 'behind the scene'. There has been no review of general and post-exercise pain. The draft guideline reflects an incomplete and psychiatrically polarised view of CFS/ME. The importance of appropriate diagnosis of CFS/ME from common psychiatric conditions has not been mentioned even once. No-where in this guideline have the exclusion criteria for CFS/ME (eg. generalised anxiety disorder, somatisation) been adequately defined and properly discussed. The guideline needs to be thoroughly revised to reflect our current understanding of this condition rather than the supposition of the psychiatrists. It would be immoral for NICE not to recognise the huge dissatisfaction about this draft guideline amongst most patients, carers and clinicians. The guideline should not re-define CFS/ME to 'fit in' CBT and GET as the recommended treatment options. Listen to patients".

A further submission from the Association of British Neurologists said the following:

"(The Guideline Development Group) is tactically promoting Oxford criteria over the more widely used and recognised international CDC (Centres for Disease Control) criteria – again, a clear evidence of psychiatrists' influence on this group".

Referring to a paragraph in the draft Guideline: *"This paragraph deals with a publication (Wessely et al, Lancet 1999) which was published as a HYPOTHESIS and which remains to be proven. However, the GDG seems to have taken it as a matter of fact. Please refer to the criticisms of this article in the Lancet. Being only a hypothesis, (it) is totally irrelevant for the purpose of a dedicated guideline on CFS/ME".*

"The GDG should also be criticised for its total lack of reference to the neurological aspect of fatigue and its overemphasis and over-reliance on the psychiatric literature from a group of psychiatrists".
"With the possible exception of some psychiatrists, most specialists prefer the international criteria to diagnose CFS/ME".

"Clearly there is very little compelling evidence at present that these patients benefit from CBT and GET".

"There is selective omission of research literature on reproducible neuroendocrine tests, with an overemphasis on research data from certain psychiatrists".

Another well-argued criticism was submitted by Dr Derek Pheby, Project Co-ordinator, National CFS/ME Observatory. For some reason, his comments were not published by NICE and he received a communication from the NICE Guidelines Co-ordinator stating: "*A number of comments and responses are still being held by the Institute and are not included in the table. These are comments which may contain defamatory or libellous wording"*. Pheby wrote back: *"Your statement is clearly defamatory of us. This is completely uacceptable, and a serious slur not only upon my reputation but also upon the reputations of the prominent and highly respected academics who are involved in the Observatory project. If you wish to argue that your statement was not intended to apply to us, and that your omission of our comments was in error and unintentional, then this lack of care calls seriously into question the quality of the exercise you have undertaken"*.

Pheby's original comments on the NICE draft guideline included the following:

"The National ME Observatory is a research collaboration, funded by the Big Lottery Fund, comprising the London School of Hygiene and Tropical Medicine, the University of East Anglia, and the Hull-York Medical School. It was established earlier this year (ie. 2006) in order to address the serious problem about a totally inadequate corpus of scientific knowledge about CFS/ME.

"The belief that evidence-based guidelines can be constructed on such an inadequate evidence base is, in our opinion, misguided. Indeed, many of the recommendations in the draft guideline appear not to be evidence-based at all (and) reflect what limited research was carried out in the 1990s and before.

"The draft states: 'When the adult or child's main goal is to return to normal activities, then the therapies of first choice should be CBT or GET'. This is very misleading. It implies that there is a group of people with CFS/ME who may not have as their main goal a return to normal activities. We have never encountered this. It also implies that, of a range of possible therapeutic approaches, CBT and GET are the two which emerge as being the most effective, whereas the reality is that there has been very little clinical trial activity involving other treatment. The statement is also misleading because it does not consider the extent to which outcomes of trials of CBT and GET do not appear representative of the population with CFS/ME as a whole.

Referring to the statement in the draft Guideline that said: *'Healthcare professionals who are responsible for the care of (people) with CFS/ME should have appropriate skills and expertise in the condition'*, Pheby commented: *" What the document does not state is what skills and expertise are appropriate, nor how they are to be acquired. Given that CFS/ME is a relatively common condition, and that a wide range of healthcare professionals are likely to be involved, this has considerable implications for education and training (which) in turn have substantial organisational and resource implications which will have to be addressed.*

"The diagnostic criteria detailed in paragraph 1.2.1.2 do not conform to any existing clinical case definition for CFS/ME and appear to be based on poor evidence.

"CBT and GET should not be regarded as the first choice of treatment or as providing a cure. To put rehabilitation before prevention or early intervention falls short of the patient-centred approach which the draft guidelines claim to be advocating.

"Greater evidence should be placed on medical interventions, including symptom control and improved access by patients to services, information and resources.
"…promoting the use of CBT and GET in severely affected people (is) extremely dubious, since there is a dearth of evidence supporting the use of these approaches in such patients, and plenty of anecdotal evidence, as well as evidence from surveys conducted by patients organisations, of these methods being at best of limited value and at worst damaging. (In relation to the use of CBT and GET in children and the severely affected, the draft guideline) states that 'There is no evidence for the use or effectiveness of these strategies in these two patient groups', and yet the guideline recommends that they may be used in such cases.

"The draft, as it stands, has obvious defects, which make it unsuitable for general application throughout the NHS. It demonstrates lack of understanding of CFS/ME (and) the evidence-base is inadequate to support the conclusions and recommendations made. The review claims to be evidence-based but in fact is mostly based on expert opinion, rather than on evidence. There is no indication that the document reflects a balanced view of expert opinion on CFS/ME. The report gives the erroneous impression that the role of these management options has been satisfactorily evidenced and widely agreed by professional and lay groups involved in this field.

"The recommendations serve only to underline the extent to which the existing evidence base is inadequate.

"We strongly recommend that the draft be rewritten to reflect more accurately the current state of scientific knowledge, and also the views of stakeholders (and) patients' organisations, which do not appear to have been taken much into account. NICE guidance is of such importance in the NHS, and has such huge repercussions on patterns of treatment and care. It therefore needs to be accurate. Where there are differences of opinion among experts, such differences should be reflected in the document".

Following the decision of NICE not to publish his submission in the table of Stakeholder Comments, Pheby commented on an internet group: "*I was dismayed to find that our comments were missing from the published tables of comments, and they have clearly had no influence in the final version. I don't like the implication that our comments may have been defamatory. It may well be that our comments said things NICE did not want to hear, but that's an entirely different matter".*

Other criticisms were submitted, including the following:

The Association for Psychoanalytic Psychotherapy noted the absence of any evidence that CBT is superior to other psychological interventions such as counselling.

The Royal College of General Practitioners (Wales) said: *"A guideline based on dysfunction and disability will inevitably remain focused on rehabilitation rather than on cure and prevention"*.

PRIME (Partnership for Research in ME/CFS) noted the GDG's acknowledgement that there are insufficient studies using outcomes that are important to patients (noted with thanks by the GDG) and that most studies often assess only fatigue and sleep, and that few studies include outcome measures that explore the wider impact of ME/CFS.

These illustrations give an indication of the strength of opposition to the dominant Wessely School beliefs about "CFS/ME".

Report of an "Evidence-based Commissioning Collaboration: Diagnostic Tests for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis" (The Trent Institute Report)

Pending the production of the NICE Guideline, an interim Report was produced by the Trent Institute. This Report was an illustration of the total circularity of the Wessely School influence about ME/CFS that pervades the UK, and was written to support the anticipated NICE Guideline on "CFS/ME".

It was completed on 22nd November 2004 and was produced by the Trent Institute of Health Sciences and Public Health Research, which is a collaboration between the Universities of Leicester, Nottingham and Sheffield in conjunction with other areas including Southampton, Aberdeen, Liverpool, Exeter and the West Midlands. The Evidence-based Commissioning Collaboration (EBCC) is made up of the North East Yorkshire and North Lincolnshire Primary Care Organisation; the North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium; The Trent Commissioning Consortium and the West Yorkshire Primary Care Organisation. All these bodies were collaborating on behalf of their respective Primary Care Trusts. The objective of the Collaboration was to share research knowledge about the cost-effectiveness of service interventions to inform the commissioning process.

The specific objective of this Report was: "*To develop a brief report outlining the current recommendations for the use of diagnostic tests in Chronic Fatigue Syndrome"*.

The Trent Report used the MRC "CFS/ME" Research Strategy (see below) and the much-criticised Royal Australasian College of Physicians Guidelines for CFS. It supported the use of the Oxford criteria for "CFS/ME", which have no predictive validity and have not been adopted anywhere but in the UK.

This Report stated: "*There is widespread controversy surrounding the existence of CFS/ME"*.

The Report's conclusions were that the only laboratory tests recommended for people with "CFS/ME" are those "*aimed at detecting alternative medical conditions*".

At its Steering Group meeting held on 15th November 2004, it was documented that the Trent Report was to present *"a holding position pending the preparation of NICE guidance"*.

It was further documented that "*CFS/ME was not a disease as such"* and that the role of the report's collaborators was to "*educate GPs"*.

It was agreed that Professor Wessely's book should be added to the Report's references (Wessely S, Hotopf M and Sharpe M (1999) Chronic Fatigue and its Syndromes; Oxford University Press).

The Report was supported by Mark Adams, Clinical Network Lead for CFS/ME for South Yorkshire and North Derbyshire, whose comments were: *"The content and conclusions of the report is in line with my understanding of the literature on this subject"*.

It is profoundly disturbing that those involved with this report appeared unaware of the vast body of international literature on ME/CFS that is of a very different nature from their recommended list of references: for them to prepare a realistic report that is fair to patients, that body of literature ought not to have been ignored.

The (finalised) NICE Guideline on "CFS/ME": 22nd August 2007

On 22nd August 2007 the finalised NICE Guideline was published (Chronic fatigue syndrome / myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome / myalgic encepyalomyelitis (or encephalopathy) in adults and children. Turnbull N et al. Royal College of General Practitioners, London, 2007).

Professor Anthony Pinching (the patients' "champion" responsible for the much-criticised Centres that deliver only CBT and GET) is singled out by the Guideline Development Group for special thanks, as is the team from the Centre for Reviews and Dissemination. The Hooper & Reid analysis of the CRD Systematic Review was ignored, which means that the so-called "evidence-base" upon which NICE recommends CBT and GET remains intrinsically flawed, relying as it does on only seven RCTs of dubious quality, all of which exclude children and the severely affected.

However, the final Guideline is like the proverbial Curate's egg: good in parts. It is clear that, to its credit, the Guideline Development Group has taken heed of many submitted representations, but that the Wessely School has retained control of the recommended management strategies, although to nothing like the extent they sought (see below), and that even those management strategies (CBT and GET) have been modified from those

previously employed by the Wessely School (which sought to force patients to change their beliefs and accept that they were not suffering from a physical disorder).

Having been given the remit by the Department of Health, NICE could hardly produce a Guideline saying that the reality is that there is no treatment apart from symptomatic (such as analgesia and anti-emetics), especially for what is clearly an immense and increasing problem. It is a reflection of existing policy that so few management options are available for those with ME/CFS (see the section on the Medical Research Council below).

Some of the helpful points in the Guideline include:

- recognition that the physical symptoms can be as disabling as multiple sclerosis, systemic lupus erythematosus and congestive heart failure and that the disorder places a substantial burden on sufferers, their families, their carers, and hence on society
- recognition that the healthcare professional should acknowledge the reality and impact of the condition (this addresses the fact that up to 50% of GPs still do not accept that the disorder exists)
- recognition that the WHO classifies CFS/ME as a neurological illness at G93.3, noting that some members of the GDG felt that the NICE guideline should recognise this classification but that others felt doing so did not reflect the nature of the illness and risked restricting research into causes and future treatments (the inclusion of the WHO classification seems to reflect a rejection of the Wessely School's determination not to accept the WHO classification, as well as a rejection of the Wessely School's wish to justify their PACE trials funded by the MRC for their psychosocial model of "CFS/ME")
- recognition that there is great variability of symptoms, which may fluctuate in intensity and severity
- recognition that it can cause profound, prolonged illness and disability
- recognition that treatment and care should take into account patients' individual needs
- recognition that people with "CFS/ME" should have the opportunity to make informed decisions about their care and treatment and should participate as partners in all decisions about their healthcare
- recognition that the healthcare professional should offer information about local and national self-help groups and support groups
- recognition that people with "CFS/ME" should have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their current or future care
- every person with "CFS/ME" should be offered assistance negotiating healthcare, benefits and social care systems
- recognition that some people with severe "CFS/ME" may remain housebound
- recognition that there is no pharmacological treatment or cure for "CFS/ME"
- recognition that many people find exclusion diets helpful in managing bowel symptoms

- recognition that rest periods are a component of all management strategies for "CFS/ME"
- recognition that healthcare professionals should work with the person with "CFS/ME" to develop strategies to minimise complications that may be caused by nausea, swallowing problems and difficulties with buying, preparing and eating food
- recommendation that for people with moderate or severe "CFS/ME" a wheelchair, blue badge or stairlift should be considered as part of an overall management plan (this is particularly welcome, as people with a psychological disability will not normally qualify for a blue badge)
- recognition that advice to undertake unstructured, vigorous exercise may worsen symptoms
- recognition that strategies for managing "CFS/ME" should not include an imposed rigid schedule of activity and rest
- if chronic pain is a predominant feature, healthcare professionals should consider referral to a pain management clinic
- people with "CFS/ME" should be advised that relapses are to be expected
- people with severe "CFS/ME" may need to use community services, including nursing and respite care
- recognition that consideration of the aetiology of "CFS/ME" was outside the scope of the Guideline: for that reason, the GDG has not made recommendations about the causes of "CFS/ME" but recommends that research in this area would be very helpful
- recognition of the anecdotal evidence that CBT/GET in children and the severely affected may be harmful or not effective
- recognition that reliable information on the prevalence and incidence of this condition is needed to plan services
- recognition that, when used for patients with "CFS/ME", the aim of cognitive behavioural therapy is to support the sufferer and does not assume that symptoms are psychological (ie. the aim is not to convince patients that they do not suffer from a physical disorder as was the case with the Wessely School regime, which in the Medical Research Council PACE trial still states that CBT '*will be based on the illness model of fear avoidance'*)
- recognition that in "CFS/ME", the aim of graded exercise is to assist the patient to be as independent as possible (ie. not to force patients to "exercise back to fitness": in the MRC PACE trial, GET *"will be based on the illness model of both deconditioning and exercise avoidance"*)
- recognition that in the NICE Guideline, pacing is defined as energy management and the keys to pacing are knowing when to stop and rest by listening to and understanding one's own body (this is anathema to the Wessely School and represents a significant rejection of their beliefs that what they call "body-watching" should be a target for intervention)
- recognition that some peoples' understanding of pacing is as "adaptive pacing therapy" in which people with "CFS/ME" use a management strategy plan, whereas patients' own understanding of pacing is a self-management strategy, and that people with "CFS/ME" generally support this approach

- recognition that there are different stages in the natural course of "CFS/ME"
- recognition of the need for employers and schools to be better informed
- recognition that there should be avoidance of a dogmatic belief in a particular view.

Concerns about the published Guideline

Even though the nature of CBT and GET in relation to "CFS/ME" is explained (and is clearly different from the earlier Wessely School model in which people were admonished to exercise no matter how sick they were and to abandon their "aberrant illness beliefs"), the major problem with the NICE Guideline remains its recommendation that CBT/GET *"should be offered to people with mild or moderate CFS/ME because currently these are the interventions for which there is the clearest research evidence of benefit*".

Not only is this is misleading, because the "evidence" upon which that statement is based has been shown to be seriously flawed as was pointed out to NICE in the clearest terms (the Hooper & Reid report), but some of the recommendations remain offensive to people with ME/CFS, as well as potentially damaging.

For example, reference is still made to *"unhelpful beliefs"*, to "*the relationship between thoughts, feelings, behaviours and symptoms and the distinction between causal and perpetuating factors"* and to the fact that the CBT plan will include "*identifying perpetuating factors that may maintain CFS/ME symptoms"* and will address "*any over-vigilance to symptoms"* (which is contradictory to the Guideline's own recommendation that keys to pacing are listening to and understanding one's own body).

This is wholly unacceptable: it demeans people with ME/CFS and it ignores the substantial evidence (over 4,000 published studies showing underlying biomedical abnormalities) that ME/CFS is not a psychosocial disorder.

It is insufficient for the GDG to claim that consideration of the biomedical evidence did not come within its remit – it was charged with providing guidance on the diagnosis of "CFS/ME", so the literature which demonstrates the clear biomedical aetiology should have formed part of the literature review.

The Guideline acknowledges the Canadian Consensus Definition yet ignores its message. Dr Bruce Carruthers, Fellow of the Canadian Royal College and principal lead of the international expert team that produced the highly respected ME/CFS Clinical Case Definition, states in the Overview:

> *"A hypothesis underlying the use of Cognitive Behaviour Therapy (CBT) for ME/CFS is based on the premise that the patient's impairments are learned due to wrong thinking and 'considers the pathophysiology of CFS to be entirely reversible and perpetuated only by the interaction of cognition, behaviour, and*

emotional processes. The patient merely has to change their thinking and their symptoms will be gone. According to this model, CBT should not only improve the quality of the patient's life, but could be potentially curative'. Supporters suggest that 'ideally general practitioners should diagnose CFS and refer patients to psychotherapists for CBT without detours to medical specialists as in other functional somatic syndromes'. Proponents ignore the documented pathophysiology of ME/CFS, disregard the reality of patient's symptoms, blame them for their illness and withhold medical treatment. Their studies have often included patients who have chronic fatigue but excluded more severe cases as well as those who have other symptoms that are part of the clinical criteria of ME/CFS. Further, their studies fail to cure or improve physiological impairments…"

Further, GDG could not have failed to be aware what the Canadian Case Definition said about the Wessely School model of "CFS/ME" and management regime for it:

"*There is much that is objectionable in the very value-laden hypothesis, with its implied primary causal role of cognitive, behavioural and emotional processes in the genesis of ME/CFS. This hypothesis is far from being confirmed, either on the basis of research findings or from its empirical results. Nevertheless, the assumption of its truth by some has been used to influence the attitudes and decisions with the medical community. To ignore the demonstrated biological pathology of this illness, to disregard the patient's experience and tell them to ignore their symptoms, all too often leads to blaming patients for their illness and withholding medical support"* (page 47).

"The question arises whether a formal CBT or GET programme adds anything to what is available in the ordinary medical setting. A well-informed physician empowers the patient by respecting their experiences, counsels the patient in coping strategies, and helps them achieve optimal exercise and activity levels within their limits in a common sense, non-ideological manner, which is not tied to deadlines or other hidden agenda" (page 49).

The reference to "hidden agenda" could hardly have been lost on members of the Guideline Development Group, yet they chose to sanction the maintenance of such an agenda.

Research that indicates potential dangers of the recommended management regime was ignored

Research that directly impinges on the safety of the NICE recommendations for graded exercise (which was available to the GDG) was also excluded from consideration and / or ignored. This was a serious omission. The AGREE Instrument with which NICE is obliged to comply in the formulation of all its Guidelines is specific: "*The health benefits, side effects and risks should be considered when formulating the recommendations"*. Of particular significance is an important paper that was published in 2005 (well within the

2004 – 2007 life of the GDG's deliberations); that paper demonstrated that exercising muscle is a prime contender for excessive free radical generation, free radicals being highly reactive molecules which can cause damage to the cells of the body. Incremental exercise challenge induces a prolonged and accentuated oxidative stress, and existing evidence has shown a good correlation between muscle pain thresholds on exercise with various blood markers of oxidative injury (Oxidative stress levels are raised in chronic fatigue syndrome and are associated with clinical symptoms. Gwen Kennedy, Vance Spence, Jill Belch et al. Free Radical Biology and Medicine 2005:39:584-589).

The recommended graded exercise plan specifies that the intensity of GET should be incrementally increased, leading to aerobic exercise. This is in direct contradiction to international ME/CFS experts such as Professor Paul Cheney from the US, who in 1999 explained why aerobic exercise should not be used: "*The most important thing about exercise is not to have them do aerobic exercise. I believe that even progressive aerobic exercise, especially in phase one and possibly in other phases, is counter-productive. If you have a defect in the mitochondrial function and you push the mitochondria by exercise, you kill the DNA*" (Lecture given in Orlando, Florida, February 1999, at the International Congress of Bioenergetic Medicine).

Professor Cheney has made a particular study of cardiac anomalies in patients with ME/CFS since the 1980s and emphasises the unassailable tenet that if metabolic demand (as in aerobic exercise) exceeds the impaired cardiac output of ME/CFS patients, even very briefly, the result is death. This information was submitted to NICE and was available to the GDG, including the evidence that 82% of ME/CFS patients have abnormal cardiac impedence and that patients have a high heart rate but a low cardiac output caused by a problem with energy production, with ischaemic changes in the inner ventricular wall. If a patient has abnormal oxygen consumption, muscles will not have enough oxygen and exercise will result in relapse. Patients' ability to work is impaired, as shown unequivocally by an abnormal serial exercise stress test which is 100% objective. This information was ignored by the GDG but impacts upon the recommended management regime.

(For more information on Professor Cheney's cardiac work in ME/CFS, see http://www.meactionuk.org.uk/Klimas_Wessely_NICE_-_Redefining_CBT.htm and for a summary of current research on the cardiovascular anomalies that have been demonstrated in ME/CFS, see
http://www.meactionuk.org.uk/Facts_from_Florida.htm).

Professor Pinching advised adapting the level of activity to levels that can include an incremental increase (page 87 of comments on chapter 1). Pinching also referred to "*the commonest co-morbidities that are well-documented in the literature*" as being depression and anxiety, yet the literature shows such levels to be no higher in ME/CFS than in disorders such as multiple sclerosis.

All these studies and conference reports have direct bearing on the safety of the recommended management regimes and as such, under the terms of the obligatory AGREE Instrument, there can be no credible excuse for NICE to have ignored them.

In endeavouring to justify CBT/GET for use in ME/CFS, the Guideline states: "*an evidence-based psychological therapy is used in many health settings, including cardiac rehabilitation and diabetes management*". This claim has been investigated by numerous people and has been found to be inaccurate, since unlike in ME/CFS, it is used as an adjunct where necessary, not as the first-line treatment of choice across the board. **In no other medical disorder apart from ME/CFS are patients offered exercise as the only "treatment" option.**

Although it is clear that the type of CBT now recommended by the Guideline differs from Wessely's original prescription, it cannot be known whether the CFS Centres set up by Pinching will continue to employ Wessely's version (about which there are so many adverse reports – see the RiME collations) or the more supportive version as outlined in the Guideline, nor is it known who will re-educate and monitor the existing staff in these Centres, which is a matter of real and justified concern.

The Guideline refers (on page 186) to the Wessely School mantra of "*predisposing, precipitating and perpetuating factors in CFS/ME"* as a key area upon which future research should be focused: unless this model of research is applied to all other medical conditions, it is inappropriate for this special pleading to apply only in the case of "CFS/ME" and reflects the Wessely School's discredited assertion that "CFS/ME" is a "faulty belief system" that can be "corrected" by CBT and aerobic exercise. The reality is that more than one Coroner has accepted ME/CFS as the cause of death, based on autopsy findings of severe inflammation of the basal root ganglia.

In line with the Wessely School beliefs, the Guideline restricts investigations that may be performed on those with ME/CFS and it also stipulates that thyroxine must not be administered to such patients, which ignores the evidence of thyroid dysfunction and the fact that basic NHS tests are too blunt to pick up this serious dysfunction.

The Guideline states that no research evidence was found to support the experience of some people with "CFS/ME" that they are more intolerant of drug treatments and suffer severe adverse side effects. There is an abundance of evidence (though not RCTs) from Professor Marty Pall in the US explaining the exact mechanism of such hypersensitivity and it is notable that the Guideline Development Group accepted anecdotal evidence when it suited their aim (for example, acceptance of the "boom and bust" concept, for which there is no RCT evidence), but rejected it in other places (such as Professor Pall's evidence), which is inconsistent.

One patient representative on the GDG who resigned just prior to publication of the Guideline is on record as stating: "*I do believe that the guideline has not fully taken into account the patient and biomedical evidence, because if it had, then it would not be recommending the widespread use of CBT and GET. It is said that patient evidence is*

not given high weighting due to it being biased". If this is true, then it is another illustration of a clear breach of the AGREE Instrument to which NICE is obliged to conform.

The Guideline recommends domiciliary support for the severely affected, yet in a climate of unprecedented financial restrictions offers no reassurance that funds will be available to implement such support.

The NICE Guideline contains examples of carelessness, for instance, the date of reference 50 is given as being "1921" when it should be "2005:19:21:38-43"; there are other incorrect dates.

Another striking example of carelessness is to be found in the table of Stakeholders' Comments and GDG Responses, where inexcusably, many comments from one respondent have been attributed to others, for example, comments submitted by LocalME have been attributed to both Newport Pharmaceuticals Ltd and to North Staffordshire Combined Healthcare NHS Trust.

Evidence that the GDG has not conceded to all the demands of the Wessely School

The Wessely School clearly endeavoured to get its own way (see quotations below from the responses submitted by Simon Wessely and Peter White to the Questionnaire) but on a number of fronts they did not succeed. The Wessely School got all its own way with the 1996 Joint Royal Colleges' Report and were infuriated that patients' views were given such weight in the 2002 Chief Medical Officer's Working Group report; this time, NICE seems to have treated them on the same basis as any other stakeholder among many, to the extent that this NICE Guideline now includes the Canadian definition, in full, over several pages. That is a significant step forwards.

Specifically, the NICE Guideline does not state that "CFS/ME" is a behavioural disorder, a psychiatric illness, a somatic/functional disorder, an illness belief, depression or anxiety.

It emphasises the need for an individualised management plan that should be provided in ways suitable for the individual, and it highlights the importance of shared decision-making between healthcare professionals and patients.

Section 5.5 of the draft Guideline stated: *"a view held by a few individuals on the GDG was that CFS/ME could not be identified or managed unless a broader view was taken"*. This "broader view" was that a "biopsychosocial" approach to ME was required, lumping it together with other states of chronic "fatigue" and thereby affording psychiatrists the right to be involved in the care of all ME/CFS patients, regardless of whether those psychiatrists were needed or wanted. One of the patients' representatives (BRAME) challenged the fact that if only "a few" members of the GDG group held that view, why was their opinion allowed to dominate the recommended management regime?

This seems to have forced the GDG into a remarkable admission: the Guideline does not accept any of the favoured theories of the Wessely School: *"In considering the explanation for CFS/ME, we have followed the report of the Gibson Inquiry, which accepts that there is insufficient evidence to fully substantiate any of the current theories of causation, and that more high quality biomedical research is needed"*.

The conclusions of the Gibson Report were concise:

- *"There is great dispute over the findings and beliefs of Professor Simon Wessely. Many patients believe Wessely and his colleagues are responsible for maintaining the perception that ME is a psychosocial illness. There is conflicting evidence regarding Wessely's true opinions"*
- The Canadian Criteria are *"a useful contribution in defining ME/CFS"*
- *"The opposing opinions about the nature of the disease are very problematic"*
- The Gibson Report refers to *"The inability of some in the medical profession to separate (other disorders) from genuine ME/CFS patients"*
- *"ME/CFS have been defined by the World Health Organisation as neurological illnesses"*
- *"In the UK, precedence has been given to psychological definitions"*
- *"Regarding CFS/ME as a physical illness has been marginalized by the psychological school of thought"*
- *"There have been numerous cases where advisors to the DWP have also had consultancy roles in medical insurance companies. Given the vested interest private medical insurance has in ensuring CFS/ME remains classified as a psychosocial illness, there is a blatant conflict of interest here. The Group finds this to be an area for serious concern"*
- *"The Group was very interested in the international evidence submitted and concerned as to why this evidence has not been seriously examined in the UK"*.

The Gibson Report of November 2006 can be found at:
http://www.erythos.com/gibsonenquiry/Docs/ME_Inquiry_Report.pdf

Professor Richard Baker, Chair of the Guideline Development Group, appeared to express exasperation at the polarised views about the nature of the disorder, saying in the Preface to the Guideline: *"A further problem created by the lack of adequate research evidence is the sometimes widely divergent and hotly contested beliefs about CFS/ME, including those about its cause. In developing the Guideline, we kept in mind the overall goal of improving care for people with CFS/ME, with the patient's preference and views firmly in the driving seat. Rather than aligning ourselves with one or other perspective on CFS/ME, we have sought to provide practical guidance for professionals and patients"*.

Quotations from the responses to the Questionnaire by some Wessely School members

Quotations from Wessely School members demonstrate their determination to claim "CFS/ME" as a behavioural disorder.

Extracts from the submission by Wessely's Chronic Fatigue Research Unit at King's College, London:

"We do not agree with what is written about the care of those with severe disability and CFS, and the best treatment options for that group. For example, it is stated that 'patient experience suggests that some of these interventions may be harmful or ineffective'. We would argue on the basis of our extensive experience that what is being reported in these negative accounts is rarely either CBT or GET. It would be more accurate to state that 'some patients' rather that 'patient experience', since the latter seems to imply that it is all patient experience. It seems likely that the same approach that works in outpatients would also be successful in severely affected".

"We disagree with the numerous statements in the guidelines that patients in the published CBT/GET trials are 'mild to moderate'. Nearly all of the published studies came from secondary or tertiary care. One would expect that these will be patients with high morbidity and the data shows that to be the case". (One can only wonder how Wessely can convince himself that people who are well enough to attend an outpatient department can be described as "severely affected"). *"Overall, this is strong evidence that the published work on CBT and GET concerns those with chronic illness and substantial disability. This needs to be addressed since if this is not corrected, there is a danger that NICE will inadvertently give credence to the oft expressed but erroneous view that CBT/GET only works in those who do not have 'real ME', those who have psychiatric disorders, or who are not very disabled".*

This submission goes on to assert that there is evidence of emotional instability assessed 25 years before the onset of "CFS/ME" and that this *"adds to the existing evidence that personality and depression increase the risk of CFS"* and asserts *"the statement on page 90 (*of the draft Guideline) *should reflect this new and definitive research".*

It is not explained how this relates to people under the age of 25 who develop ME/CFS, which includes children as young as five years old.

The submission states: *"We note the omission of any reference to what is now a well cited and accepted body of research on the role of psychiatric disorders and CFS, which is definitely of interest to clinicians considering treatment options. It is sometimes said that depression or anxiety is merely a consequence of disability. However, there is now a well-replicated body of evidence that shows this not to be the case. It has been established that the rates of psychiatric disorder in the CFS patients are too high to be explained as a simple reaction to disability. Such is the consensus in this area that studies are no longer being performed".*

Commenting on page 134 of the draft Guideline which related to Wessely's own paper in the Lancet (1999:354:936-939) '*CFS has been described as part of a broader condition that includes a range of disorders including fibromyalgia, irritable bowel syndrome etc'*, this submission states: "*True, and this will be well received by many doctors, since it reflects their views and emphasises ways in which we can increase our knowledge of one 'syndrome'*, to which the GDG response was that it accepts the conclusions of the Gibson Report.

<u>The submission from Peter White's Chronic Fatigue Services at St Bartholomew's Hospital</u> said:

"We think it illogical to mix symptoms and disability. We do not think the evidence supports separating severe from very severe. We emphasise that CBT and GET can also help patients who do not wish to return to normal health".

"There are too many symptoms included, which will encourage practitioners to attribute symptoms such as palpitations to CFS/ME".

"The (draft) guideline emphasises the importance of investigations, with little guidance about examining the patient. Examination should include a proper mental state examination. The guideline could usefully provide guidance about illness insights and beliefs".

"The emphasis here would be appropriate for someone suffering from an incurable chronic disease, which CFS/ME is most often not". The GDG response was terse: *"The Guideline Development Group had to balance a positive outlook with the recognition that some people will not recover".*

"Equipment and aids may hinder recovery as much as help it", to which the GDG response was: *"The view of the GDG is that equipment can help to maintain independence".*

In response to the GDG draft text on "recovery" times which said: "*When planning a programme of GET, the health professional should recognise that it may take weeks, months or even years to achieve goals"*, Peter White's Unit stated: "*These goals should include recovery, not just exercise and activity goals*". The comment of the GDG was: "*The statistic indicate that total recovery is relatively rare".*

The GDG draft text on drug intolerance in ME/CFS said: "*Adults and children may experience greater intolerance and more severe adverse / side effects from drug treatment (so) drug treatment used for symptom control should therefore be initiated at a lower dose than usual".* In 1994, at the Dublin International Meeting on CFS (under the auspices of the Ramsay Society and the World Federation of Neurology), Charles Poser,

Professor of Neurology at Harvard and author of the seminal paper "Disseminated Vasculomyelinopathy" which explains the neurological, immunological and vascular components of post-viral states (Acta Neurol Scand 1969: S37:7-44) was categoric that such drug intolerance was one of the most important criteria in (ME)CFS and was "*virtually pathognomonic*" of the disorder. There is also the work of Professor Marty Pall referred to above. However, Peter White's response was: "*We are not aware of any reliable and replicated evidence to support the statement that patients with CFS/ME are more intolerant or have more severe adverse side effects. We do not agree that drug treatment should be initiated at lower doses than usual. This possible myth is repeated within the guideline at various points*".

Commenting on the GDG draft text about anti-spasmodics, Peter White's Unit stated: "*Anti-spasmodics are not treatment for CFS/ME since bowel symptoms are not part of CFS/ME*". Contrary to White's assertions, there is a large literature showing that bowel problems are a key symptom of ME/CFS.

"The advice regarding drug treatment should (not imply that) neuropathic pain and IBS are part of CFS/ME".

"Weight loss is not part of CFS/ME at any age", to which the GDG response was: "*The view of the GDG is that some children may lose weight and require nutritional support*".

"Sometimes acting as an intermediary between a patient and employer may encourage dependence rather than fostering recovery", to which the GDG's response was: *"Facilitating a dialogue with employers about adjustments to work often helps to remove barriers for the patient"*.

"Referral to specialist care should depend on the severity of the disability, not severity of symptoms", to which the GDG replied: *"The GDG considered the wording to be appropriate"*.

Quoting from the draft Guideline that said: *"We need reliable information on prevalence and incidence of this condition to plan services"*, Peter White's response was: *"Do we really?"*, to which the GDG replied: *"The GDG considered the research recommendations to be appropriate"*.

As the above illustrations show, the Wessely School did not succeed in all its demands.

In the light of the submission from Peter White's Unit at Barts, it is noted that on 16th August 2007, St Bartholomew's CNCC (Clinical Network Co-ordinating Centre) issued the following Statement: *"We can confirm that Barts CNCC does not consider CFS/ME to be a psychiatric illness"*.

Evidence that the Wessely School knows that CBT and GET provide no lasting benefit in ME/CFS

Despite their ruthless determination to implement CBT and GET across the board for people with ME/CFS, Wessely School members have previously acknowledged that there is no long-term benefit from CBT, for example:

- at the American Association for CFS (AACFS, now the IACFS/ME) International Conference at Cambridge, Massachussets on 10-11th October 1998, Wessely School psychiatrist Michael Sharpe went on record stating that the benefits of CBT faded with time

- in a personal communication dated 12th October 1998 to Professor Fred Friedberg, Michael Sharpe stated about his often-quoted 1996 study (BMJ 1996:312:22-26) that outcome measures had begun to decline 17 months after treatment termination (quoted in JCFS 1999:5:3/4:149-159)

- on 3rd November 2000, Sharpe again confirmed: "*There is a tendency for the difference between those receiving CBT and those receiving the comparison treatment to diminish with time due to a tendency to relapse in the former*" (www.cfs.inform/dk)

- the very modest benefit in only some patients who have undergone CBT has been shown to last for only 6-8 months and *"observed gains may be transient"* (Long-term Outcome of Cognitive Behavioural Therapy Versus Relaxation Therapy for Chronic Fatigue Syndrome: A 5-Year Follow-Up Study. Alicia Deale, Trudie Chalder, Simon Wessely et al. Am J Psychiat 2001:158:2038-2042)

- in his Summary of the 6th AACFS International Conference in 2003, Charles Lapp, Associate Clinical Professor, Duke University and Director, Hopkins-Hunter Centre, NC, stated about CBT that Dr Daniel Clauw (who had studied 1,092 patients) found that at 3 months there were modest gains, but at follow-up at 6 and 12 months, those modest gains were lost (this being an example of "evidence-based" medicine)

- Wessely himself is on record stating that CBT doesn't work for all: in his Editorial (JAMA 19th September 2001:286:11) he stated that CBT and GET are only "*modestly effective*" and that neither is "*remotely curative*"

- Wessely is also on record as stating: "*It should be kept in mind that evidence from randomised trials bears no guarantee for treatment success in routine practice. In fact, many CFS patients, in specialised treatment centres and the wider world, do not benefit from these interventions*" (The act of diagnosis: pros and cons of labelling chronic fatigue syndrome.

Marcus JH Huibers and Simon Wessely. Psychological Medicine 2006:36: (7): 895-900).

It should not be forgotten that after a course of CBT, there is no objective evidence of improvement (only subjective) and that the transient gains may be illusory (Interventions for the Treatment and Management of Chronic Fatigue Syndrome – A Systematic Review. Whiting P, Bagnall A-M et al. JAMA 2001:286:1360-1368).

Some initial responses to the final Guideline

Action for ME issued a Statement supporting the Guideline: "*We believe that the guidelines represent an opportunity to drive forward the improvement of services for those with ME and it is for that reason we support them*". AfME did note that the Guidelines still contain flaws and "*are still influenced by the history of research in this area, which has produced findings that can not be generalised to all people with ME and which therefore once again place an over-emphasis on cognitive behavioural therapy and graded exercise therapy*".

The response of the Northern Ireland ME Association noted its disappointment that these new guidelines bring us no nearer a cure, and noted that the NHS in Northern Ireland is poorly equipped to implement these new national guidelines.

Invest in ME noted that the reasons why the draft Guidelines were almost universally condemned was due to the poor quality of analysis and their lacking ability to serve the needs of people with ME and their families, and that initial reaction to the final version can be summed up as continued dismay that NICE has again highlighted CBT and GET as the most effective forms of management.

Ellen Goudsmit PhD commented on the confusion, the bias and the inconsistencies in the Guideline; she noted the dominance of the CBT School; the promotion of unproven techniques such as activity management; the lack of recognition of subgroups of "CFS"; the lack of differentiation of ME or CFS from somatisation disorder and the recommendation that CBT should be offered to mild cases, given NICE's interest in saving money, when counselling and self-help may be enough.

Kevin Short of Anglia ME Action quoted Dr Sarah Myhill on the central problem of ME/CFS being mitochondrial failure resulting in poor production of ATP, which shows that CBT, GET and antidepressants are irrelevant in addressing the root cause of this disorder; he feared that scientific and democratic integrity are now dead in the UK, having been sold out by the Government which has placed corporate interests over and above the interests of patients, and he commented: *"To be ill and abused for it is nothing less than a living hell"*.

John Greensmith PhD: replying to an article in the Daily Mail on 23rd August 2007 which said: "*Well thought–out exercise regimes can help patients overcome the debilitating*

symptoms, although there used to be resistance from ME campaigners to psychiatric approaches", Greensmith wrote: *"The NICE report with its lax terminology and its reliance on questionable experimental designs and interpretations, produced by a disproportionate number of advisers with a psychiatric backgrounds – already in favour of and using these treatments – was much too narrow to make any material difference to ME patients. ME sufferers will not, in practice, be treated as equal partners. Things will not change until the biomedical research supported by appropriate funding, comes first"*.

Overall assessment of the Guideline

Overall, this Guideline has accepted much that was submitted by the ME/CFS community. It was, however, limited by the narrowness of its remit: as in all reports about ME/CFS commissioned to support policy, the remit seems to have been deliberately constructed in a way that would achieve the outcome desired by the Wessely School, which meant that a significant amount of published biomedical literature was not considered by the GDG, which is to the continuing detriment of patients.

On the issue of guidance about diagnosis, there can be little doubt that the Guideline has failed those with ME/CFS (although it does recommend biomedical research and does recommend the need for informed discussion around diagnosis). The ignoring of such a significant published body of biomedical abnormalities when those abnormalities clearly assist in diagnosis is indefensible, especially as that body of evidence would be invaluable in distinguishing between ME/CFS and behavioural disorders.

On the issue of "treatment", the Guideline does highlight the need for a range of treatment options to be discussed.

Key questions remain, however. Given that the notion of ME/CFS as a mental disorder has been so assiduously and successfully established in the perception of healthcare professionals and agencies of the State over the last 20 years by the Wessely School (and when something is repeated often enough, it becomes regarded as fact), and given that it is perception that influences people, how much notice will healthcare professionals who are deeply mired in Wessely School misinformation about ME/CFS take of the useful parts of the Guideline?

Will they simply ignore it and carry on as at present, with many of them dismissing ME/CFS as non-existent or as a behavioural disorder?

Will the Medical Royal Colleges accept the Guideline? It is, by definition, only a guideline.
The Wessely School did not accept the findings of the 1994 National Task Force Report and the result was the Joint Royal Colleges' Report of 1996. What will be their response to this Guideline?

Three members of the Wessely School (Peter White, Anthony Cleare and Trudie Chalder) have already made known their plans for future CBT studies in "CFS/ME" to a group of MPs (the Gibson Inquiry) and their belief that CBT can reverse the HPA axis dysfunction seen in ME/CFS.

The Wessely School has already obtained funding for their "Biomedical Research Unit" at the Institute of Psychiatry, which is funding a project called "Emotional Processing in Psychosomatic Disorders". The Section of General Hospital Psychiatry at the IoP was advertising for a psychology graduate to work on the project, which will "*involve working across the Section on Eating Disorders and the Chronic Fatigue Research and Treatment Unit*". The closing date for applications was 13th July 2007. The job reference was 07/R68.

Applicants were informed that "*The Chronic Fatigue Syndrome Research and Treatment Unit receives about 400 referrals per year. The multi-disciplinary team assesses and treats patients with chronic fatigue syndrome and carries out research into both causes and treatment efficacy.* ***Anorexia Nervosa (AN) and chronic fatigue syndrome (CFS) are classical psychosomatic disorders where response to social threat is expressed somatically. Aberrant emotional processing is a strong candidate as a maintaining factor for these disorders****. The post holder will work under the immediate supervision of Professors Ulrike Schmidt (AN) and Trudie Chalder (CFS)*".

Other IoP job advertisements for "CFS" that can be found on the website include one for a "Cognitive Behavioural Psychotherapist" for the Chronic Fatigue Research and Treatment Unit, accountable to Professor Trudie Chalder, which requires the applicant to possess "***the ability to maintain a high degree of professionalism in the face of highly emotive problems, verbal abuse and the threat of physical abuse***" and ***"an understanding of the needs of people with mental health problems****"*.

Will anything really change for hapless ME/CFS patients as a result of this NICE Guideline?

Probably not, as the well-oiled "misinformation machine" was smoothly rolled out by the psychiatric lobby in an Editorial in the subsequent issue of the BMJ (Chronic fatigue syndrome or myalgic encephalomyelitis. Peter White et al. BMJ 2007:335:411-412). Co-authors included Sir Peter Spencer, CEO of Action for ME.

Extracts from the Editorial include the following:

"It is a welcome relief that NICE has just published clinical guidelines on the diagnosis and management of (CFS/ME)".

"What are the main messages for doctors? CFS/ME exists and effective treatments (sic) are available".

"We remain unsure how to classify it".

"Controversy has previously centred around management, and it is here that the NICE guidelines are particularly helpful. Cognitive behaviour therapy and graded exercise therapy should be available, because these treatments 'show the clearest research evidence of benefit' " (referencing the NICE Guideline that relies on the flawed CRD Systematic Review, thus perpetuating the same cycle of misinformation).

"Will the guidelines be useful and can they be implemented? The answers are yes and why not? The guidelines may seem too obvious to be useful, but this view underestimates the previous disagreement about how to help patients. This guidance should remove arguments about whether to provide a service and what such a service should provide".

This commissioned Editorial is a classic example of the manipulative circuitry that is so characteristic of the psychiatric lobby but this time, White does declare his competing interests (which were not declared in the NHS Plus National Policy Guideline) as (i) working with someone who was on the Guideline Development Group for the NICE Guideline, (ii) doing consultancy work for the Department for Work and Pensions, and (iii) working for the re-insurance company Swiss Re.

4. **The Department of Health**

The UK Department of Health is in danger of becoming a department of derision.

In response to a letter about myalgic encephalomyelitis (ME) sent to the Secretary of State for Health (then Dr John Reid), a reply dated 31st March 2004 was sent from the Department of Health on his behalf and was signed by Karen Nicolayson from "Research and Development". On the issue of whether ME/CFS is a physical or psychological disorder, the reply stated: "*The Department of Health is neutral on this issue*".

A look at information previously provided by the Department of Health is revealing because it shows that the above statement is at variance with what is on the public record.

1. ME was recognised as a physical disorder by the Department of Health on 27th November 1987 (see Hansard (House of Commons) for 27th November 1987, column / page 353).

2. In an undated begging letter shortly after this (distributed under the auspices of the UK ME Association) signed by Professor James Mowbray (Professor of Immunpathology at St Mary's Medical School, London), he wrote "*In November 1987 ME was recognised as an organic disorder by the Department of Health.* I know the feelings of frustration and anxiety felt by ME sufferers. If you will help, I know research is the best way to find the answers".

3. In 1988 there was an Early Day Motion (EDM) on ME in the House of Commons; it stated: *"That this House strongly condemns the Yorkshire Television programme 'Where there's life' broadcast by the Independent Broadcasting Association on Wednesday 8th June 1988 on the illness myalgic encephalomyelitis: agrees that the programme was based on inadequate and ill-informed research: questions the motive of the programme: concludes that such a programme debases the reputation of Broadcasting and betrayed the thousands of sufferers throughout the country who suffer from the terrible illness, Myalgic Encephalomyelitis"*. One of the signatories to that EDM was Dr John Reid (former Secretary of State for Health).

4. The ME Sufferers' Bill was presented to the House of Commons by Jimmy Hood MP on 23rd February 1988 and passed its first reading unopposed. The second reading was on 15th April 1988. The Bill asked for an annual report to Parliament: *"It shall be the duty of the Secretary of State (for Health) in every year to lay before each House of Parliament a report on the progress that has been made in investigating the causes, effects, incidence and treatment of the illness known as ME"*. Hansard (House of Commons) for 23rd February 1988 at columns 167-168 records *"There is no doubt that ME is an organic disorder. The sufferers are denied proper recognition, misdiagnosed, vilified, ridiculed and driven to great depths of despair"*.

5. In one of her published diatribes on ME sufferers, journalist Caroline Richmond (who, together with Nick Ross -- recently retired from the BBC CrimeWatch -- was one of the founders of HealthWatch), stated: *"Myalgic encephalomyelitis is the first and indeed the only disease legally recognised in Britain, thanks to a private member's Bill passed in 1988*" (Myalgic Encephalomyelitis, Princess Aurora, and the wandering womb. BMJ 1989:298:1295-1296).

6. On 16th August 1992, Stephen Dorrell MP, Minister of Health, went on public record confirming that *"ME is established as a medical condition"* when he addressed a meeting of the Leicestershire ME Group.

7. On 18th January 1996, the official view of the Department of Health was set out in a letter to Geoffrey Clifton-Brown MP in terms: *"The Government accepts that ME/CFS can follow a post-viral infection"*. This letter was signed by Baroness (Julia) Cumberlege in her capacity as Parliamentary Under Secretary of State for Health.

8. A letter dated 30th May 2001 from the Department of Health signed by Linda Percival of the Health Services Directorate (ref: TO 2001 / 15353) states: *"To improve services for people with long-term illnesses, the Government recently announced a National Services Framework (NSF). The NSF will have a particular focus on the needs of people with neurological disease. It is very likely that chronic conditions such as ME/CFS will be included"*.

The information on the National Service Framework merits more scrutiny, because by letter dated 8th June 2001, Chris Clark, former CEO of AfME, wrote: "*I had been told ME was definitely NOT to be included in the neurological NSF. If this message is true* (ie. the one referred to above from Linda Percival at the Health Services Directorate) *it is sensational"*. Who told Mr Clark that ME/CFS was not to be included or accepted as a neurological disorder? Was it the Wessely School psychiatrists, with whom he so closely co-operated? Was it because the psychiatric lobby would not tolerate any departure from their own agenda to reclassify ME/CFS as a behavioural disorder?

In its magazine ME Essential, Spring 2005, issue 94, the ME Association said: "*Launch of the new National Service Framework. The new NSF for people with long-term neurological conditions was launched by the Department of Health on March 10 (ie. 2005). The NSF sets standards of treatment, care and support across health and social care services. Diane Newman, ME Association Trustee, commented: 'This particular NSF focuses on neurological conditions and ME/CFS falls in that remit' "*.

In case further confirmation is needed, it is provided in Hansard for 6th March 2006 (HC: Column 1200W), where the Under Secretary of State for Health, Liam Byrne MP, stated categorically: "*National Health Service organisations are expected to demonstrate that they are making progress towards achieving the level of service quality described in the National Service Framework (NSF) for long-term conditions. The NSF sets out a clear vision of how health and social care organisations can improve the quality, consistency and responsiveness of their services and help improve the lives of people with neurological conditions,* ***including CFS/ME****"*.

Yet more confirmation was provided on 12th May 2006 by Ivan Lewis MP, Parliamentary Under-Secretary of State at the Department of Health: "*Those most severely affected by chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) have access to the full range of health and social services support as outlined in the National Service Framework for long-term conditions (NSF)"* (Hansard, 12th May 2006).

From the above, it can be seen that the Department of Health is not "neutral" about ME/CFS as claimed on behalf of the then Secretary of State Dr John Reid.

What can be clearly seen is that either the Department of Health does not know what it is doing from one day to the next or, on no good evidence, it has allowed itself to be overly influenced by the psychiatric lobby. This makes its present unquestioning acceptance of the Wessely School's expediently constructed psychiatric paradigm all the more culpable, because although people are justified in relying implicitly on these documents from the official bodies quoted above, they are being badly let down when they attempt to do so.

It is certainly the case that in his post as Parliamentary Under Secretary of State for Community Care at the Department of Health, Dr Stephen Ladyman MP, grossly misled both MPs and the public: it was he who by letter dated 7th October 2003 (ref: PO 1036444) stated in support of Professor Wessely's personal view that: "*The WHO ICD-10 classifies CFS in two places; as neurasthenia / Fatigue Syndrome on the mental health*

chapter (F48.0) and as Postviral Fatigue Syndrome / Benign Myalgic Encephalomyelitis in the neurology chapter (G93.3). The WHO has essentially put the same condition in both places".

A letter of 31st March 2004 from Karen Nicolayson at the Health Services Directorate concedes this to be erroneous: *"I confirm that the World Health Organisation (WHO), the WHO Collaborating Centre and the Department of Health have now agreed a position on the classification of CFS/ME (and it) has been indexed to the neurology chapter".*

In view of what the Department of Health has previously stated about ME/CFS, and given the formal confirmation on 11th February 2004 from the Health Minister (Lord Warner) that the correct classification for ME/CFS is as a neurological disorder at G93.3 in ICD-10, and given that the National Service Framework specifically includes ME/CFS as a long-term neurological condition, what more clarification is needed to persuade the UK Departments of State and their supporting agencies that ME/CFS is not a mental disorder?

NHS Plus Policy Guidance

Despite what is on record from the Department of Health, in October 2006 and without waiting for the NICE Guideline to be published, a section of the same Department (NHS Plus) published a Policy Document entitled "Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline" (ref: 2006/273539 / DH Publications).

This is yet another Report that fails the ME/CFS community as it is likely to have a devastating impact upon those with ME/CFS who are of working age. It is based on Wessely School psychiatric bias and misinformation and comprehensively ignores the vast biomedical literature about ME/CFS.

The Guideline Development Group included Wessely's colleague Professor Trudie Chalder, a behaviour therapist, and Chris Clark, who until April 2006 was Chief Executive Officer of the charity Action for ME. It was he who in January 2002 announced his intention to collaborate with Professors Simon Wessely and Michael Sharpe (Lancet 2002:359:97-98). For most of the time the NHS Plus policy guidance was in preparation, its Guideline Development Group had no patient representative (as required), nor any physicians holding a view of the disorder other than psychiatric.

The two external assessors were Wessely School psychiatrists Peter White and Michael Sharpe, both of whom believe that "CFS/ME" is a behavioural disorder.

Under "Conflicts of interest", the NHS Plus Guideline states: "*none declared*", yet the two external assessors (Sharpe and White) are long-time medical advisers to the insurance industry and White does consultancy work for the Department for Work and

Pensions, so failure to declare such obvious conflicts of interest would seem to be a serious matter.

Also of concern is that the searches upon which so much reliance is placed are limited to those that will deliver the desired outcome: *"Due to time and resource limitations, the "grey literature" on CFS* (ie. international research conferences) *was not comprehensively searched. The two external assessors are experts in the field of CFS and they indicated that they were content that all relevant research had been identified in the review*".

Unsurprisingly, this National Guideline states: "*in the past 20 years, the medical profession has increasingly come to recognise that the symptoms of individuals with CFS are not readily explained by recognisable organic disease*".

It concludes that the two treatments for which there is the greatest weight of evidence are CBT and GET and its "Key priority for implementation" states: "*Ill health retirement should be deferred until CBT/GET has been explored"*.

Peter White is well-known for his belief that medicine is currently travelling up a "blind alley" by following the biomedical approach and he believes that the biopsychosocial approach is the way forwards. Whereas the biomedical model accepts that ill-health is directly caused by diseases and their pathological processes, White and other members of the "Wessely School" prefer the psychosocial approach which incorporates thoughts, feelings and behaviour --- they believe it is what they deem to be "aberrant" beliefs that result in and perpetuate ill-health (see http://www.meactionuk.org.uk/PROOF_POSITIVE.htm).

The timing of the appearance of these documents seems to indicate a co-ordinated tactical strategy by the psychiatric lobby to achieve its aim of widespread implementation of psychotherapy for patients with "CFS/ME" via national guidelines.

NHS Plus issued three leaflets promoting its Policy Document, all claiming to be "evidence-based"; they are intended for employers, employees and healthcare professionals. The Policy Document itself and the three promotional leaflets all fail to present a balanced view of ME/CFS and reflect unequivocal support for the Wessely School psychosocial model of the disorder. All failed to state that the correct WHO classification for ME/CFS is neurological.

Importantly, the Policy Document is at odds with the National Service Framework, which accepts ME as a chronic, long-term neurological disorder.

In a joint Statement, twenty-five ME organisations comprehensively condemned the NHS Plus Guidance on the grounds that it was foolhardy and reckless and was unfit for purpose.

At the All Party Parliamentary Group on ME (APPGME) meeting held at on 17th May 2007 at the House of Commons, Dr Ira Madan, an Occupational Health Consultant and Director of the NHS Plus project that produced the guidance, was the main speaker.

She confirmed that one of the psychiatrist assessors had been recommended by Chris Clark of AfME and that Mr Clark had signed the guidance in March 2006 shortly before he left the charity in April 2006.

She confirmed that the group had used the Systematic Review prepared by the Centre for Reviews and Dissemination at York as the basis for its literature review.

Because of the legitimate concerns that had been expressed, Dr Madan agreed to meet a single representative from both the ME Association and from Action for ME, saying that if more than two people turned up, she would refuse to see anyone at all. Dr Madan made it clear that the Policy Document itself would not be changed but that she might consider amendments to the three promotional leaflets. This seemed to some people to be little more that a placatory gesture that would have no impact on the published Policy Guidance itself and would therefore serve little practical purpose.

From Statements issued by AfME on 17th August 2007 and by the ME Association on 20th August 2007, it is known that this meeting with Dr Madan was attended by the Chairman of the ME Association, Neil Riley, and Sir Peter Spencer, CEO of AfME and that it took place on 16th July 2007 at the Royal College of Physicians in London. It seems that Dr Madan appeared receptive to a number of proposed amendments to the three NHS Plus leaflets and she later sent a revised draft of each leaflet to both the ME Association and AfME.

The ME Association believed that any approval of Dr Madan's amendments must have the support of a majority of the twenty-five organisations that had signed the original joint Statement of concern. This was not acceptable to Action for ME, who informed the ME Association that AfME would not be constrained to comments that had the majority support of those who had signed the original Statement and that AfME would be issuing its own Statement. According to the ME Association, AfME's Statement intimates that AfME had throughout taken the lead in dealings with NHS Plus and that it was their own evidence that had resulted in a revision of the text of the leaflets. There was no mention of the joint approach of the 23 other ME organisations, and in effect AfME was reserving the right to act as it thought fit. The ME Association believed that a combined response would be more persuasive to Dr Madan.

It is not the first time that AfME has publicly taken credit for the work of others, having in the past claimed outright success for improvements in the ME/CFS situation that had in reality been achieved by behind-the-scenes hard work of others who sought no credit, and misleading information in this regard is still to be found on AfME's website.

The present situation about the leaflets is that discussions are on-going: to date, some of the more flagrant misinformation has been adjusted, and instead of referring throughout

to "CFS", the term used is now "CFS/ME". However, it seems that the glowing recommendation for CBT/GET is to remain and the "evidence" for CBT is given a Grade A listing (which means "*a body of high quality evidence demonstrating overall consistency of results"*). The leaflet for healthcare professionals still claims: "*CBT was significantly more likely to lead to full recovery (sic) with fewer relapses, than was a programme of relaxation*".

5. **The Department for Work and Pensions**

Like the Department of Health, the Department for Work and Pensions has a record of inconsistency in its pronouncements about ME/CFS.

In the British Library Current Awareness Topics Update for March 2000 is listed (on page 6) the following: *"Social Security Ruling, SSR 99-2p; titles II and XVI; evaluating cases involving chronic fatigue syndrome (CFS). Fed Regist 1999 Apr 30;64(83);23380-4:"In accordance with 20 CFR 402.35(b)(1), the Commissioner of Social Security gives notice of Social Security Ruling SSR 99-2p. This Ruling clarifies disability policy for the evaluation and adjudication of disability claims involving Chronic Fatigue Syndrome (CFS). This Ruling explains that, when it is accompanied by appropriate medical signs or laboratory findings, CFS is a medically determinable impairment that can be the basis for a finding of "disability". This Ruling ensures that all adjudicators will use the same policies and procedures in evaluating disability claims involving CFS, and provides a consolidated statement of these policies and procedures".*

This was reported in the Disability Rights Bulletin, Summer 2000 in the following terms***:*** *"In assessing DLA higher rate mobility component for people with ME, recent guidance advises decision makers to assume in the vast majority of cases that the claimant has a physical disablement. The Commissioner, in CDLA/2822/99, held that an award of the higher rate mobility component can be made on the basis of the physical element of the condition. Guidance (DMG Memo Vol 10-3/00) advises decision makers that, in the vast majority of claims, if a doctor says the claimant has ME or CFS then that can be taken as an opinion that they have a physical disablement".*

On 5th June 1991 the UK Attendance Allowance Board Secretariat at The Adelphi, 1-11 John Adam Street, London WC2N 6HT (which works in close liaison with the Department of Health) sent a letter signed on behalf of Mrs CV Dowse that confirmed: *"Recent research indicates that ME must be a physical reaction to some type of virus infection".*

By letter dated 13th March 1992 to James Pawsey MP (ref: POH (3) 2484/200), in his capacity as Parliamentary Under Secretary of State for Health, Stephen Dorrell MP set out the official view on ME of the Department: referring to the Disability Handbook produced by the Disability Living Allowance Board, Mr Dorrell stated: *"The Handbook recognises that in some persons with ME there is evidence of persisting viral infections in*

muscles, with some evidence of muscle damage. Hence, a physical cause for ME is recognised".

In a letter dated 15th March 1992, this exact view was repeated by the late Nicholas Ridley MP, who wrote to a constituent that: *"The Disability Living Allowance Board recognises that in some persons with ME there is evidence of persisting viral infection in muscles, with some evidence of muscle damage. Hence, a physical cause for ME is recognised".*

Notwithstanding the above, the ME community in the UK will doubtless be aware of the publication of the fourth edition of "Fitness for Work – The Medical Aspects" edited by Keith T Palmer, an MRC Clinical Scientist (Oxford University Press, March 2007), to which Professor Mansel Aylward has contributed a chapter entitled "Support and Rehabilitation – Restoring Fitness for Work".

For more information about the detrimental role played by Mansel Aylward in relation to ME/CFS, both in his former capacity as Chief Medical Adviser, Medical Director and Chief Scientist at what is now called the Department for Work and Pensions and in his current posts as the first Chair in Psychosocial and Disability Research at Cardiff University and Director of the UnumProvident Research Centre for Psychosocial and Disability Research (which Aylward has developed with a £1.6 million grant from UnumProvident) see
http://www.meactionuk.org.uk/Wessely_Woodstock_and_Warfare.htm and
http://www.meactionuk.org.uk/HOOPER_CONCERNS_ABOUT_A_COMMERCIAL_CONFLICT_OF_INTEREST.htm and
http://www.meactionuk.org.uk/PROOF_POSITIVE.htm

The back cover of the book says: *"This edition also reflects the current government emphasis on a more holistic approach to health problems in employment and initiatives to encourage people to stay at work, rather than supporting them in the benefits system".*

In this guide, Chapter 6 is entitled "Specific Neurological Disorders" and is written by Richard Hardie and Robert Willcox. Hardie is Director of Neurorehabilitation at St George's & Atkinson Morleys Hospitals, London. Willcox is an Occupational Health Consultant; he is also the Managing Director of One-Click Health, an internet tool for managing short term sickness absence. The use of the term "*specific* neurological disorders" in relation to "CFS/ME" implies that the authors do not regard it as a genuine neurological disorder and this is borne out by their text, which is based on a psychosocial model, not a neurological model.

In what seems to be remarkable defiance of the WHO ruling that dual classification of the same disorder is not permitted as it is contrary to taxonomic principles, "Chronic Fatigue Syndrome" also appears in chapter 7, which is entitled "Mental Health and Psychiatric Disorders (Common Psychiatric Disorders)". Chapter 7 is written by Martin Deahl and Eric Teasdale. Deahl is Consultant and Senior Lecturer in Psychological Medicine at St Bartholomew's Hospital, London (where Peter White works). Teasdale pursued a career

in Occupational Medicine and became Manager of the Occupational Health function in the Pharmaceuticals business of ICI. He is currently Chief Medical Officer for the pharmaceutical company AstraZeneca (see below for information about AstraZenca's funding of the Science Media Centre, a body that controls the scientific / medical information that the UK media may report and whose Scientific Advisory Panel includes Simon Wessely).

The following are quotations about "Chronic Fatigue Syndrome" from chapter 6 ("Specific" neurological disorders) on page 145:

"The incidence rates of chronic fatigue syndrome, myalgic encephalomyelitis or ME, and fibromyalgia have risen. This is likely to reflect fashions in diagnostic labelling"

"Prognosis depends on patients' beliefs, together with coping skills and not focusing on symptoms"

"Chronic fatigue (sic) is strongly associated with psychological distress without evidence for genetic co-variance"

"The GP or specialist therapist needs to be encouraged to persist with energetic treatment"

"Therapies for chronic fatigue syndrome (sic) that show promise are cognitive behavioural therapy and graded exercise therapy, the latter being more than a simple recommendation to exercise but involving a specific graded programme"

"It is crucial to consider co-morbidity in all forms of fatigue (sic)"

"Medical retirement is rarely if ever justified particularly in the light of current knowledge of permanence as a required criterion".
The references in support of this chapter include papers by psychiatrists Simon Wessely, Matthew Hotopf and Michael Sharpe.

The following are quotations from chapter 7, which includes "Chronic fatigue syndrome (CFS or ME G93.3)" under "Common Psychiatric Disorders" on page 158:

"There are several definitions of Chronic Fatigue Syndrome, all of them require an illness that lasts at least six months, impairs daily activities in the absence of any abnormal physical examination findings and laboratory investigations"

"Co-morbid depression and other psychological disorders are common"

"Contrary to stereotype, chronic fatigue (sic) often improves spontaneously and effective treatment does exist, and the successful management of CFS with a good outcome is possible"

"Crucially, the patient's attitude towards treatment is important"

"Graded exercise and cognitive behavioural psychotherapy are of proven efficacy in the treatment of CFS"

"Lack of motivation can be a problem for the treating physician as well as the patient"

"It is important to resist applications for ill-health retirement for at least two years following a diagnosis of CFS/ME (sic). If the possibility of there being an option of retiring on health grounds is voiced, this is likely to impair progress".

No references are provided in support of these assertions. "Resources" are stated as being the charity MIND (National Association for Mental Health) and The Samaritans.

It seems evident that by deliberately including the same disorder under two different classifications against the specific mandate of the WHO, the psychiatric lobby remains obdurate in its determination to subsume ME under "CFS" and eventually to succeed in classifying "CFS" as a "Common Psychiatric Disorder".

For how much longer can the State countenance supporting these psychiatrists and allow them to sweep aside the irrefutable research evidence-base that clearly has no impact on their reasoning but which equally clearly proves both parties to be wrong?

<u>The latest (July 2007) DWP Guidance about "CFS/ME" for Decision-Makers</u>

It seems that the State has no intention of discontinuing support for the Wessely School. Professor Peter White is in charge of the section on "CFS/ME" in the new Department for Work and Pensions (DWP) Guidance on "CFS/ME" for decision-makers. The guidance has been through no less than ten revisions in "consultation" with ME sufferers' representatives and charities. The final version was published in July 2007. It will adversely affect applications for Disability Living Allowance and Carer's Allowance because it is heavily biased in favour of the Wessely School's psychosocial model of "CFS/ME".

The ME Association has been in negotiation with the DWP about this guidance for over two years in an attempt to produce guidance that is free from psychiatric bias and which properly reflects the spectrum of ill-health and disability experienced by those with ME, especially those who are moderately or severely affected. The ME Association has made it clear that previous drafts of the guidance have been unfit for purpose and would do nothing to improve the current situation whereby far too many people with ME/CFS are having to go to appeal over their application for DLA.

Under current UK law, a claimant cannot be eligible for the higher rate of the mobility component of the Disabled Living Allowance unless their disability is classified as

"physical", and the Guidance does state that for this purpose, CFS/ME is a "physical" disorder.

However, the DWP has previously advised its decision-makers that it is not the name or nature of a disorder by which claimants qualify for benefit, but the degree of assistance needed, and on that crucial score, patients with "CFS/ME" are unlikely to qualify, apart from a very small number who have become de-conditioned through inactivity.

Despite the DWP having declared "CFS/ME" to be a "physical" disorder for this purpose, all the major UK patients' charities – including Action for ME -- have unanimously condemned this DWP guidance.

The guidance states that CFS is also known as ME and although there is some difference of opinion over whether ME is different from CFS, most authorities refer to the condition as "CFS/ME". It states that there is no evidence of persistent infection. It quotes the Wessely School mantra: "*Certain factors may be important – these are usefully divided into predisposing, triggering and maintaining factors. Other factors may help to keep the illness going, for example, a concurrent mood disorder*". The guidance recommends cognitive behavioural therapy and graded exercise therapy: "*People are encouraged to view symptoms as reversible rather than evidence of a disease process, by trying out a programme of graded activities, which help to challenge these beliefs. Addressing fears and re-interpreting symptoms allows the person to make a gradual improvement in their level of functioning*".

Action for ME rejected it on the basis that too much weight has been given to a small number of random controlled trials which have made invalid claims about the effectiveness of cognitive behavioural therapy and graded exercise; that the experience of patients and non-psychiatrist clinicians has been ignored and that it is inconsistent with the Government's own policy, including the National Service Framework for Long Term Conditions.

The ME Association also rejected this DWP guidance on the basis that reliance on the guidance will mean that few people with either moderate or severe ME will qualify for benefit and because the guidance provides an uncritical and unbalanced view of behavioural approaches to management (ie. it favours cognitive behavioural therapy and graded exercise therapy). The ME Association statement of 11th July 2007 says "*We fear that this new guidance is going to make the current unacceptable situation even worse for people with moderate or severe ME/CFS. We cannot therefore endorse the new medical guidance*".

The Young ME Sufferers Trust also rejected the new guidance on the basis that it is misleading and potentially damaging to people with ME due to the continued dominance of (its CFS/ME) advisers. This statement notes the persistent blocking of all efforts to include in the guidance the WHO classification of ME as a neurological disease, even though the Department of Health (supposedly) recognises WHO classifications. The statement also notes that physical abnormalities revealed in many studies have been

ignored, so the guidance fails to recognise that mobility needs are not just the result of "tiredness". The Trust places on record that in meetings, it drew the attention of the DWP to the good evidence of persisting infection which would suggest that such infection is responsible for the continuation of the illness, and that by omitting such a fact, the DWP perpetuates the biopsychosocial model of "CFS". The Trust's Statement says: "*We are forced to conclude that it is on the basis of sloppy science and bias that Benefits Decision Makers are being asked to work*"

The 25% ME Group for the Severely Affected rejected it most strongly because it fails:

- to state how serious, how chronic and how progressive ME is, especially for those severely affected
- to acknowledge that graded exercise therapy is harmful / unhelpful to a high proportion of ME sufferers
- to acknowledge that ME is not caused by abnormal illness beliefs
- to acknowledge that ME cannot be diagnosed without physical (neurological) signs
- to acknowledge the numerous physiological and biochemical abnormalities found in ME
- to acknowledge that many ME patients actually have more derangement of the brain on a biochemical level than Parkinson's or Alzheimer's patients
- to acknowledge that although there is no single definitive test, there is an abundance of research which shows that ME is an organic illness which can have profound effects on many bodily systems
- to acknowledge that cycles of severe relapse are common, as are the development of further symptoms over time. Around 30% of ME cases are progressive and degenerative and sometimes ME is fatal
- to acknowledge that all autoimmune disorders have a female preponderance due to hormonal influences
- to acknowledge that there are serious cardiac issues in ME
- to describe the need of the severely affected for help with washing, toileting, food preparation, feeding, drinks, housework and medication
- to acknowledge that the person with severe ME requires care 24 / 7
- to acknowledge that the person with severe ME spends their day in great suffering.

The Statement concludes: "*The (DWP) document is irresponsible and inaccurate. (It) will probably endanger lives, either because sufferers will be too ill to fight to obtain their benefits or they will be given an unsatisfactory level of award, meaning that they will not be able to pay for the care that they so desperately need. The DWP has consistently failed to take account of the appropriate, informed research into the physical basis of this illness*".

The situation with regard to Incapacity Benefit is no better. As Jonathan Rutherford pointed out in his article "New Labour and the end of welfare" (http://www.compassonline.org.uk/article.asp?n=563), key advisers to Departments of

State include those who believe "*illness is a behaviour (and incapacity benefit) trends are a social cultural phenomenon rather than a health problem. The solution is not to cure the sick, but a 'fundamental transformation in the way society deals with sickness and disabilities'. No-one who is ill should have a straightforward right to Incapacity Benefit".*

In 2008, Incapacity Benefit will be replaced by an Employment and Support Allowance. 'Customers' who fail to participate in work-focused interviews or to engage in work related activity will lose benefits.

In its magazine ME Essential of October 2004, the ME Association said: "*The proposals would force those who claim Incapacity Benefit to have a medical check-up every three months and to undergo 'continuous assessment'. Mrs Mary Daley, a member from Lincoln, wrote: 'I claim the benefit and find the annual review stressful enough. These changes amount to harassment of very ill people. ME sufferers have a hard enough time claiming their rightful benefits, and then to be physically and mentally tortured in this way is a terrible prospect' ".*

Such people may be too sick to take on board just what is happening and just how disastrous the consequences may be for them.

All this augers particularly badly for those with ME/CFS, especially as it is now known that ME/CFS has been specifically targeted in order to de-legitimise it in order to save society's resources and medical insurance company profits.

6. **The Medical Royal Colleges and The Royal Society of Medicine**

The Joint Report of the Royal Colleges of Physicians, Psychiatrists and General Practitioners on Chronic Fatigue Syndrome, October 1996 /CR54, published by the Royal College of Physicians

Ostensibly from the Academy of Medical Royal Colleges, this Report was written to oppose the 1994 Report of the UK National Task Force on Chronic Fatigue Syndrome, Postviral Fatigue Syndrome and Myalgic Encephalomyelitis that had been funded by the now defunct charity Westcare and the Department of Health; that Report found ME to be a distinct and particularly severe subgroup of "CFS", with patients suffering exhaustion, pain and malaise, together with other distressing symptoms including loss of balance, painful hypersensitivity to the touch of bedclothes, daylight or the sound of a human voice, bladder problems, vasomotor instability, bowel disturbances, palpitations and breathlessness, episodes of collapse with shaking, food intolerances and seizures.

The Task Force Report was compiled by group of distinguished clinicians and scientists from backgrounds including molecular pathology, immunology, neurology, paediatrics, pharmacology, cancer epidemiology and infectious diseases, who were unequivocal that *"the picture is complicated by selection and observer bias"*. In his Foreword, the Task

Force Chairman, the late Dr David Tyrell, CBE, FRS, DSc, FRCP, FRCPath said: "*We have no doubt that such a condition exists"* and referred to the problem of nomenclature, stating that this is not just a semantic problem but that it "*encompasses serious disagreements which have sadly led to ill-will and abusive remarks as (to) whether the syndrome exists. Some doctors continue to believe that (it) does not exist. We should be prepared for the long haul. It will be years before the chronic fatigue syndrome(s) are conquered comprehensively"*.

The main conclusions of the Task Force Report (which was almost wholly ignored by the UK medical press and press coverage in general was stunningly silent) were:

- the syndrome(s) pose a significant health problem which needs to be addressed
- there is widespread ignorance and mismanagement of chronic fatigue syndrome(s)
- chronic fatigue syndrome(s) are recognised by characteristic clinical features
- cases vary greatly in severity and duration
- chronic fatigue syndrome(s) can cause severe and persistent disability. A significant number of patients remain severely disabled and make little progress, despite good motivation
- progress in understanding chronic fatigue syndrome(s) is hampered by (i) the use by researchers of heterogeneous study groups (ii) the use of study groups which have been selected using different definitions (iii) the lack of standardised laboratory tests and (iv) the invalid comparison of contradictory research findings stemming from the above.

The Task Force Report concluded that: "*No advantage has been reported for the use of cognitive behavioural therapy"*.

Wessely, however, did not accept the Task Force Report. It remains widely believed that he was the prime mover of the Joint Royal Colleges' Report, which seemed to have as its main agenda an official "de-recognising" of ME as a nosological entity. Out of the sixteen members of the Joint Royal Colleges' "expert committee", eight were psychiatrists of the Wessely School and most of the remainder publicly subscribed to their view of "CFS", with six members having been signatories to the much criticised 1991 Oxford criteria that by definition excludes ME. The "expert committee" did not include a single medical expert who did not subscribe to the Wessely School beliefs.

Out of the 256 references cited by the Joint Report, half were by the same or associate group of authors, with 10% being by Wessely himself; nine had not been published or reviewed. Some of the references quoted as being in support of the Joint Report's views did not in fact support those views, for example:

(i) Wessely et al mentioned a paper by Buchwald, Gallo and Komaroff et al (reference 128 in the Report) but dismissed it, stating: "*White matter abnormalities occur in a number of settings and their significance remains to be determined"*, whereas the paper itself concludes that patients with

ME/CFS: *"may have been experiencing a chronic, immunologically-mediated inflammatory process of the central nervous system"* and that the scans revealed a punctate, subcortical area of high signal intensity consistent with oedema or demyelination in 78% of cases

(ii) Wessely et al refer to a paper by Bombadier and Buchwald (reference 173 in the Report), clearly conveying that this paper supports their own stance, whereas the paper itself actually says: *"The fact that the same prognostic indicators were not valid for the group with (ME)CFS challenges the assumption that previous outcome research on chronic fatigue is generalizable to patients with chronic fatigue syndrome"*.

(iii) Wessely et al mentioned a paper by Sandman et al (reference 153 in the Report), claiming it in support of their own view that results of neuropsychological testing have been *"inconsistent"*, when the referenced paper actually concludes that *"the performance of the (ME/CFS) patients was sevenfold worse than either the control or the depressed group. These results indicated that the memory deficit in (ME/CFS) was more severe than assumed by the CDC criteria. A pattern emerged of brain behaviour relationships supporting neurological compromise in (ME)CFS"*

The above examples, of which many more exist, are clear illustrations of the biased and misleading personal interpretation of the available evidence by the authors of the Joint Report.

As customary with Wessely School authors, the Joint Report was forceful:

"Patients may wish to keep (the term) 'ME' because only with that label are they eligible to call upon the welfare state for help" (section 3.4)

"The group with more symptoms, profounder (sic) fatigability, greater disability and longer illness duration is the subset with the strongest associations with psychological disorder" (section 3.5)

"(*Immunological) abnormalities should not deflect the clinician from the biopsychosocial approach and should not focus attention towards a search for an 'organic' cause"* (section 6.4)

"*We urge against over-interpreting the (immunological) abnormalities described to date"* (section 6.5)

"Psychological disorders are one component of the aetiology of CFS. Other factors include altered health perception and deconditioning" (section 7.7)

"*Several studies suggest that poor outcome is associated with social, psychological and cultural factors. Chronicity is likely to be associated with perpetuating factors which may include unaddressed psychosocial issues"* (section 8.16)

"*We have concerns about labelling someone with an ill-defined condition which may be associated with unhelpful illness beliefs"* (section 9.6). The WHO does not regard ME as an "unhelpful illness belief".

"*We see no reason for the creation of specialist units"* (section 12.1). This is notable, given the subsequent establishment of the "CFS" Centres throughout the nation at a cost of £8.5 million that are based on the Wessely School misperception of ME/CFS and which deliver only CBT and GET.

"*Appropriate clinical practice is not to be defined by special interest groups"* (section 12.4)

ME is dismissed: "*Previous studies have counted people with ME, but these studies reflect those who seek treatment rather than those who suffer the symptoms"* (section 13.3)

"*No investigations should be performed to confirm the diagnosis"* (Appendix 4)

"*The report finds no consistent evidence that CFS is associated with muscle disorder save that resulting from inactivity"* (Appendix 4).

The Joint Report was excoriatingly criticised, especially in an Editorial in the Lancet (1996:348:971) and in the CFIDS Chronicle (<u>The Royal Colleges' Report on CFS: Insidiously Biased and Potentially Harmful</u>.
T Hedrick. 1997:10:1:8-13).

The cascade of damage from this flawed and biased report continues to date and has been catastrophic for patients with ME/CFS. The lives of some patients with ME/CFS have been virtually destroyed by the cruel and dangerous behaviour of NHS doctors as a consequence of the Joint Royal Colleges' Report, with some severely affected patients having been made homeless as a result.

It is little wonder that some psychiatrists are despised and mistrusted, when they refuse to accept that conviction of physical disease may not be dysfunctional thinking but may be rational and justified.

<u>The Royal College of Paediatrics and Child Health (RCPCH) 2002</u>

In January 2002 the Royal College of Paediatrics and Child Health produced a document entitled "<u>The Next Ten Years: Educating Paediatricians for New Roles in the 21st</u>

Century", which was a joint training project with the Royal College of Psychiatrists; it categorised children with ME/CFS as having mental health problems.

The Royal College of Psychiatrists

In parallel with the joint training project referred to in the above paragraph, the Royal College of Psychiatrists produced a series of "Fact Sheets" entitled "Mental Health and Growing Up: Fact Sheets for Parents, Teachers and Young People". Fact Sheet 33 listed "CFS" as a mental illness.

The Royal College of Paediatrics and Child Health 2005

In January 2005 the RCPCH launched its Report "Evidence-based guideline for the management of CFS/ME in children and young people".

The Report recommended cognitive behavioural therapy and graded exercise therapy for children and young people with ME/CFS which, as noted by Jane Colby, Executive Director of The Young ME Sufferers Trust, in her newsletter "The Brief" March/April 2005, are likely to prove problematic for many young patients and their families.

Poor attendance at school for children with ME/CFS is twice referred to as a psychological problem.

The Clinical Algorithm (flow chart) displays a box advising that where investigations are abnormal, the condition is not "CFS/ME". Another box advises that if all results are normal, it is likely to be "CFS/ME". Tests not included in the Guideline may well be abnormal.

The Guideline is described as "evidence-based", so recommendations on treatment reflect the choice of evidence consulted.

Randomised controlled trials were given higher rating than evidence from patients describing their own experiences, and some RCTs have not included the experience of patients who dropped out, which skews results.

The Report says: "*There is no evidence for the efficacy or otherwise of pacing as an effective management strategy for children and young people with CFS/ME*", but this sidelines the evidence from patients themselves, which indicates that pacing is the most helpful form of self-management.

The Guideline began over-running its original timetable early on in the process, but the RCPCH nevertheless decided to publish almost on time. This meant a significant contraction of the consultative process and that a number of experts were not able to contribute due to other commitments.

The Royal Society of Medicine

Despite having formally accepted ME as a nosological entity as long ago as 1978, the Royal Society of Medicine has now joined in the Establishment warfare of attrition.

The RSM Section of Psychiatry is currently running a competition. It is called "The Mental Health Essay Prize". The closing date for entries is 7th January 2008. Two prizes will be awarded for an original essay on the subject of "The primary impact of psychiatric illness on physical health". The notice states: "*Candidates might like to consider contentious disease entities such as ME from a psychiatric perspective*".

7. **The Science Media Centre**

The Science Media Centre (SMC) was set up under New Labour nominally as "*an independent venture*" whose goal is "*to help renew public trust in science by working to promote more balanced, accurate and rational coverage of the controversial science stories that now regularly hit the headlines*".
(http://www.sciencemediacentre.org/downloads.consultationreport.pdf).

Other people see it differently: in The Guardian on 11th February 2003, Professor David Miller of Strathclyde University was critical of the SMC: "*The Science Media Centre is not as independent as it appears; its views are largely in line with government scientific policy. 70% of its funding comes from business, which could be said to have similar interests*".

It is funded by, amongst others, the pharmaceutical companies AstraZeneca, Dupont, GlaxoSmithKline and Pfizer and also, perhaps surprisingly, by The Royal College of Physicians, although perhaps it is not so surprising when one knows that a Past President of the Royal Collage of Physicians, Professor Sir George Alberti, sits with Simon Wessely on the SMC's Scientific Advisory Panel. It is this Science Advisory Panel that guides the SMC.

The SMC's Director is Fiona Fox, who has diligently used the SMC to promote the views of industry and to launch fierce attacks upon those who question them. The SMC operates like a newsroom, providing journalists with nuggets of scientific information that conform to "policy"; it also runs a range of activities, including "media training".

Wessely is on record as saying about the SMC: "*We need to defend scientific expertise as a basis for sound policy decisions*".

In its "Consultation" document, the SMC sets out what it will do:

"The SMC will promote itself to news-desks of national and local media on science stories that hit the headlines"

"The Centre will offer: to refer journalists to the appropriate specialists on the story; to offer sound-bites and comments from key spokespeople; to offer opinion pieces for comment pages; to facilitate events in the SMC that will bring scientists and journalists together; off-the-record briefings with key figures at the centre of controversial issues who want to communicate with the media without being quoted directly; a team with strong contacts".

Such media manipulation is inevitably linked to the suppression of justified concern from a disempowered population, as has been shown to be the case – at least two broadsheet Health Editors have confirmed that it is not editorial policy to report biomedical findings in ME/CFS and that they will use only information on "CFS/ME" that they get from the SMC. Given the fact that Wessely is a member of the SMC's Scientific Advisory Panel, such confirmation is unsurprising.

Almost without exception, journalists have shunned biomedical research conferences on ME/CFS held in the UK, despite invitations and prior Press Releases.

In its efforts to control the research information that the public should consume, the SMC has taken on key roles in the infrastructure of public communication used by the scientific and medical establishment. Is this because members of the public must never be permitted to question the supreme authority of scientists about disorders such as ME/CFS? Is it all about state control?

Given the power and influence of such a media machine as the Science Media Centre, is it surprising that the long-established values of clinical observation in medicine and the voices of patients themselves are crushed, since they cannot hope to conform to industry-backed SMC "policy"?

8. **NHS Direct**

NHS Direct became operational throughout England and Wales between 1998 and 2000.

The online information on "Chronic Fatigue Syndrome" is disgraceful: *"Chronic Fatigue Syndrome (CFS) is long-term tiredness (fatigue) that does not go away with sleep. CFS is also known as ME (myalgic encephalomyelitis). CFS is the term that is often used to describe long-term tiredness by GPs and medical professionals. That is usually the preferred term rather than ME. ME is often the preferred term of people who have CFS"* (see: http://www.nhsdirect.nhs.uk/articles/article.aspx?articleId=102).

9. **The Medical Research Council**

Following publication of the Chief Medical Officer's Working Group Report on "CFS/ME" in January 2002, it was announced that the Government had asked the Medical Research Council to *"develop a broad strategy for advancing biomedical and health services research on chronic fatigue syndrome CFS/ME"*.

Brief background about the Chief Medical Officer's Working Group Report on "CFS/ME", January 2002

In 1998, the Chief Medical Officer, then Sir Kenneth Calman, commissioned a supposedly "independent" report on "CFS". Right from the outset, when it became known who were the behind-the-scenes players on the CMO's Working Group, the ME community was unsurprised to learn that the remit of the Group was notably narrow: it was restricted to just one aspect, namely, to advising UK clinicians as to "best management practice" of "CFS/ME". Thus the conclusions of the report were widely expected to be disappointing, which was the case. The report side-stepped the vital issue of definition, classification and terminology, failing -- despite numerous written communications -- to state that ME/CFS is classified as a neurological disorder by the World Health Organisation.

The aim of the psychiatric lobby that dominated the Key Group responsible for the CMO's Working Group Report had been to get "CFS/ME" documented as a primary psychiatric disorder. When it became obvious that they were not going to succeed, Professor Peter White (the same Peter White who is responsible for the DWP Handbook entry on "CFS/ME") led a walk-out by the psychiatric lobby, which refused to endorse the final report because they did not sufficiently get their own way. Apart from Peter White, those who resigned included psychiatrists Anthony Cleare and Elena Garralda, as well as nurse therapist Trudie Chalder and Dr Alison Round, a public health doctor who has published work supporting the psychosocial model of the disorder. The British Medical Journal reported the resignations: " *The government's long-awaited report on the treatment of CFS could be in jeopardy after key members resigned from the working group. The move throws doubt on the validity of the report. A total of ten people have resigned since it was set up in 1998. (The psychiatric lobby says) the report plays down the psychological and social aspects of the condition and concentrates on a medical model"* (BMJ 2002:324:7, 5th January).

What seemed extraordinary was that during the life (1998-2002) of the Chief Medical Officer's Working Group on ME/CFS, members were ordered not to discuss the deliberations and were even threatened with the Official Secrets Act. If the psychiatric lobby which dominated that Working Group was so confident that they were right, why the need to force the suppression of opposing views by resorting to threats of prosecution under the Official Secrets Act in a Working Group that had nothing to do with State security but was supposed to be acting simply in the best interests of sick people?

At the launch on 11th January 2002 of his Working Group's Report, the Chief Medical Officer, by then Professor Sir Liam Donaldson, went on record saying: "*CFS/ME should*

be classed as a chronic condition with long-term effects on health, alongside other illnesses such as multiple sclerosis and motor neurone disease" (BBC News /Health, Friday 11th January 2002).

The Chief Medical Officer was at once derided by Michael Fitzpatrick, a GP known for presenting and promoting the views of Simon Wessely, for his perverse and immoderate attacks on those with ME/CFS and for his association with Sense about Science, a sibling of the Science Media Centre (see above), who wrote: "*The CFS/ME compromise reflects a surrender of medical authority to irrationality. The scale of this capitulation is apparent when Professor Donaldson claims that CFS/ME should be classified together with conditions such as multiple sclerosis and motor neurone disease"* (ME: the making of a new disease online at http://www.spiked-online.com/Articles/00000002D3B6.htm).

The MRC's reputation

In some respects, the MRC has an unfortunate reputation.

In 1993 the BMJ carried a leading article by its editor (Richard Smith) about problems of management at the MRC (Management at the MRC: old fashioned and in need of reform. BMJ 1993:306:1627-1628). The same issue carried two papers about the MRC: Management within the Medical Research Council and Is medical research well-served by peer-review?.

Management at the MRC: old fashioned and in need of reform: "*The challenge must be to give power to those close to the research while making sure that they operate within a strategy that will bring benefits to those paying for the research. Two papers in this week's journal look at the management structure of the Medical Research Council (MRC) from the point of view of the directors of its smaller units. All of the unit directors cooperated with the study, but the central MRC bureaucracy was unhelpful. This in itself is a bad sign: organisations that want to move forward welcome opportunities for critical examination. The (MRC head office) is seen by the unit directors as bureaucratic and dictatorial. A survey of middle managers at the MRC's head office described the organisation as 'introspective, secretive, paternalistic, bureaucratic, compartmentalised, lacking in team spirit, perfectionist, slow and amateur in approach to managing'. If management styles of the research councils are not radically reformed, then nothing will change"*.

Management within the MRC**:** "*The picture painted by nearly 24 hours of interviews with the MRC's key active research managers, its unit directors, does little to support the council's assertions of managed excellence. Neither effectiveness nor efficiency could be claimed to be good. The purchaser-provider system envisages that executive funding bodies commissioning research could be separate from research providers….the commissioning bodies would offer research programmes of three types: curiosity-driven research; mission-oriented research, and experimental development. Many would question whether the MRC has the will or the management ability to change at the pace*

required simply to keep up with its changing environment. In its reaction to this challenge to look into the future, the MRC has shown again that its culture does not embrace change easily".

Is medical research well-served by peer review?: "*Within the MRC, peer review is carried out by ad hoc panels of the 'great and the good' from the scientific community, who are asked to review researchers' future plans. The flaws in this system result in many lost opportunities. Peer review makes the assumption that intellect and integrity go hand in hand…recent work calls this premise into question. Views current within the MRC would seem to uphold these concerns. Six of the unit directors regarded the system as unfair. One said of the process: 'It's just not honest'. Another was more acerbic: 'It's a stitch-up. They know the outcome they want and the referees and committee members are chosen in the expectation of the view they will deliver' ".*

Ten years later, has anything changed for the better, and is there any indication that the driving motive for research should be potential benefit to patients and not only to "*those paying for the research"*?

In March 2003 the House of Commons Select Committee on Science and Technology produced its report on "The Work of The Medical Research Council" (HC 132) in which MPs issued a damning judgment on the MRC, lambasting it for wasting funds and for introducing misguided strategies for its research. MPs found evidence of poor planning and of focusing on "politically-driven" projects that have diverted money away from top-quality proposals. The unprecedented attack was the result of a detailed probe into the workings of the MRC.

On 25th March 2003 The Times newspaper carried an article by Mark Henderson entitled "Research funding wasted on useless projects, say MPs". The article noted that the MRC's annual budget for 2001-2002 was £416 million, and that the MRC had four Boards to advise on priorities in particular fields. The article said: "*Dozens of the best medical scientists are being starved of money because the Government's funding body prefers to support speculative projects (and) is squandering resources. At the same time, it is refusing far too many high-quality grant applications (and is) ignoring bread–and-butter research in favour of high-profile projects that had not been thought through. Financial mismanagement meant that studies of second-rank quality had been supported, only for more important research to be rejected".* The Report said the research community's anger was understandable and justified, and said that many scientists have had to focus on charity rather than public funding for their work.

On the same day, 25th March 2003, The Guardian carried a similar article by Donald MacLeod ("Medical Council accused of bad management"). That article said: "*The Committee found evidence of poor financial management and poor planning, leading to large numbers of top quality grant proposals being turned down".* The article quoted from the House of Commons Report: "*Our impression is that a case has been put together by the funders to support a politically driven project".* The article went on to

quote Peter Mitchell of the Association of University Teachers: *"Decisions are taken in secret and no explanations (are) provided"*.

Similar articles appeared in The Edinburgh News (*"The House of Commons Science and Technology Committee today reported 'areas of serious concern' about the way the MRC distributes its grants. Committee Chairman Dr Ian Gibson said: 'Something has gone badly wrong at the MRC' ")* and The Scientist *("Perhaps the most disturbing accusation is that some of the best medical scientists in the UK have been starved of cash because of the MRC's preference").*

Wessely was a member of three Boards at the MRC: the Monitoring and Evaluating Steering Group which conducts evaluations of the MRC's research funding policies; the Neurosciences and Mental Health Board and the Health Services and Public Health Research Board.

During the MRC's Public Consultation period for ME/CFS in 2002-2003, more members of the Wessely School were appointed to MRC Boards, including Trudie Chalder (a mental nurse who became a behaviour therapist, now Professor of Cognitive Behavioural Psychotherapy at the Institute of Psychiatry), Anthony Cleare (Senior Lecturer in Affective Disorders and Director of the National Affective Disorders Unit at the Institute of Psychiatry, specialising in "CFS/ME"), Anthony David (Professor of Cognitive Neuropsychiatry at the Institute of Psychiatry and Consultant Psychiatrist), Anne Farmer (Professor of Psychiatric Nosology at the Institute of Psychiatry), Michael Sharpe (who now holds a Personal Chair in Psychological Medicine and Symptoms Research at Edinburgh), Til Wykes (Professor of Clinical Psychology at the Institute of Psychiatry) and Peter White (Professor of Psychological Medicine, Barts and Queen Mary's School of Medicine).

As Dr Jonathan Kerr from the Department of Cellular and Molecular Medicine at St George's University of London (whose grant application for gene research in ME/CFS was rejected by the MRC) said on the record at the Invest in ME International Conference in May 2007 held in London, as long as psychiatrists control the MRC, it will never fund biomedical research into ME/CFS.

On 9th November 2005 the House of Commons Science and Technology Committee agreed to hold an inquiry to examine the way in which Government obtains and uses scientific advice in the development of policy.

The inquiry intended to focus on the way guidelines governing the use of such advice were being applied across Government and to test the extent to which policies were "evidence-based". In particular, the inquiry intended to look at what mechanisms were in place to ensure that policies were based on available evidence. Launching the inquiry, the Committee Chairman, by then Phil Willis MP, said: "*We keep hearing from Government Ministers that policy is based on evidence. We want to test that, and find out what it means in practice to both the specialist communities and to the public*".

Five months earlier, on 22nd June 2005, Laurie Taylor presented a programme called "Thinking Allowed" on the UK's Radio 4, one of a series of programmes in which contributors discussed topical items coming out of the academic and research worlds. Taylor ended that particular programme with an explosion: "*….the last word on methodology, and the importance of valid and reliable empirical work, must go to the anonymous political insider who recently characterised the present Government's approach to research: it is not"*, he said, *"so much evidence-based policy-making as policy-based evidence-making"*. Never was there a truer word, as the ME/CFS community knows to its considerable cost.

The Office of Science and Technology monitors all government funding of research grants and controls official science policy; it is "policy" which determines the research that is funded: "*The Department funds research* ***to support policy***" (Hansard, 11th May 2000:461W – 462W).

This "policy-based evidence-making" has now reached such an extent that it has been likened to a cancerous metastatic spread (Stephen Ralph, 25th June 2005: http://health.groups.yahoo.com/group/MEActionUK/). There could hardly be a better analogy: metastatic spread takes hold by replicating itself until it eventually dominates and overwhelms, just as the unsubstantiated views about "CFS/ME of the Wessely School psychiatrists have spread throughout the medical profession, the media (perhaps through the activities of the Science Media Centre – see above), Government, and even some of the patients' support organisations, most notably Action for ME and the local groups that support it.

The MRC Research Advisory Group (RAG) on CFS/ME

Following publication of the Joint Royal Colleges' Report on CFS in 1996 -- a report that was internationally condemned for its extreme psychiatric bias -- the Editor of the Lancet, Richard Horton, courageously spoke out against it, saying on the record: "*The college representatives interpreted every piece of evidence pointing to a biological cause in a negative light. Medical paternalism seems alive and well in Britain today*" ("Why doctors are failing ME sufferers". Dr Richard Horton. Observer Life, 23 March 1997).

Horton has won plaudits for his scrutiny of the pharmaceutical industry and his stance has made enemies. On 18th June 2005 he was the object of a major vitriolic attack from establishment scientists in The Times, which carried banner headlines proclaiming: " 'Scaremongering' Lancet accused of causing harm to health and wasting millions". The signatories, thirty Fellows of the Royal Society, accused Horton of "*desperate headline-seeking over sound science, to the detriment of human health*", and a disregard of a balanced assessment of the best evidence.

Of interest to the ME/CFS community was that one of the 30 signatories was neuroscientist Dame Nancy Rothwell.

This was the same Professor Nancy Rothwell who was Chair of the Medical Research Council's Research Advisory Group (RAG) on the direction of future research into "CFS/ME".

Announcing the formation of the MRC's RAG and speaking at a meeting of the All Party Parliamentary Group on ME, Dr Diana Dunstan, Director of the MRC Research Management Group, said the MRC Research Advisory Group on CFS/ME that had been chosen comprised leading experts from various fields "*who did not previously specialise in CFS/ME because it was felt appropriate to get a wide range of specialties and to have an independent and fresh look at the issue*".

Patients in the UK with ME/CFS include clinicians, radiologists, medical scientists (including vascular biologists and neurobiologists), lawyers (including High Court judges and their families), university lecturers, academics, teachers, nurses, Members of Parliament, editors, journalists, social workers and a former principal violinist with a renowned BBC Symphony Orchestra, amongst others. Although physically and cognitively impaired on various levels, their intelligence remains intact and many of them have an excellent professional knowledge of the literature on ME/CFS. Within moments of this announcement it was realised that it was misleading if not false, and that some of those appointed to the RAG were far from "fresh" to the field.

Two names in particular stood out: Professor Alan McGregor and Professor Philip Cowan.

Professor Alan McGregor works at King's College, London and has co-authored papers on "CFS" with Simon Wessely (Journal of Affective Disorders 1995:34:(4):283-289; Biological Psychiatry 1995:32:245-252), so was hardly "fresh" to the issue. Further, he is listed as a Member of the Linbury Trust Advisory Panel on CFS; it is the Linbury Trust that has granted Wessely School psychiatrists over £4 million for research into "chronic fatigue".

The beliefs of the Linbury Trust members about CFS are noteworthy. In July 1998 the Linbury Trust produced its first "Research Portfolio on Chronic Fatigue" published by the Royal Society of Medicine. Sixty three percent of the contributors were psychiatrists who might be said to belong to the Wessely School. Seventy percent of the reported work contained in the "Portfolio" has a psychiatric or psychological dimension. Much of the work was based on the same poor epidemiology: the psychiatrists continued to confuse ME with chronic fatigue and with psychological illnesses such as depression. Evidence that shows ME to be an organic disorder was excluded or devalued. The plight of the severely affected and children was ignored altogether. Concerning "treatment", the Linbury Trust approach states that it "*deals only with graded exercise, cognitive behaviour therapy and antidepressants*". The message from the Linbury Trust is clear: cognitive behavioural therapy will control the patients' mis-attributions and **"searching for causes is not only futile but may prevent recovery"**. ("A Research Portfolio on Chronic Fatigue". Edited by Robin Fox for the Linbury Trust. Published by The Royal Society of Medicine Press, 1998).

Professor Philip Cowan holds strong views on "CFS" and was co-author of a paper entitled "Abnormalities of Mood" published in the second Linbury Trust Portfolio on Chronic Fatigue (New Research Ideas in Chronic Fatigue. Edited by Richard Frackowiak and Simon Wessely for The Linbury Trust. Published by The Royal Society of Medicine Press, 2000). Cowan has also co-authored papers on "CFS" with Michael Sharpe and other members of the Wessely School (Journal of Affective Disorder 1996:41: (1):71-76).

Another member of the RAG was Professor Til Wykes, who, like Simon Wessely, works at the Institute of Psychiatry and whose views about CBT are on record: "*If you encourage them to do things as part of a treatment called cognitive behaviour therapy, then you do see improvement. It's a way of getting people to take control of their lives. It works"* (http://www.observer.co.uk/international/story/0,6903,515180,00.html)

Representations were therefore made to Professor Sir George Radda, then Chief Executive of the MRC, who in a written reply dated 15th July 2002 was obliged to concede: "*We are aware of Prof Macgregor's involvement with the Linbury Trust"*; then, somewhat weakly, he stated: "*You cite papers from some years ago"*. Inevitably, Radda was forced to support the MRC, saying: "*The inclusion of Profs Macgregor and Cowan is consistent with MRC's intention to select the working group from experts in various fields who do not specialise in CFS/ME"*. This unconvincing response failed to reassure the ME community that the legitimate concerns they had raised would be competently addressed.

With this knowledge about members of the RAG, the outcome of the RAG Report was anticipated by the ME/CFS community and once again, their anticipation proved realistic.

The MRC Draft RAG Report

The MRC Research Advisory Group (RAG) released its draft Report on "CFS/ME" on 17th December 2002 for public consultation. The author of that draft Report was Dr Chris Watkins, MRC Programme Manager for Research on Mental Illness.

The draft Report was replete with misinformation and skewed thinking. It claimed to be a strategy which "*reflects the current state of knowledge of CFS/ME and which aims to provide a rational framework for advancing the understanding of the illness and its management"* but it blatantly ignored the significant amount of biomedical evidence that was submitted.

It advised that studies of causal pathways would not increase understanding of "CFS/ME". It suggested that given "*the present difficulties in identifying priorities for research"*, it was not appropriate to make "CFS/ME" research a priority. It deliberately did not consider the defining topic of terminology.

It asserted – erroneously – that: *"there are separate entries in the WHO ICD-10 for chronic fatigue syndrome and myalgic encephalomyelitis"*. Given the number and nature of the documents known to have been sent to the MRC, it was not credible to assume that the error about ICD-10 classification was a simple mistake or over-sight, or that the members of the RAG were unaware of the correct classification.

The draft RAG Report claimed that predisposing factors for "CFS/ME" include female gender, personality and previous mood disorder.

It blatantly asserted: *"Many reported findings in the area of pathophysiology are not published in peer-reviewed literature"*, stating that in those studies which had found evidence of abnormalities, *"the lack of methodological rigour means that many of these claims find little support from the wider medical community, but may have strong currency among some patients and practitioners"*. Such a claim was not only patronising and arrogant, it was preposterous. Evidence was promptly submitted to the RAG listing 65 international peer-reviewed journals, some of high impact factor, that had carried informative articles about the pathophysiology of ME/CFS. Authors of those papers included world-renowned experts including Professors of Medicine and Professors of Immunology. This was ignored by the MRC RAG; its members in fact stated that they had purposely not considered the current level of scientific knowledge on the aetiology or pathogenesis of CFS/ME; instead, members relied on the Wessely School literature.

The draft Report dismissed the documented immunological disturbances seen in ME/CFS and instead referred to *"sickness behaviour syndrome"*. It referred to the effects of *"suggestibility"*. It specifically advised against identifying subgroups of "CFS", which was contrary to advice from prestigious international experts who were highlighting the urgent need for the study of subgroups.

Inevitably, the draft Report recommended that the interventions of choice should be CBT and GET.

Many people sent in detailed responses to the RAG draft Report, almost all of which seem to have been ignored.

The finalised MRC RAG Report

The MRC RAG final Report was released on 1st May 2003 ("MRC CFS/ME Research Advisory Group: CFS/ME Research Strategy").

Evidence submitted to the MRC RAG of international research findings underpinning the serious organic nature of ME/CFS included creatine excretion in urine (a sign of muscle damage), low total body potassium, abnormal lung function parameters, autoimmune components in anti-lamin B1 nuclear envelopes, consistently low NK cells, lack of recovery of muscle function after exercise, less than 60% oxygen delivery in blood,

altered peroxinitrite, involvement of the liver, pancreas and heart, plus much more. It was all disregarded.

As part of its consultation process, the MRC had asked the Public Health Resource Unit (based in the Institute of Health Sciences at Oxford) to analyse the consultation questionnaire. The PHRU is an NHS unit that was set up in 1997 to support change and development within the NHS.

A total of 187 responses to the questionnaire were received, some being from patients with ME/CFS, some from carers, some from charity representatives and some from clinicians and researchers. On 6th May 2003 the Senior Project Officer herself confirmed to an inquirer that she had provided the MRC with a detailed and comprehensive 25 page document on the responses to the questionnaire which addressed the data that had been provided by respondents. She further confirmed that Elizabeth Mitchell of the MRC did not want to use this document, saying it would be "*too overwhelming*", and ordered the Senior Project Officer to submit just a summary of her document.

As one long-time advocate on behalf of the ME/CFS community noted: "*We are satisfied that no failure lies with the Public Health Resource Unit as it has been established that RAG members were aware of the submitted evidence. We are thus compelled to conclude that RAG members have been deliberately selective and that such selectivity is likely to be in accordance with a pre-set agenda as so relentlessly promulgated by the Wessely School, about which we have publicly raised legitimate concerns for the last decade*" (Co-Cure ACT: 4th January 2004).

The Senior Project Officer further confirmed that the petition submitted by Research into ME (RiME) – which contained over 16,000 signatures calling for biomedical research into ME -- was wholly ignored because the cut-off period ended on Friday 30th August and the petition did not arrive until the following Monday, 2nd September 2002.

As in the draft Report, the MRC RAG final Report erroneously stated: "*There are separate entries in the WHO ICD for "chronic fatigue syndrome" and "myalgic encephalomyelitis";* as noted above, before publication of the final version of their Report, RAG members had had this error specifically pointed out to them. The repeated ignoring of the evidence on this issue must therefore be seen as deliberate, and reflects the determination of Wessely School psychiatrists to re-classify ME/CFS as a psychiatric disorder, no matter what the evidence to the contrary.

The MRC document referred to "*the effects of gender", "mood disorder", "the effects of suggestibility", "personality factors", "sickness behaviour syndrome*" and abnormalities induced by "*immobility*" in relation to ME/CFS and it stated that "*studies investigating causal pathways and mechanisms would not have immediate impact on increasing understanding of CFS/ME".*

This seemed to echo the Linbury Trust view as expressed by Simon Wessely in the second Linbury Trust Portfolio referred to above: "*It is usual to try to discover the cause*

of an illness before thinking about treatment (but) some illnesses are treated without knowledge of the cause; examples include chronic fatigue syndrome".

Essentially the Report was, as widely predicted, simply "more of the same" from a Government agency which was under the nominal political control of the Labour Science Minister Lord (David) Sainsbury (whose Linbury Trust has for so long financially supported those UK psychiatrists of the "Wessely School" who claim that ME does not exist and that "CFS" is a mental disorder which must be managed by cognitive behavioural therapy and graded exercise).

Unsurprisingly, the MRC Strategy document recommended that there was no need for research into biomedical aspects of "CFS/ME"; plainly, the agenda was pre-determined, as the Report stated that the RAG members had "*chosen to consider how the evidence-base for potentially effective management options can be strengthened"*. This seemed to indicate a disturbing narrowness of approach that was not in patients' best interests, given the amount of documented information recording how patients have been actively harmed by graded exercise regimes.

Unheeding, the RAG report stipulated that the way forwards was to be further research into psychiatric interventions of cognitive behavioural therapy and graded exercise therapy and that *"there may be a need for specific measures to promote multidisciplinary collaborations (which would) offer established centres of excellence the kind of new scientific opportunities that are essential if (those existing centres) are to sustain their competitiveness internationally"*.

The only "centres of excellence" for "CFS" are psychiatric units, since clinics for "pure" ME patients (ie. as described by the late Dr Melvin Ramsay) in NHS hospitals such as Preston have been summarily closed. In the case of Preston, there was an 18 month waiting time and this did not meet New Labour waiting time targets, so the hospital managers simply closed the clinic and therefore were not in danger of losing financial inducements to meet waiting time targets dictated by central government.

Equally, the ME clinic at the Royal Free Hospital that was run by Dr Ramsay's successor-in-post Dr William Weir (a well-respected advocate for the UK ME community) was perfunctorily closed, with patients being referred to a "Fatigue Clinic" run by a GP and then referred to Wessely's CFS unit at King's College.

There was much public unease about Professor Rothwell's RAG, not least because her advisory group chose not only to flout but to ignore entirely the elementary rules of procedure to which adherence is *de rigueur* except, apparently, in the case of ME/CFS. It was the RAG's deliberate policy not to consider any of the existing published medical literature that indicates unequivocal organic, multi-system dysfunction in ME/CFS, with the inevitable and possibly intentional result that its conclusions could not sit squarely on the foundation of existing knowledge about ME. By proceeding as if this substantive body of mainstream knowledge did not exist, Professor Rothwell's group laid itself open to suspicions of frank intellectual dishonesty.

The MRC's links with commercial interests

As reported in the Financial Times, the then Science Minister who was responsible for the MRC, Lord (David) Sainsbury, a keen supporter of the Science Media Centre, was proud of the fact that scientific research at British universities had spun off 199 companies in 2000, up from an annual average of just 67 in the previous five years. "*It's a dazzling record*", Lord Sainsbury is quoted as saying. Not everyone shared his enthusiasm. Professor Stephen Rose of the Open University Biology Department commented critically on this emerging corporate science culture: "*The whole climate of what might be open and independent scientific research has disappeared*".

In relation to the FINE psychiatric trials that are wholly funded by the MRC and which involve domiciliary "rehabilitation" for those severely affected by ME/CFS (see below), on 24th June 2005, replying to a request for information under the Freedom of Information Act, Alan Carter from the Directorate of Corporate Services at the University of Manchester, wrote: "*If the treatments under investigation in this Trial are successful, the University of Manchester would wish to develop training packages for use by Primary Care Trusts, as mentioned in the Trial protocol. If the manuals were put into the public domain, this would endanger the University's commercial interests in developing the treatment packages. The University has concluded that whilst there is a significant public interest in the treatment of CFS/ME, this is outweighed by the interest that potentially valuable research can be utilised successfully*".

On 31st July 2007, Sir John Chisholm, who was appointed Chairman of the MRC in October 2006, had been criticised by MPs on the Science and Technology Committee, who said they had "*serious reservations*" about his suitability (New medical research chair unfit for job, say MPs; Education Guardian, 31st July 2007).

On the BBC Radio 4 Today programme on 22nd August 2007, Sir John Chisholm was interviewed. His contribution was preceded by that of Phil Willis MP, Liberal Democrat Chairman of the House of Commons Science and Technology Committee. Mr Willis spoke of his Committee's concerns about Sir John: "*There is no doubt that when he came before our Committee, there was real disquiet as to whether he did have the passion for basic science (and) we are in danger of losing that and having the MRC become an agency of the NHS and Government priorities*".

Replying to the question: "*Are research scientists dissatisfied with you?*" Sir John fully supported commercial involvement in Government research funding, implying that concern about such commercial interests was unwarranted.

The current emphasis on commercial interests in relation to funding preferences by the MRC does not bode well for patients with ME/CFS who are crying out for biomedical research, since commercial bodies have no interest in biomedical funding, only in

maintaining ME/CFS as a psychiatric disorder (which, in the interests of Big Pharma, may then become a "life-style" life-time disorder).

As the issue of commercial interests is so relevant to people with ME/CFS because of the known vested interests of members of the Wessely School, the following paragraphs provide information about Big Pharma.

The House of Commons Health Select Committee Inquiry into the Influence of the Pharmaceutical Industry

In October 2004 the House of Commons Health Select Committee under the chairmanship of David Hinchliffe MP invited submissions and took oral evidence detailing concerns about the power, bias and influence of the pharmaceutical industry (and flowing from this, upon those doctors who are financially linked to it) and the effect of such influence upon patients.

Evidence given to the Health Select Committee told of payments to medical consultants by the pharmaceutical industry of £5,000 plus expenses for a one hour talk (with the audience being unaware that speakers were in the pay of the industry) and of senior doctors receiving consultancy fees from drug companies of more than £20,000 for a few hours' work. A senior consultant (Dr Peter Wilmshurst, consultant cardiologist, Royal Shrewsbury Hospital) told the Inquiry that this was common practice, and that the sums offered to him for a few hours work were £22,000, this being the level of payment made by drug companies to consultants such as himself, but that professors could earn "*considerably more*".

MPs were told that family doctors' practices can make profits of over £50,000 per year from drug companies and that doctors are inundated with gifts from the pharmaceutical industry. Professor David Healy, Head of Psychological Medicine, University of Cardiff, said: "*People like me come out of meeting halls with our arms stuffed full of bags of free gifts*".

Explaining about such payments, Professor Healy said: "*The industry is very clever at how they organise these things. If I am working in a consultant capacity for one of the pharmaceutical companies, I will have had media training often. Let's say some issue blows up and the media gets told: 'You can approach Dr Healy'. I will be able to say, and the media and the pharmaceutical company will be able to say, 'No money passed hands'. The money comes from elsewhere; it actually comes from the trips to the Caribbean; it comes from being asked to chair meetings which involve no work at all; it comes from having my papers written for me and then I am paid as though I have written the papers. That is where the money comes from*".

The Select Committee heard of the efforts made by the industry to arrange for the country's leading medical experts ("opinion leaders" in various medical disciplines) to put their name to reports that endorse products and strategies, even though the leading

experts had not written the articles concerned. This practice, known as "ghost-writing", is very common. Professor Healy told MPs that doctors maintain they are not influenced by the free gifts but are influenced by "evidence", and that this "evidence" now consists of articles that have been ghost-written. The problem is that such ghost-written articles (handsomely paid for by the industry) do not represent the raw data but do influence physicians, who believe them to be "evidence-based medicine".

Committee member Dr Doug Naysmith MP asked Professor Healy: "*Are you suggesting that eminent clinical scientists, academics, add their names to papers that they do not really write*?", to which Professor Healy replied: *"It may be worse for psychiatry than elsewhere, fifty percent of these articles are ghost-written. It may be higher. (The) most distinguished authors from the most prestigious universities are approached precisely because they are the most distinguished authors from the most prestigious universities*". Dr Naysmith's response was: *"This is pretty disturbing stuff*".

The Chairman asked: "*Do people not see through what is going on?"*, to which Dr Wilmshurst replied: *"People do not always know, because people do not always declare their conflicts of interest. Some people were earning considerably more from individual pharmaceutical companies by talking for them every fortnight, twice a month, than they were earning from the university or the NHS that they work for"*.

When asked about the role of the Royal Colleges in relation to the improper publishing by the industry, Professor Healy said: *"You are trying to force a financial camel through the eye of a scientific needle. This comes close to fraud"*.

Asked what proportion of continuing professional education is typically funded by the industry, Dr Wilmshurst replied: "*Ninety per cent plus*".

In his written submission, Emeritus Professor Andrew Herxheimer, a medical pharmacologist, stated: "*The influence of the industry on medical practice and on the regulation of medicine is perverse, overwhelming and relentless"*.

Dr Des Spence, a GP from Glasgow, encapsulated the issues succinctly as being: "*the current relationship between the industry, health care professionals and government as a whole. It is that close relationship that gives them an undue sway over the health agenda"*. He was unequivocal: the industry has a major influence over health care policy and that it has a "*very clear agenda, which is predominantly that of profit"* and that this agenda is *"in direct conflict with the responsibilities of the NHS"*.

The Inquiry also heard evidence about the deliberate creation by the industry of so-called "lifestyle" conditions that could lead to unnecessary use of medicines and to distorted prescribing behaviour, and it heard of the indoctrination of the public that they need drugs (such as anti-depressants) in order to cope with their lives.

One submission to the Inquiry was from a group of consultant psychiatrists calling itself "Critical Psychiatry Network"; it was founded in Bradford in 1999 and the submission bears the name of a Dr Philip Thomas.

That submission stated what the ME/CFS community knows only too well: "*The problems of definition and validation of illness in psychiatry mean that the field is more open to manipulation by commercial interest than other areas of medicine. Psychiatry is unlike any other branch of medicine in that patients may be compelled to take medication for lengthy periods of time against their consent. The government is about to introduce new legislation to replace the 1983 Mental Health Act* (now implemented), *in which these powers of compulsion will be extended into the community. This change in the law has major ethical implications. Perhaps more so than any branch of medicine, psychiatry is open to the influence of external interests. This can be seen in the influence that the industry has on the design, conduct and reporting of psychiatric research. We are deeply concerned about the influence of the pharmaceutical company representatives in shaping the opinions of mental health professionals. Their work represents the triumph of the science of marketing over the marketing of science"*.

Members of the Select Committee are on record as being "*horrified*" by the evidence they heard (see "Drug companies are accused of putting patients' lives at risk" by Colin Brown, Deputy Political Editor, The Independent, 15th October 2004).

The MRC PACE trial into "CFS/ME"

On 15th May 2003 the MRC announced the funding of two trials to evaluate the effectiveness of "rehabilitative treatments" for "CFS/ME".

The first trial, known as the PACE trial (Pacing, Activity and Cognitive behavioural therapy: a randomised Evaluation) was to take place in six clinics over a period of four years. Action for ME declared that it was proud to announce its support for the four-year study which "*will evaluate pacing against other exercise and behavioural-led approaches in the care of people with ME"*.

The PACE trial was to be led by Dr (now Professor) Peter White of Barts, Dr (now Professor) Michael Sharpe of Edinburgh, and Dr (now Professor) Trudie Chalder of Kings College, London. It was to be co-funded by the MRC, the Scottish Chief Scientist's office, the English Department of Health and the Department for Work and Pensions.

The second trial was the FINE trial (Fatigue Intervention by Nurse Evaluation), a form of what the MRC terms "rehabilitation therapy" to be delivered by specialist community nurses in patients' own homes -- though what "fatigue intervention" has to do with severely affected ME patients who require tube feeding was not specified. It was to be led by Alison Wearden PhD at the University of Manchester and was to be wholly funded by the MRC.

The MRC media release proclaimed that with the PACE trial, *"people can be helped towards recovery";* in the media release, Peter White said: *"I'm particularly pleased that the study has been designed in collaboration with the leading patients' charity Action for ME"*.

One month later, the ME/CFS community became aware that on 12th-13th June 2003, Peter White delivered a lecture entitled "Central Nervous System and Autonomic Nervous System Responses to Exercise in Patients with CFS" in Bethesda, Maryland, USA, at which Dr White explained that the cognitive behavioural model of CFS posits that the symptoms and disability of CFS are perpetuated predominantly by dysfunctional illness beliefs and avoidant coping. White said that beliefs associated with a poor outcome in CFS include the belief that exercise is damaging, that the cause of CFS is a virus, and that CFS is a physical illness.

The MRC website described the FINE trial as follows: *"Pragmatic rehabilitation is delivered by specially trained nurses who give patients a detailed explanation of symptom patterns. This is followed by a treatment programme focusing on graded exercise. CFS/ME does not refer to a specific diagnosis"*.

In response to an enquiry from a Member of Parliament, on 24th October 2003 Professor Colin Blakemore (who had just succeeded Professor Sir George Radda as CEO of the MRC) wrote: *"(Your constituent) has raised three main points. The first is that research should be done into the causes of CFS/ME before looking into treatments. It is appropriate to explore potential interventions in the absence of knowledge of causation. For example, the cause(s) of diabetes is not known, but knowledge of the underlying pathophsyiology has meant that effective treatments have been developed. (Re:) the second point (referring to MRC funding priorities), the key factor in deciding whether a proposal is funded or not is the quality of the science and its potential contribution to human health. Neither the PACE nor the FINE trials will provide a cure for CFS/ME but that is not their purpose. The trials are intended to assess a number of possible treatments (sic) to see if they are beneficial to those suffering from CFS/ME"*.

As Christine Hunter of the Alison Hunter Memorial Foundation in Australia pointed out, knowing the cause and knowing the pathophysiology are two different things: pathophysiological research was a priority for diabetes, so why not for ME/CFS? (Christine Hunter's daughter Alison tragically died from severe ME aged 19; the cause of death on the death certificate stated: *"Severe progressive ME"*. The pathologist confirmed that Alison had severe oedema of the heart, liver and brain. Alison also suffered seizures, paralysis and gastrointestinal paresis).

On 16th January 2004, Dr Charles Shepherd from the ME Association posted an item on Co-Cure ACT:RES in which he said: *"In response to recognition for more research, the MRC went on to conclude that research into the underlying cause should not command any high priority. Instead, the MRC recommended yet more money should be spent on researching lifestyles and psychological aspects of management, the results of which may not add any significant information to what patients and their doctors already know. The*

situation regarding a lack of any encouragement to researchers to pursue the underlying physical cause of ME/CFS remains indefensible".

There was considerable confusion about both the start date for the trials and the entry criteria, with The Times correspondent Peta Bee claiming on 2nd February 2004 that the MRC trial was: *"now in its second year"* ("Fit to fight fatigue", The Times, 2nd February 2004). The BMJ concurred: *"Exercise is the best way to fight chronic fatigue syndrome. In the MRC study, now in its second year, patients are advised to follow a carefully graded plan. Dr Trudie Chalder, from King's College, London, says: 'The psychological benefits of following a fitness routine for people with CFS are great' ".*

Since in January 2004 the MRC's website stated that the start date was 2nd January 2004 and that the Oxford (Wessely School) criteria were being used, it was confusing to be informed just one month later by the BMJ that the trial was in its second year.

It was even more confusing to be informed by the Health Minister (Lord Warner) on 26th February 2004 that the entry criteria for the trials: *"have not yet been finalised"* (Hansard: 26th February 2004: HL1273).

Matters became yet more perplexing when the Health Minister confirmed on 10th March 2004 that: *"the current estimated start of recruitment of patients into both trials is the summer or autumn of 2004. Unconfirmed criteria for both trials are that participants will meet the Oxford diagnostic criteria for CFS".*

The UK ME/CFS community noted with bemusement that it is customary for the trial protocol to have been rigorously scrutinised, modified if necessary, and approved by the relevant Ethics Committee before funding was granted. This appeared to be a case of the psychiatric lobby rushing things through willy-nilly.

In March 2004 an advertisement for "PACE Trial Manager, Research Grade 3, Centre for Psychiatry, Institute of Community Health" to be based at St Bartholomew's Hospital, London (closing date 6th April 2004), announced: *"This is a prestigious MRC funded study of promising new treatments (sic) for a condition of considerable public health importance. Other members of the team include Professor Simon Wessely. The lead statistician is Dr Tony Johnson. The Clinical Trials Unit of the Institute of Psychiatry will be leading on database management and analysis".* Then came the following: *"Mind body medicine and liaison psychiatry are relevant research areas for our centre. Recent successes include studies using the General Practice Research Database (GPRD).* ***The GPRD studies have shown that diagnostic labels for CFS used in UK primary care have radically changed in the last 14 years and that these labels both reflect and affect prognosis".***

What exactly was this radical change in diagnostic labels, who was responsible for it, and on what evidence did it rely? The ME community has little doubt about the answers to those questions.

The PACE Trial Identifier (the Funding Application to the MRC)

In about April 2004 the UK ME/CFS community managed to obtain a copy of the PACE Trial Identifier, which unless one is involved in the process, is usually impossible. The Identifier contained misleading statements (*"Predictors of a negative outcome with treatment include membership of a self-help group, being in receipt of a disability pension [and] focusing on physical symptoms")*; vital information was totally omitted; it referred to "treatment" when it would have been more accurate to describe the proposed interventions as "management strategies"; there was to be no subgrouping, and it relied on the biased Systematic Review from the CRD at York.

It stated that the results of the trial: *"will allow health planners, clinicians and patients to choose treatment on the basis of both efficacy and cost (and will) define the essential aspects of effective treatment"*.

It acknowledged that: *"There is a discrepancy between patients' organisation reports of the safety of CBT and GET and the published evidence of minimal risk from RCTs"*.

It undertook to monitor for any adverse effects: "*We will undertake a detailed assessment, at home if necessary, for any subject who drops out of treatment for this reason, following which they will be offered appropriate help"*. "Appropriate help" was not defined.

It described CBT: "*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 activity, with a graduated return to normal activity, (c) challenging unhelpful beliefs about symptoms and activity"*.

It described GET: "*GET will be based on the illness model of both de-conditioning and exercise avoidance. Therapy involves an individually designed aerobic exercise programme with set target heart rate and times"* (3.4).

The inclusion criteria were to be "*the operationalised Oxford criteria for CFS.* ***We chose these broad criteria in order to enhance recruitment****. Subjects who also meet the criteria for 'fibromyalgia' will be included"* (3.6). The Oxford (1991) criteria were formulated by the Wessely School and have been criticised for being too broad -- they specifically include those with psychiatric fatigue and they potentially capture people suffering from "fatigue" that occurs in 33 different disorders -- and for specifically excluding those with neurological disorders such as ME. The Oxford criteria have no predictive validity and have never been adopted for use outside the Wessely School. They were superseded by the US Centres for Disease Control (CDC) Fukuda criteria in 1994.

The assumptions of outcome were given: "*At one year we assume that 60% will improve with CBT (and) 50% with GET"*.

Information about the day-to-day management of the trial said: "*The trial will be run by the trial co-ordinator, with the PI (Principal Investigator). He/she will liaise regularly with staff at the Clinical Trials Unit (CTU) who will be responsible for randomisation and database design and management (overseen by the centre statistician Dr Tony Johnson), directed by Professor Simon Wesssely*".

The UK ME/CFS community noted with some surprise the involvement of Dr Tony Johnson, Deputy Director of the MRC's Statistical Unit at Cambridge, because his published views on CBT were already known. In 1998, Johnson published a major review entitled "Clinical trials in psychiatry: background and statistical perspective" (Statistical Methods in Medical Research: 1998:7:209-234) in which he came to some unequivocal conclusions.

Johnson noted that psychiatric studies have been beset by poor design, inadequate data and incorrect analysis, and he noted the existence of studies produced by psychiatrists that claim "*inordinate enthusiasm*" for certain therapies.

He stated that a major requirement in any clinical trial is to determine the nature of the disease which will be investigated; he noted: "*sophisticated technological examination is important in psychiatry to eliminate organic causes of psychiatric symptomatology*", a view that Wessely School psychiatrists seem not to share.

Wessely maintains that there is an attractive cost implication of CBT ("*The only treatment strategies of proven efficacy are cognitive behavioural ones. We have developed a more intensive therapy; this form of therapy is acceptable to patients, safe, and more effective than either standard medical care or relaxation therapy. It has also been shown to be cost effective*". "Chronic fatigue syndrome. A practical guide to assessment and management" Sharpe M, Chalder T, Wessely S et al. Gen Hosp Psychiatry 1997:19:3:185-199) but Johnson disagreed, stating that a course of psychotherapy typically lasts for 12 weeks or longer and "*a major limitation is its cost*".

The involvement of Dr Tony Johnson in the PACE trial

Dr Johnson's involvement in the PACE trials merits closer scrutiny. He is the son-in-law of Dr Elizabeth Dowsett, who was formerly Medical Advisor to and President of the ME Association and who is currently Medical Advisor to the 25% ME Group for the Severely Affected. Correspondence exists between an ME/CFS sufferer and Dr Johnson himself, but which also involves Dr Anthony C Peatfield, Head of MRC Corporate Governance and Policy. The correspondence arose from the MRC's Biostatistical Unit's progress report for the years 2001 to 2006 that was placed on the website of the MRC Biostatistics Unit (BSU), taken from the BSU's Quinquennial Review of 2006.

One part of the Quinquennial Review states: "*Our influence on policy-makers has largely been indirect, through scientists' work on advisory committees, in leading editorials, in personal correspondence with Ministers, Chairs or Chief Executives (such as of*

Healthcare Commission or NICE), Chief Medical Officers and Chief Scientific Advisers, or through public dissemination when the media picks up on statistical or public health issues that our publications have highlighted.

"The Unit's scientists must remain wary of patient-pressure groups. Tony Johnson's work on chronic fatigue syndrome (CFS), a most controversial area of medical research, has had to counter vitriolic articles and websites maintained by the more extreme charities and supported by some patient groups, journalists, Members of Parliament, and others, who have little time for research investigations".

This contention that "CFS" research is beset with vitriol and "extreme" charities was re-iterated by Johnson himself in his own Report within the Quinquennial Review; under "Chronic Fatigue Syndrome (CFS), with P White, T Chalder (London), M Sharpe (Edinburgh)", Johnson's Report stated:

"*CFS is currently the most controversial area of medical research and characterised by vitriolic articles and websites maintained by the more extreme charities supported by some patient groups, journalists, Members of Parliament, and others, who have little time for research investigations. In response to a DH (Department of Health) Directive, MRC called for grant proposals for investigations into CFS as a result of which two RCTs (PACE and FINE) were funded and have started despite active campaigns to halt them. I am part of the PACE study, a multi-centre study comparing cognitive behaviour therapy, graded exercise training, and pacing in addition to standardised specialist medical care (SSMC), with SSMC alone in 600 patients. I have been fully engaged in providing advice about design of PACE and I am a member of both Trial Management Group and Trial Steering Committee. I am not a PI (Principal Investigator) because of familial involvement with one of the charities, a perspective that has enabled me to play a vital role in ensuring that all involved in the PACE trial maintain absolute neutrality to all trial treatments in presentation, documentation and assessment".*

Johnson's Report on "CFS" research rang alarm bells within the ME/CFS community, since it openly stated that he, personally, had a *"vital"* role to play in ensuring what ought to have been taken for granted in any MRC trial, namely the *"absolute neutrality"* of the PACE trial.

Upon seeing this on the MRC BSU website, an ME/CFS sufferer wrote first to the MRC Biostatistics Unit and then to Dr Johnson himself, requesting the names and details of all the charities, patient groups, journalists, Members of Parliament and "others" who have little time for research investigations, together with references for all the vitriolic articles and websites mentioned on the MRC BSU website.

There was no acknowledgment from either the MRC BSU or from Dr Johnson; however just after the letters had been sent to the MRC, it was observed that much of Dr Johnson's Report had been removed from the MRC BSU website, indicating that this was a matter of some importance to the MRC.

In statistical terms, the deletions from Dr Johnson's Report amounted to a substantial 42% of the entire Report.

Almost a full month later, a letter dated 10th October 2006 was received from Dr Anthony Peatfield, which said: *"You refer to some text that was recently published on the website of the MRC Biostatistics Unit. The comments to which you refer were drawn from a progress report produced by an individual member of staff. The comments have now been removed from the website. I would like to take this opportunity to apologise, on behalf of the MRC, for any offence these comments may have caused either to yourself or any other individual. While the comments were ill-judged, it was not the intention of the individual who wrote them, nor the Unit in publishing them, to cause offence"*.

Curiously, Dr Peatfield further advised that should anyone else contact the MRC about this same matter: "*we shall reply to any further requests such as your own as indicated in the third paragraph, above*", meaning that he would simply offer an 'apology' regardless of what information or clarification was being requested.

Peatfield's reply implied that those damaging comments were not made by anyone of significance at the MRC, when in fact they had been written by the Deputy Director of the MRC Biostatistics Unit who was intrinsically involved with the actual design of the PACE trial.

Out of ten Reports that constituted the Quinquennial Review, the only individual report from which sections were removed, including the Abstract, is that of Dr Johnson.

The Abstract could not, however, be removed from the Review Index, where all ten Abstracts by different individuals are located, with links to their full documents. In the case of Dr Johnson's "re-edited" document (see below), the link to the Abstract no longer works, but the link works for all the other Abstracts. Was this a ploy by the MRC to conceal Johnson's Abstract, with its references to his close association with the Institute of Psychiatry (see below)?

Amongst large amounts of text removed from Dr Johnson's Report were details of exactly how influential Dr Johnson has been within the MRC and with the Institute of Psychiatry, particularly in terms of securing MRC funding, along with other details of his close connections to key individuals involved in the PACE trial. The following extracts are taken from the Abstract, which was removed in its entirety from the body of Dr Johnson's Report:

"Abstract

"I have initiated, developed, and collaborated in both clinical trials and epidemiological studies in four challenging medical specialties working with a large number of collaborators geographically dispersed throughout UK, Europe, and beyond. These have resulted in major advances in the understanding of the efficacy of cognitive therapy.

"Over many years my programme has contributed to the successful completion of the three largest clinical trials, all of major international importance. My programme will be exploited in the future in further collaborations with the pharmaceutical industry.

"I have enabled a successful collaboration linking the research programmes of this Unit with the MRC Clinical Trials Unit (MRC CTU) in London, that has resulted in the establishment of a new Clinical Trials Unit dedicated to mental health and neurological sciences at the Institute of Psychiatry in London. The linkage has enabled my expertise in clinical trials to be extended to chronic fatigue syndrome and the setting-up of a major MRC study to evaluate the efficacy of four different interventions.

"I have advised many clinical trialists on the setting-up of organisational structures including Steering and Data Monitoring Committees, and Management Groups".

Some of Dr Johnson's credentials, however, remained on the MRC BSU website: *"I present my eighth and final Unit review report since joining MRC Neuropsychiatric Research Unit in 1968; a period exceeding 37 years during which I have been very privileged to engage fully in the research programmes of MRC, be a co-editor for 18 years of the first major journal in medical statistics (Statistics in Medicine), found an international society (Society of Pharmaceutical Medicine), draft the Constitution for another (International Society for Clinical Biostatistics), and contribute to UK Government, European, and International working parties and committees.*

"In view of my retirement in September 2008 I describe only my research programme over the past five years without reference to the future". The following text was removed: *"but note that none of my projects will terminate in the near future, for they will be continued and expanded by others, many of whom I have trained for that purpose. My role within MRC changed radically in 2001, resulting in my switching from independent band 2 to core scientist. My expertise in clinical trials was needed to expand the activities of the Department Without Portfolio into areas such as mental health (and) chronic fatigue, currently the focus of government health policy".*

From the above, it can be seen that Dr Johnson is an influential figure in the MRC BSU and, as Deputy Director, his in-house review was a substantial document. For the MRC Head of Corporate Governance and Policy (Dr Anthony Peatfield) to have referred to Johnson as a mere "*member of staff*" and to imply that the comments in question were not connected to anyone of significance at the MRC seems to indicate an intention to avoid accountability and to purposefully mislead the public. Johnson's Report was an important official communication from one professional to others. Coming from such a senior figure within the MRC, and considering his level of involvement with the PACE trials, Johnson's adverse comments about CFS would have carried considerable authority and influence.

Moreover, it seems that Dr Johnson may have been advising the Wessely School psychiatrists how best to obtain MRC funding from the advantage of his influential and

knowledgeable position as a core MRC scientist through the close links he had forged with the Institute of Psychiatry.

Disturbingly, it seems that in his material which was removed from the MRC website, Johnson revealed that he had used data (which he described as a *"perspective"* that he had been able to obtain through *"familial involvement with one of the charities"*) to assist in the design of the PACE trial. If this is so, what is he implying? The PACE trial is about challenging ME/CFS sufferers' beliefs: is Johnson somehow using the *"perspective"* he has obtained through *"familial involvement with one of the charities"* to design a trial whose aim is to promote a management regime that has already caused so much harm to members of that charity?

Most disturbingly of all, as mentioned above, Johnson stated that he was playing a *"vital"* role in maintaining *"absolute neutrality"* by *"all involved in the PACE trial"*. This clearly indicates that Johnson believed that without his own *"vital"* role, "*absolute neutrality*" would <u>not</u> be achieved.

The word "vital" means "essential", so was Johnson effectively conceding that he knew the PACE trial was fundamentally biased but that he – as an individual -- was dealing with the people involved in the trial who are known to be intent on dismissing "ME" and on promoting their own beliefs about the use of CBT/GET for those with "CFS"? Why is it only his own *"vital"* role that will ensure the "*neutrality"* of the PACE trial?

Having taken seven months to reply to a letter that had been sent to him personally, on 7th November 2006 Johnson attempted to exonerate himself, stating that the views he had expressed were not intended to represent the views of the MRC and that they had been *"the initial version of my progress report"*, and writing: *"I regret the words that I used"*.

Having earlier informed colleagues in his Report that: *"CFS is currently the most controversial area of medical research and characterised by vitriolic articles and websites maintained by the more extreme charities supported by some patient groups, journalists, Members of Parliament, and others, who have little time for research investigations"*, Dr Johnson stated in his letter: *"I did not have specific individuals or groups in mind and consequently, I cannot provide you with the names and details of the charities, patient groups, journalists, Members of Parliament, and others, who I believed had little time for research. I do not have, and I have never thought about, attempting to compile such a list. Similarly, I do not possess, and have never possessed, a list of vitriolic articles and websites, so I cannot provide these"*.

Also in his letter of 7th November 2006, Dr Johnson simultaneously did "*not know when CFS/ME became controversial or why*" but nevertheless proffered his speculation that *"controversy sometimes arises when the evidence base is slender as many views and ideas can be put forward without any means of resolving them. The publication of a large number of research papers in the medical literature, some of poor quality or based on small samples only leads to further confusion"*.

This is an interesting piece of conjecture, given that the post of Statistician Clinical Trials Unit (CTU) Division of Psychological Medicine Ref No: 06/A09 is described as the "Johnson_Wessely_Job" (07/07/2006) at the The Institute of Psychiatry where: "*The team works under the direction of Professor Simon Wessely, the Unit Director. The team is supported by the regular input of a Unit Management Group from within the Institute of Psychiatry. The statisticians within the Unit also have regular supervision meetings with Dr Tony Johnson from the MRC Clinical Trials Unit. The post holder will be directly responsible to the CTU Manager (Caroline Murphy), supervised by the CTU Statistician (Rebecca Walwyn) and will be under the overall direction of the Head of Department, Professor Simon Wessely"*.

As no satisfactory response had been received to a perfectly valid request for further clarification (ie. the names of individuals involved with the PACE trial who, Johnson believed, would, without his own *"vital"* intervention, be unable to maintain the requisite "*neutrality*" which he was able to ensure through his "*familial involvement*" with one of the charities), the ME/CFS sufferer wrote again with the same request.

Over five months after that request, Dr Johnson sent a further letter dated 2nd April 2007 in which he wrote: "*The issues that you raise here are complicated. First it is important to realise that there is a substantial range of opinion among clinicians about the relative merits of some treatments"*.

Johnson's reply was a five-page masterpiece of confabulation but still did not answer the question asked.

Instead, amongst other diversions, he wrote at length about SSMC (standardised specialist medical care) for those with ME/CFS as part of the PACE trial, causing another ME/CFS sufferer to ask:

"What is the accepted definition of standardised specialist medical care (SSMC) for those with ME/CFS? In order to achieve an accurate assessment of the PACE trial outcomes, there must be a definition of standardised specialist medical care, so what is this definition and where is it accessible? (It is a matter of record that there isn't one). Tony Johnson accepts that an early design for the current PACE trial did not include an SSMC group but he seems to have expediently overlooked the reality that there is **no** *SSMC for those with ME/CFS, as Catherine Rye made plain in 1996 about the Sharpe et al paper of the Oxford trial of CBT/GET: 'I am a sufferer and participated in the Oxford trial. There are facts about the trial that throw into doubt how successful it is. It is stated that patients in the control group received standard medical care. I was in that group but I received nothing' "* (Independent, 30th March 1996, page 16).

The same ME/CFS sufferer also asked:

"*What is Tony Johnson's statistical rationale for deliberately mixing patient cohorts in the PACE trial? Against the evidence that mixing study populations is inadvisable, the PACE trial is mixing at least three different groups of patients.*

"Fibromyalgia patients are included in the Principal Investigator's own selection of those with "CFS/ME" for the MRC PACE trial, as well as those with other states of chronic fatigue, including psychiatric states, yet all three categories are taxonomically different and are classified differently by the WHO.

Fibromyalgia is classified at ICD-10 M79.0; ME/CFS is classified at ICD-10 G93.3 and other fatigue states are classified at ICD-10 F48.0.

"In a reply dated 15th April 2005 to Neil Brown, Simon Burden of the MRC wrote: 'When researchers put together a proposal they are required to define the population they are studying'. Why does this basic requirement not apply to the PACE trial and how will the outright abandonment of this MRC principle affect Johnson's statistical analysis of the PACE trial?

"How does this accord with what Simon Burden asserted was the MRC's requirement for 'the high scientific standard required for funding'?

"Johnson acknowledges in his reply (on page 4) that: 'It is important to realise that there is a substantial range of opinion among clinicians about the relative merits of some treatments'. Indeed, this is so. What, then, is his statistical explanation for the MRC's undue reliance on the ill-founded beliefs of Wessely School psychiatrists, given the large body of undisputed published evidence that their beliefs about the nature of ME/CFS are simply wrong? Johnson states in his reply: 'in designing the trial we had to guess the outcomes and our guesses (were) mostly based on published studies". For what statistical reasons did the MRC rely on Wessely School studies, when there is abundant published criticism of those very studies and their flawed methodology in the literature?

"This published criticism is readily accessible to all and sundry. The work of the Wessely School on "CFS/ME" has been stringently criticised in the international literature for flawed methodology; particularly for use of a heterogeneous patient population (studies using mixed populations are not useful unless researchers disaggregate their findings); for selective manipulation of others' work, claiming it supports their own findings when such is not the case; for their focus on the single symptom of "fatigue" whilst ignoring other significant signs and symptoms associated with the cardiovascular, respiratory, neurological and immunological systems; for generating conclusions before generating the data to support such conclusions; for advising Government bodies that the reported biomedical abnormalities 'should not deflect the clinician away from the biopsychosocial approach and should not focus attention towards a search for an 'organic' cause', and for their recommendation that no advanced tests should be carried out on "CFS/ME" patients when it is those very tests that reveal the unequivocally organic nature of the disorder.

"Throughout his reply, Johnson uses the terms: 'In designing a clinical trial (of CBT/GET) we have to estimate the number of patients'; 'Estimation essentially requires a guess at what the results will be'; 'In guessing what the results may be…'; 'The

assumptions we make…'; 'Broadly, we assumed that around 60% of patients in the CBT group would have a 'positive outcome' at one year follow-up….'; 'We speculated that….', ***so there is now written confirmation from the MRC Biostatistics Unit that the whole PACE trial is based on guessing, speculation and assumption. Would Tony Johnson explain how this accords with the MRC's supposed requirement for high standards?".***

It was suggested that Johnson be asked to explain how statistics had suddenly become a matter of guesswork, speculation and assumption.

In his Report, Johnson had referred disparagingly to *"websites maintained by the more extreme charities"* but did not mention that it was two of the UK's major charities (The ME Association and the 25% ME Group for the Severely Affected) that were calling for the PACE trial to be halted.

The ME Association has been adamant that the PACE and FINE trials should be halted and on 22nd May 2004 posted the following on its website (which was printed in its magazine "ME Essential" in July 2004):

"The MEA calls for an immediate stop to the PACE and FINE trials

"A number of criticisms concerning the overall value of the PACE trial and the way in which it is going to be carried out have been made by the ME/CFS community. The ME Association believes that many of these criticisms are valid. ***We believe that the money being allocated to the PACE trial is a scandalous way of prioritising the very limited research funding that the MRC have decided to make available for ME/CFS, especially when no money whatsoever has so far been awarded for research into the underlying physical cause of the illness. We therefore believe that work on this trial should be brought to an immediate close and that the money should be held in reserve for research that is likely to be of real benefit to people with ME/CFS****. We share the concerns being expressed relating to informed consent, particularly in relation to patients who are selected to take part in graded exercise therapy. The Chief Medical Officer's Report (section 4.4.2.1) noted that 50% of ME/CFS patients reported that graded exercise therapy had made their condition worse, and we therefore believe that anyone volunteering to undertake graded exercise therapy must be made aware of these findings".*

It is notable in this respect that Lord (David) Sainsbury of Turville, who at the time was responsible for the MRC, stated in the House of Lords: "*Because the trial participants will have provided informed consent, they will receive no compensation if they become more ill, whether or not as a result of the particular treatment"* (Hansard [Lords]: 18th November 2004: 4830).

The ME Association notice additionally called for all further work on the FINE trial to be halted, saying the MEA *"is not convinced by the evidence so far put forward in support of this approach"*.

From this whole episode concerning Dr Johnson's Report, the ME/CFS community was left in no doubt about the bitter contempt for sufferers, some charities, and those MPs who support them that exists at the MRC, or that the seam of Wessely School dismissal and denigration does indeed run deep.

Representations to the MRC setting out concerns about the PACE trials

It is known that enormous public and professional concern was expressed to the MRC about the PACE and FINE trials. Some of the written representations were sent by Recorded Delivery. Few were acknowledged and all seem to have been disregarded.

Those legitimately expressed concerns include the following:

Concern about the huge waste of money at UK tax-payers' expense

Originally the MRC PACE and FINE trials of CBT/GET were said to be costing £2.6 million, but according to Michael Sharpe, one of the Principal Investigators, the current figure is £4 million. From the figures awarded by the MRC for "fatigue" research on the National Research Register, the amount that has gone to biomedical research into ME/CFS is virtually non-existent. In March 2005, the MRC confirmed that since 2002, it had funded two further studies into "CFS/ME" (one for Professor Creed [see below] on psychiatric aspects and one on "Chronic fatigue (*sic*) and ethnicity"), and that it had received 12 applications for funding related to CFS/ME that were not granted. Of the applications that the MRC rejected, seven were under the heading "Pathophysiology of CFS" and included studies regarding genetics / biomarkers, immunology and neuroimaging; three were regarding epidemiology, as well as studies in primary care and clinical and laboratory characterisation of ME/CFS. As mentioned above, the ME Association pointed out that the results of these psychiatric trials may not add any significant information to what patients and their doctors already know, so on what ethical grounds does the MRC justify spending such a vast amount of money to the exclusion of studies with real potential to benefit ME/CFS sufferers?

As William Bayliss stated on an internet group on 2nd Nov 2004: "*The MRC's PACE trial has been very cleverly designed to exclude most true ME sufferers and include sufferers of mental illness. As such, the trial is a deceitful national scandal and a gross abuse of taxpayers' money*"

Concern about the design of the study

This is an area of extreme unrest, because the design of the study may well be relevant to the aims of the study, and these are known to be the nationwide promotion of CBT and GET as the management regimes of choice. It is apparent to many people that by using the all-encompassing Oxford criteria, the trial objectives have been set so as to achieve

this pre-determined agenda and to meet the requirements of political and commercial paymasters.

The Oxford criteria expressly include people with psychiatric disorders in which "fatigue" is a prominent symptom (thereby, as noted above, potentially catching at least 33 other disorders that fit the Oxford criteria), but expressly exclude people with neurological disorders; indeed, the Oxford criteria claim to use people with neuromuscular disorders as controls, so by any logical reasoning, ME/CFS (an internationally classified neurological disorder) would be excluded.

There can be no credible doubt that the Oxford criteria exclude those with ME as distinct from the Wessely School definition of "CFS" and this was confirmed in 1991 by psychiatrist Anthony David (colleague and co-author with Wessely) who described the Oxford criteria shortly after they were published: ***"British investigators have put forward an alternative, less strict, operational definition which is essentially chronic fatigue in the absence of neurological signs (but) with psychiatric symptoms as common associated features"*** (Postviral syndrome and psychiatry. AS David. British Medical Bulletin 1991:47:4:966-988). Given such clarification, how can it be ethical for the MRC to claim that the PACE trials will include those with Ramsay-defined ME?

The MRC, however, insists that people with "CFS/ME" will be included in the trials.

On 16th June 2005, Dr Sarah Perkins, Programme Manager for the MRC Mental Health Board, wrote: ***"The main entry criteria for the PACE trial are the Oxford criteria. Their use will ensure that the results of the trials will be applicable to the widest range of people who receive a diagnosis of CFS/ME.*** *The exclusion criterion of 'proven organic brain disease' will be used to exclude neurological conditions of established anatomical pathology. It will not be used to exclude patients with a diagnosis of ME".*

Concern that the MRC classifies "CFS/ME" as a mental disorder

Given that the psychiatric lobby demands 100% proof of an organic pathoaetiology for ME/CFS before they will "allow" it to be accepted as a "real" organic disease as distinct from a mental disorder, why does the MRC not require a similar standard of proof from these psychiatrists that ME/CFS is a mental disorder, as they assert?

It cannot be emphasised enough that what Wessely School psychiatrists choose to call "CFS/ME" is not Ramsay-defined ME and should not therefore be included as though it were the same disorder. To do so is both a failure of a duty of care towards patients and a corruption of the scientific process.

Without doubt, the false beliefs about ME/CFS demonstrated by the MRC are known to be carefully-constructed "policy-based evidence", as can be seen from the 32 page Report from a Working Group of the Medical Research Council's own Neurosciences and Mental Health Board (NMHB) Strategy and Portfolio Overview Group (SPOG) of

January 2005. The aim of that Report was to consider the balance of the current MRC research portfolio, and it confirms what the UK ME/CFS community has long recognised – that ever since the advent of Simon Wessely, the MRC has considered "CFS/ME" as a mental disorder and will continue to do so: at paragraph 6.2 the Report is unequivocal: "*Mental health research in this instance covers CFS/ME"*.

Other points of note in the SPOG Report include:

- the MRC research agenda should be optimally aligned with the injection of Government funding

- mental health represents a vast potential market for pharmaceutical companies

- under "Mapping the UK research portfolio in mental health", the Report states: "*The analysis will capture all peer-reviewed grants that are live at a given date, which will be classified in terms of a list of mental health conditions based upon ICD-10 classifications*" (could this explain the determination of Wessely School psychiatrists formally to re-classify ME/CFS as a "mental" disorder?).

- In a BBC Radio Five Live broadcast transmitted on 22nd February 2005, the Chief Executive of the MRC, Professor Colin Blakemore, exhibited a serious lack of knowledge about ME/CFS, claiming that it does not matter whether "CFS/ME" is an organic or psychological condition. Does he really see no need to search vigorously for the cause(s) of ME/CFS? If not, why does such an approach relate only to ME/CFS and not to all illnesses whose cause is as yet unknown, including cancer, multiple sclerosis and lupus?

That the MRC specifically and deliberately classifies "CFS/ME" under "mental health" research is at diametric variance with the Health Minister's written confirmation given one year prior to the publication of this MRC SPOG Report, which demonstrates the determined defiance of medical science by the psychiatric lobby.

Concern about mixing study cohorts

The WHO is resolute that taxonomic principles must be observed, but the at the behest of the psychiatric lobby, the MRC is sanctioning the breaching of these taxonomic principles in the "CFS/ME" trials by deliberately mixing study cohorts from the outset. Is this not contrary to the high standards that the MRC claims it requires for all the studies it agrees to fund?

The PACE and FINE trials are flawed from the outset by this deliberate mixing of study cohorts and by excluding those with true ME yet claiming that the results will refer to those with ME.

This is important because **"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"** (D. Ho-Yen; BMJ 1994:309:1515).

By lumping together as many states of "chronic fatigue" as possible into what they insist is one "somatoform" syndrome, the psychiatric lobby ignores the known and established differences between fibromyalgia (FM) and ME/CFS, and many in both the FM and ME/CFS communities believe they have a right to know why patients suffering from two different disorders are to be amalgamated in the MRC trials that claim to be studying "CFS".

In his letter of 15th April 2005 to Neil Brown, Simon Burden of the MRC (referred to above) stated that researchers applying to the MRC for funding are *"required to define how they will find participants in the study"*. In the case of "CFS/ME" -- which is to include fibromyalgia -- the methods include financial inducements (which in other areas may be described as "bribery"). If clinicians have to be tempted by financial rewards to refer patients to these MRC trials, then something is very wrong, but such financial inducements are indeed being offered to GPs to identify and refer patients to the new "CFS" Centres and into the PACE and FINE trials. This was confirmed in July 2004 by Minister of State Dr Stephen Ladyman MP at the All Party Parliamentary Group on Fibromyalgia (now disbanded).

Further, in the case of the MRC FINE trials, whilst in the Patient Information Sheet patients are assured that "*Your GP is not being paid for his or her participation in this trial"*, there is a different message for the GP because in the GP invitation letter it states: "*Practices will be recompensed by the Department of Health for time spent in identifying and recruiting patients (£26.27 per referral*)". Does such a discrepancy accord with the MRC's own definition of "high standards"? (On the subject of high standards, what can be the explanation for the MRC-funded FINE trial literature using the term "*myalgic encephalitis*", which is not the same as "myalgic encephalomyelitis"? Is accuracy no longer considered a component of "high standards"?).

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. The systematic review is unequivocal: **"Studies including patients with fibromyalgia were not selected for the review"** (JAMA 2001:286:1360-1368).

Why, therefore, on whose authority and on what evidence, was it decided to include patients with FM in the MRC trials of CBT in a "CFS/ME" population?

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*)

More recent (2007) evidence from Spain presented at the ME Research UK (MERUK) International Research Conference on 25th May 2007 at Edinburgh demonstrated that FM and ME/CFS are two different diseases with two different genetic profiles and that there are very clear distinctions, with a 95.4% specificity. Many polymorphisms in the genes were different (Genetic Profiles in Severe Forms of Fibromyalgia and Chronic Fatigue Syndrome Dr Estibaliz Olano: this presentation is available on DVD obtainable from MERUK, telephone number 01738-451234).

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.

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 Chief Medical Officer'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 entitled "*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).

Is the MRC still content that the PACE trial proposal 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 discrete biomedical and genetic profiles that are entirely distinct from those found in ME/CFS?

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?

Concern about Ethical Standards in the PACE Trial

Mrs Connie Nelson wrote to the MRC asking four pertinent questions about the PACE trial: (a) who will decide if the patient has been harmed? (b) in the event of such harm, what will be the speciality of the clinicians who will visit the patient at home? (c) what will be considered a "serious adverse event" within the PACE study? and (d) what would be considered "appropriate help" if the PACE study exacerbates a patient's condition?

On 26th July 2005, Dr Sarah Perkins replied: "*The investigators responsible for this trial have established a robust set of procedures regarding the management of any adverse events*". Included in adverse events was listed "*any episode of self-harm*". Dr Perkins explained that: "*As part of the peer-review process, a comprehensive assessment of any safety and ethical issues was made before the award of the trial grant*" and she said the PACE trial was "*proceeding under good clinical practice guidelines, which includes independent supervision. This comprises an independent Data Monitoring and Ethics Committee*".

On 25th August 2005, Mrs Nelson again wrote to the MRC asking for the composition of the Data Monitoring and Ethics Committee. She pointed out that as this was a publicly funded trial, she would like to know who was on that Committee; she also asked for a copy of the "comprehensive assessment" of safety and ethical issues undertaken as part of the peer-review before the award of the trial grant, saying that -- given the evidence that exercise makes ME/CFS patients worse -- this may help clarify why the trial was ever funded.

Mrs Nelson further asked whether an ME relapse would be recognised and accepted as "clinical change", given that many people feared that the assessor(s) may not believe in ME or in the reality of a relapse. Her final question asked if the published papers of the PACE trial would include – as is normal practice for contentious treatments – details of all drop-outs and adverse events in each trial group.

On 21st September 2005, Dr Perkins provided the names of PACE Trial Steering Committee Members and the membership of the Data Monitoring and Ethics Committee. Names of particular concern to the ME/CFS community included Professor Janet Darbyshire (MRC Clinical Trials Unit); Professor Peter White; Professor Michael Sharpe and Professor Tudie Chalder. The Observers included two names of particular concern: Professor Mansel Aylward and Mr Chris Clark of the charity Action for ME. The three names on the Data Monitoring and Ethics Committee were Professor P Dieppe, Dr C Feinmann and Professor A Fletcher. Dr Perkins then stated: "*Although we are committed to being as open as possible, we have decided not to release peer review comments*".

Concern about misleading information supplied by the MRC

In December 2005 a Member of Parliament informed a constituent that: "*It is encouraging to see that epidemiological research is being conducted which may yield*

improved understanding of (ME/CFS)", when the reality was that the MRC had granted Professor Francis Creed funding for yet more psychosocial research, Professor Creed being well-known for his Wessely School views about "CFS/ME" (see http://www.meactionuk.org.uk/Proof_Positive.htm). Creed is Professor of Psychological Medicine at the School of Psychiatry and Behavioural Sciences at Manchester; one of his main research areas is somatisation disorders (which the Wessely School insist includes "CFS/ME"). He is Editor of the Journal of Psychosomatic Research and has failed to respond to letters written to him in his editorial capacity asking that the Journal present a more accurate and balanced view of ME/CFS. The Member of Parliament had thus been misled. Many MPs erroneously believe that the Government has done a good job in funding the well-publicised "CFS Centres" and are unaware that those Centres will deliver only psychotherapy regimes that have already been shown to make some ME/CFS patients worse.

Concern about post-funding alterations to the study Identifier and Protocol

Following the outcry by the ME/CFS community about the use of the Oxford criteria as entry into the PACE trial, the MRC announced that a "*secondary analysis"* would be performed using the *"London criteria"*.

Was this approved by the Data Monitoring and Ethics Committee, given the legitimate concern about the so-called "London" criteria that was submitted to the MRC?

The "London" criteria have never been published and are not available as a reference for identification. They were mentioned in the National Task Force Report in 1994 as being one of nine different proposed definitions and descriptions.

The "London" criteria have never been used in research (before criteria can be used in research, they need to be submitted for peer review and published in an accessible form).

The "London" criteria have not even been consistently defined – there are different versions of them and a definitive version has not been identified.

The authors of the "London" criteria remain to be established as there are divergent claims about who the authors might be.

The "London" criteria have never been accepted into common usage, nor have they ever been validated or operationalised.

On what scientific basis can the MRC approve any "*secondary analysis*" using non-existent criteria? The "London" criteria have no justifiable or validated legitimacy that would in any way provide acceptable criteria for use by the MRC.

Moreover, no amount of "*secondary analysis"* using any additional criteria can select patients with ME/CFS who were by definition excluded from the MRC trials in the first

place by virtue of neurological disorders being expressly excluded from the Oxford entry criteria (which basically catch patients with chronic "fatigue").

It should be noted that the so-called "London" criteria are not the same as the Dowsett and Ramsay clinical criteria for investigation of ME, which are exceedingly useful (Postgrad Med J 1990:66:526-530).

Other post-funding amendments to the PACE trial are more worrying.

It seems that the Trial Investigators will have the option to "select out" patients whom they believe will not respond in the desired way to the programme or who are too unwell to remain in the trials.

The list of what constitutes an "adverse reaction" has been shortened.

Regarding outcome measures, the only objective measure of improvement seems to have been dropped, in that it seems the trialists no longer propose to use an actometer (an objective measure of activity) as an outcome measure of improvement.

The only symptom actually being measured is subjective "fatigue", which is not an objective scientific measurement and cannot therefore provide a robust clinical evidence base.

"Recovery" has been re-defined. It will now be defined by participants meeting all four of the following: (i) a Chalder Fatigue Questionnaire score of 3 or less; (ii) an SF-36 physical function score of 85 or above, rather than the working age norm of 90 (the SF-36 measures social and role functioning); (iii) a Clinical Global Impression (CGI) score of 1 (the self-rated CGI has a score range of 1 – 7 and provides only a subjective interpretation), and (iv) the participant no longer meeting the trial entry criteria.

To most people, "recovery" means being able to return to full-time work and being able to be self-supporting.

Did the MRC Data Monitoring and Ethical Committee approve such significant changes to the trial protocol after funding had been granted? If so, was this in collusion with one of the MRC trial sponsors (ie. the Department for Work and Pensions)?

As it seems there will now be no objective evidence from the MRC PACE trials of <u>no</u> activity improvement, will this particular sponsor of the trials continue to maintain that there is no physical disability in ME/CFS patients who are claiming benefit?

<u>Concern about the competing interests of the psychiatric lobby who are running the MRC trials</u>

Concerns have been expressed that it is simply wrong for the psychiatrists who are carrying out these MRC trials to be paid for studying the regimes which they themselves formulated (Gen Hosp Psychiatry 1997:19:3:185-199), particularly in view of the proven evidence of their commercial interest in obtaining their desired outcome from these regimes.

Concern about the MRC's refusal to heed the existing evidence that CBT/GET does not work

As outlined above in the section on NICE, the proponents of the CBT/GET regime themselves are on record as stating that in relation to ME/CFS, it is not *"remotely curative"*, that relapses occur, that the very modest benefits do not last, and that *"many CFS patients, in specialised treatment centres and the wider world, do not benefit from these interventions"*.

Further, as noted above, the CRD Systematic Review of CBT/GET studies (the Wessely School "bible") points out that there is no objective evidence of improvement and that the subjective gains may be illusory (JAMA 2001:286:1360-1368).

As also mentioned above, the MRC's Chief Executive Officer, Professor Colin Blakemore, stated on 24th October 2003: *"Neither the PACE nor the FINE trials will provide a cure for CFS/ME but that is not their purpose. The trials are intended to assess a number of possible treatments to see if they are beneficial to those suffering from CFS/ME"*.

Given that this information is already known, the ME/CFS community pleaded with the MRC to halt the PACE and FINE trials and to use the money in a more constructive way. The MRC ignored these requests.

Concern about the persistent refusal to heed the evidence that graded exercise may be dangerous for people with ME/CFS

Substantial published evidence of the organic basis of Ramsay-defined ME/CFS (ICD-10 G93.3) was submitted to the MRC. There are over 4,000 such papers. It was all dismissed or ignored.

Of particular concern was the refusal of the MRC to heed the evidence that aerobic exercise (as in graded exercise that is part of the PACE trial) might be dangerous for some patients with ME/CFS and the fact that the Principal Investigators of the PACE trial were not screening for potentially life-threatening cardiac anomalies in trial participants.

Cardiac problems in ME have been documented in the medical literature for over half a century – the fact that normal loss of blood flow may be persistent in ME was documented by Gilliam in 1938. Other cardiac problems have been consistently

documented in the literature since that time, for example, Wallis (1957); Leon-Sotomayer (1965) and Ramsay (1950s-1980s). In his 1988 CIBA Foundation lecture, Professor Peter Behan from Glasgow confirmed that he was regularly able to demonstrate micro-capillary perfusion defects in the cardiac muscle of ME patients. Also in 1988 he noted that: "*Evidence of cardiac involvement may be seen: palpitations, severe tachycardia with multiple ectopic beats and occasional dyspnoea may occur and are quite distressing. It is of great interest that some patients have evidence of myocarditis*" (see Crit Rev Neurobiol 1988:4:2:157-178). In 2001, in her Research Update presentation to the Alison Hunter Memorial Foundation Third International Clinical and Scientific Conference on ME/CFS held in Sydney, Professor Mina Behan from Glasgow (now deceased) stated: "*Convincing evidence of cardiovascular impairment can be demonstrated*".

[For the early references, see "The Clinical and Scientific Basis of ME/CFS" edited by Byron Hyde, Jay Goldstein and Paul Levine, published in 1992 by The Nightingale Research Foundation, Ottawa. See also BMJ 1989:299:1219; Postviral Fatigue Syndrome ed. Rachel Jenkins and James Mowbray, pub. John Wiley & Sons, 1992; Inf Dis Clin Practice 1997:6:327-333; Proc Soc R Coll Physicians Edinb 1998:28:150-163; Hum. Psychopharmacol.Clin.Exp 1999:14:7-17; Clin Physiol 1999:19:2:111-120; JCFS 2001:8:(3-4):107-109].

The difficulty with some of the earlier references is that the documented clinical observations may not have been scientifically evaluated and in the current climate which dictates that "evidence-based medicine" is the only acceptable medicine, such observations are dismissed and ignored because there is no "evidence-based data". In the 21st Century, this is called progress in medicine.

The Government, Big Pharma and the medical insurance industry all prefer to accept the Wessely School dogma that "CFS/ME" is *"medically unexplained chronic fatigue"* and is therefore a primary behavioural disorder. It is the case that the Government-funded "CFS" Centres will employ only the psychiatric interventions recommended by the Wessely School.

Because this is such a crucial issue, the cardiac anomalies that have been documented in ME/CFS are summarised here.

An update of the paper by Carol Sieverling was posted on Co-Cure on 10th April 2005 ("The Heart of the Matter: CFS and Cardiac Issues" – a 41 page exposition of Dr Paul Cheney's experience and expertise), from which the following notes are taken and to both of whom grateful acknowledgement is made.
Cheney's focus is based on the paper by Dr Ben Natelson (neurologist and Professor of Neurology) and Dr Arnold Peckerman (cardiopulmonary physiologist) at New Jersey Medical Centre (ref: "Abnormal Impedance Cardiography Predicts Symptom Severity in Chronic Fatigue Syndrome". Peckerman et al: The American Journal of the Medical Sciences: 2003:326:(2):55-60).

This important paper says that, without exception, every disabled ME/CFS patient (sometimes referred to as Chronic Fatigue and Immune Dysfunction Syndrome or CFIDS in the US) is in heart failure.

The New Jersey team looked at many things in CFIDS patients: what they found was the "Q" problem. "Q" stands for cardiac output in litres per minute. In CFIDS patients, Q values correlated -- with great precision – with the level of disability. Q was measured using impedance cardiography, a clinically validated and Government agency-recognised algorithm that is not experimental.

Normal people pump 7 litres of blood per minute through their heart, with very little variance, and when they stand up, that output drops to 5 litres per minute (a full 30% drop, but this is normal). Those two litres are rapidly pooled in the lower extremities and capacitance vessels. Normal people do not sense the 30% drop in cardiac output when they stand up because their blood pressure either stays normal or rises when they stand up -- the body will defend blood pressure beyond anything else in order to keep the pulse going. This is critical to understanding what Cheney believes happens in CFIDS patients.

What the New Jersey team found in people with CFIDS was astonishing – **when disabled CFIDS patients stand up, they are on the edge of organ failure due to extremely low cardiac output as their Q drops to 3.7 litres per minute (a 50% drop from the normal of 7 litres per minute).**

The disability level was exactly proportional to the severity of their Q defect, without exception and with scientific precision.

To quote Cheney: **"When you push yourself physically, you get worse"**. CFIDS patients have a big Q problem; to quote Cheney again: "**All disabled CFIDS patients, all of whom have post-exertional fatigue, have low Q and are in heart failure"**.

Post-exertional fatigue (long documented as the cardinal feature of ME/ICD-CFS but not of other, non-specific, states of chronic fatigue) is the one symptom that always correlates with Q. Among disabled CFIDS patients, 80% had muscle pain; 75% had joint pain; 72% had memory and concentration problems; 70% had unrefreshing sleep; 68% had fever and chills; 62% had generalised weakness; 60% had headaches, but 100% had post-exertional fatigue.

Cheney posits that when faced with a low Q, the body sacrifices tissue perfusion in order to maintain blood pressure: ie. microcirculation to the tissues of the body is sacrificed to maintain blood pressure so that the person does not die in the face of too low a cardiac output. This compensation is what is going on in the CFIDS (ME/CFS) patient.

In the Peckerman study, the data on the disabled CFIDS patients reveals that even when they are lying down, their Q is only 5 litres per minute. The lower the Q, the more time

the patient will spend lying down because lying down is the only time they come close to having sufficient cardiac output to survive.
Cheney states that it is important to note that the body does not sacrifice tissue perfusion equally across all organ systems: instead, it prioritises the order of sacrifice and one can observe the progression of ME/CFS in a patient by noting this prioritisation.

Two organ systems in particular have a protective mechanism (the Renin Angiotensin System, or RAS) against restricted tissue perfusion: the lung and the kidneys. These organs can sustain the greatest degree of Q problems because of this extra protection. Additionally, the heart and the brain also have this extra protection, even in the face of an extremely low Q. Therefore the lung, the brain, the kidneys and the heart are a bit more protected from a drop in Q than the liver, the gut, the muscles and the skin.

Certainly, Cheney's submission seems to tally with the experience of long-term ME/CFS sufferers about the order in which tissue perfusion is sacrificed.

<u>The first to be affected is the skin</u>: if the microcirculation of the skin is compromised, several problems can arise. One is that without adequate microcirculation to the skin, the body cannot thermoregulate anymore: the patient cannot stand heat or cold and if the core temperature rises, the patient will not be able to sleep and the immune system will be activated. In order to regulate that problem, the body will kick in thyroid regulation which will down-regulate in order to keep the body temperature from going too high. The result of this is that the patient develops compensatory hypothyroidism, which means that now the patient will have trouble with feeling cold. Also, the body will not be able to eliminate VOCs (volatile organic compounds), which are shed in the skin's oil ducts, so VOCs build up in the body's fat stores and the patient becomes progressively chemically poisoned by whatever is present in the environment -- in other words, the patient develops Multiple Chemical Sensitivity.

<u>The second effect</u>: if things get worse, the next microcirculation to be sacrificed is that to the muscles and the patient will have exercise intolerance and cannot go upstairs. If things get still worse, the patient begins to experience fibromyalgic pain in the muscles. Cheney posits that if the microcirculation to the joints becomes compromised, it may precipitate pyrophosphoric acid and uric acid crystals and the patient starts to have arthralgia linked to this circulatory defect.

<u>The next system to be compromised</u> is the liver and gut. One of the first things the patient may notice in this stage of disease progression is that there are fewer and fewer foods that can be tolerated, partly because microcirculation is necessary for proper digestion. Also the body will not secrete digestive juices so whatever food is tolerated will not be digested: if food cannot be digested, there will be peptides that are only partially digested and therefore are highly immune-reactive; they will leak out of the gut into the bloodstream, resulting in food allergies and / or sensitivities. The body will be unable to detoxify the gut ecology, so the gut will begin to poison the patient, who will feel a sense of toxic malaise, with diarrhoea, constipation, flatulence and all kinds of gut problems. If this gets worse, a malabsorption syndrome will develop, resulting in

increasing toxicity in which the patient feels “yucky” and which can manifest as a variety of skin disturbances (for instance, a rash), as well as problems in the brain.

The fourth affected system is the brain: Cheney posits that there is a devastating effect in the brain as a result of liver / gut dysfunction, which can quickly toxify the brain, resulting in disturbances of memory and of processing speed. Also, the hypothalamus begins to destabilise the patient from the autonomic nervous system perspective. In all probability, the brain and heart suffer simultaneous compromise, but patients usually notice the brain being affected much earlier than the heart – this is because heart muscle cells have the greatest mitochondrial content of any tissue in the body, so when the mitochondria are impaired, the heart muscle has the greatest reserve. Even if the patient is sedentary with not too much demand on the heart, they can still think and make great demands on the brain, and energy is energy, whether it is being used physically or cognitively.

The fifth affected system is the heart: Cheney posits that the effect of compromised microcirculation upon the heart has an “a” part and a “b” part: part “a” is the manifestation of microcirculation impairment and part “b” is “the event horizon”.

Part “a”: manifestation of microcirculation impairment: the initial manifestation of microcirculatory impairment of the heart is arrhythmia with exercise intolerance: when the patient goes upstairs, more cardiac output is needed but the patient cannot sustain it. As it gets worse, there will be mitral valve prolapse (MVP) because of inadequate capillary function. Finally, when there are even more severe microcirculatory problems, the patient starts to get chest pain as the myocardial cells die because they cannot get adequate oxygen.

Part “b”: the event horizon: (once this line is passed, there is no going back): Cheney’s view is that when the microcirculation defect within the heart itself begins to impact Q, a vicious circle begins – microcirculation impairment reduces the Q, which produces more microcirculation impairment, which produces even more Q problems, so down goes the patient into the next phase of cardiac failure, which involves the lungs.

The sixth affected system is the lung and kidney: this leads to congestive heart failure and pulmonary oedema, then the kidney is affected (the kidney is the last to go because it has the RAS back-up system). Combined with liver impairment, this stage is known as hepatorenal failure, which is the cause of death due to compensated idiopathic cardiomyopathy.

A patient will know if s/he eventually loses the ability to compensate if, when they lie down, they are short of breath.

Cheney’s view is that cardiac muscle has lost power because the mitochondria are dysfunctional (ie. there is an energy-production problem in the cells).

As long ago as the 1980s, Dr Les Simpson in New Zealand found that the red blood cells of patients with CFIDS were deformed and when deformed, they cannot get through the capillary bed, causing pain. An indication of such deformity is a drop in the sedimentation rate (SED, or ESR) and Cheney has observed that when measured in a laboratory, CFIDS patients' sedimentation rate is the lowest he has ever recorded, which confirms to Cheney that CFIDS patients have an induced haemoglobinopathy. He believes that the CFIDS patients with the lowest sedimentation rate may have the greatest degree of pain. The more deformed the red blood cells, the more pain may be experienced. Some CFIDS patients have a problem similar to that of sickle cell anaemia in this regard, and sickle cell patients have unbelievable pain. Cheney emphasises that it is bad enough when patients do not perfuse their muscles and joints (because of poor microcirculation) but it is even worse when red blood cells are so deformed that they can barely get through the capillaries or are blocked entirely.

Cheney notes that in the Laboratory Textbook of Medicine, there are only three diseases that lower the sedimentation rate to that level: one is sickle cell anaemia (a genetic haemoglobinopathy); the second is ME/CFS (an acquired haemoglobinopathy) and the third is idiopathic cardiomyopathy.

Cheney observes that in order to improve cardiac output in CFIDS, patients need to lie down, as this increases the cardiac output by 2 litres per minute. He notes that some patients need to lie down all the time to augment their blood volume in order to survive. He has found increasing the intake of potassium to be helpful (potassium induces aldosterone, a hormone that significantly increases blood volume), and that magnesium is beneficial as it is a vasodilator and helps reduce the resistance the blood encounters.

Since Professor Cheney has shown that in ME/CFS patients, cardiac output struggles to meet metabolic demand, how can forced aerobic exercise which forms a major part of the MRC PACE and FINE "rehabilitation" trials help such patients remain as functional as possible?

In the light of the Peckerman et al paper that was published in 2003, are the psychiatrists and their peer reviewers at the MRC who approved the PACE trial protocol still convinced that these trials (and the exercise regimes to be meted out by the new Centres) pose no harm for those with ME/CFS?

Perhaps they are content to rely on the certainty that they themselves can never be held accountable for any harm to any patient because all participants must sign a compulsory waiver which means that no participant can ever pursue any claim for medical negligence or damages?

<u>Concern that the Principal Investigators of the MRC PACE and FINE trials repeatedly reject published evidence of biomarkers of ME/CFS</u>

The psychiatric lobby repeatedly asserts that there is no single, definitive biomarker for "CFS/ME", yet they themselves are the very people who are instrumental in preventing the research in the UK that would be likely to demonstrate such a biomarker. Even when potential biomarkers are demonstrated by means of non-MRC funding, for example, the finding by Kennedy et al from Dundee of raised levels of isoprostanes that precisely correlate with ME/CFS patients' symptoms – a laboratory finding that is unique to ME/CFS (Free Radical Biology & Medicine 2005:39:584-589). Other useful biomarkers already exist, including hsCRP (high sensitivity C-reactive protein, a well-established marker of inflammation) and low NK (natural killer) cells, but the psychiatric lobby will not accept such compelling findings as evidence that their own beliefs about the nature of "CFS/ME" are erroneous.

Concern about the uncritical acceptance of the "evidence" for the alleged effectiveness of CBT/GET

The Systematic Review from the CRD has been exposed in the Hooper & Reid Review (mentioned above) and this evidence has been submitted to the MRC. It is beyond belief that the MRC continues to condone the acceptance of such a flawed "evidence-base" for the basis of the PACE and FINE trials, or that the Data Monitoring and Ethics Committee apparently remains unaware of (or uncaring about) this evidence.

News reached the ME/CFS community that Professor Colin Blakemore, CEO of the MRC, regarded all the efforts to halt the PACE trials as "water off a duck's back"; that he was defending the MRC referees who had approved the PACE trials; that he took the view that "CFS/ME" was not his concern and that he was simply amused by the situation.

The Countess of Mar was so concerned at the damaging and destructive influence of the Wessely School that she requested a meeting with Professor Blakemore. This took place at the House of Lords on 20th April 2004 and lasted for two hours. Earl (Freddie) Howe was also present. Both the Countess of Mar and Earl Howe were seasoned debaters in the House of Lords and both were profoundly disturbed at what occurred at that meeting, the outcome of which was fruitless.

Professor Blakemore was accompanied by Elizabeth Mitchell of the MRC and she did most of the talking. It was apparent that as far as the MRC was concerned, Professor Wessely is greatly revered and what he says about "CFS/ME" will be accepted. It was also apparent that the MRC's mind had been made up and was firmly closed. There was to be no consideration of the biomedical evidence that proved Wessely et al to be wrong.

On 10th May 2004, an article called "Why won't they believe he's ill" by Jerome Burne in The Independent quoted the Countess of Mar: *"A campaigner who has long opposed the purely psychiatric approach is scathing about the MRC trials. '**They are a farcical, cynical exercise and a huge waste of money' the Countess of Mar said".*** The article continued: *" 'Whatever their findings', says Dr Vance Spence, Senior Research Fellow at the University of Dundee and a leading scientist in the field, 'they won't tell us anything*

useful about the best way to treat CFS/ME because they are not properly selecting patients with the disease. There is widespread concern about this' ".

In a letter dated 11th May 2005, Professor Blakemore confidently claimed that the PACE trials *"were peer-reviewed and awarded funding on the basis of the excellence of the science".*

Concern about patients' dissatisfaction with the MRC trials

In January 2005 there were disturbing accounts posted on the internet by participants in the FINE trial, and people made known their wish to withdraw. One person who had been forced to suspend from university gave the reasons: *"Data they collected about me was misleading. Only questionnaires were used; the questions were leading and did not reflect my true feelings. Also, the researchers spent 2-3 hours with me each time, which was so exhausting that I didn't really know what my replies were. The trial totally disregards ME/CFS as an illness. It is based on a theory that symptoms are due to de-conditioning and maladapted beliefs about exercise. The disregard of the illness was reflected on a practical level – they said that if I recover from exercise in ten minutes then I am working at the right level. I abided by this rule and later crashed due to delayed and accumulated effects. How this is ethical I do not know. The therapist had very selective hearing and she would adapt whatever I said to fit into what she wanted to hear (I have examples). The therapist was critical of me and was unsupportive. I believe the consent process was unethical. I was not aware what I was letting myself in for (they did not explain the details of the intervention until after I had consented). In addition, the de-conditioning theory was presented as fact (I have since read research that goes against the de-conditioning theory). It frightens me to think that this research will be used to support clinics offering this in the future".*

In respect of the FINE trial, it is worth noting that the trial information says that for severely affected participants who are isolated, the trial may be carried out by means of the telephone or by computer. The sheer impracticality of these two methods reveals how little understanding the Principal Investigators have of the reality of the daily lives of those with severe ME/CFS. How many home-bound severely affected ME/CFS patients have got – or are able to use – a computer? Who is going to pay for the purchase and installation of a computer for those who do not possess one, and who is going to pay for and arrange lessons in basic computing skills (even supposing participants were well enough to undertake such lessons)? People who are severely affected by ME/CFS are unable to talk on the telephone for more than just a few minutes, so three-hour telephone sessions are unfeasible, but none of these practicalities seems to trouble the MRC Principal Investigators or the Data Monitoring and Ethics Committee.

Overall, there has been immense concern registered about the MRC PACE and FINE trials and about the psychiatrists who are leading them.

The support of AfME for these MRC PACE and FINE trials is disturbing; even more disturbing is the fact that AfME's website states: "*Some evidence suggests that the inactivity and resulting loss of fitness (de-conditioning) that occurs with ME can make the illness last longer and that graded exercise can help to reverse this*". Perhaps AfME is unaware of the results of a Belgian study on over 3,000 patients with "CFS" who were referred to multi-centre clinics. Out of those who undertook the "rehabilitation" programme consisting of CBT and GET, whereas before "rehabilitation", 18.3% were in paid employment, following "rehabilitation", this figure was reduced to 14.9% (ie. participants were working less hours after "rehabilitation"). Equally, perhaps AfME is unaware of a Dutch study which found that at the one year follow-up following "rehabilitation", 17% of ME/CFS patients who were previously working were no longer able to do so.

It is AfME's duty to be aware of the medical literature and to use it effectively to support the best interests of its members.

Moreover, AfME seems to be extraordinarily inconsistent: in its press release of 22nd August 2007 issued to coincide with the publication of the NICE Guideline on "CFS/ME", AfME stated: "*Many patients have reported little or no benefit from CBT and others have experienced seriously adverse effects from GET*", yet the following week, in an Editorial in the BMJ (1st September 2007:335:411-412), AfME's CEO, Sir Peter Spencer, agreed with psychiatrist Peter White that these same interventions show "*the clearest research evidence of benefit*".

When a charity such as AfME -- which claims to be the leading UK charity for ME/CFS -- has so obviously allowed itself to be a Trojan horse for the psychiatric lobby, something is clearly seriously wrong.

AfME might care to consider just why the MRC has a secret file of records and correspondence on ME/PVFS that dates from at least 1988 and is held at the Government Archive at Kew, and why this file is deemed so sensitive and controversial that it has been classified as top secret and cannot be made public until the 1st January 2023. AfME may like to recall that members of the CMO's Working Group were threatened with the Official Secrets Act. In the best interests of its members, AfME might also wish to ascertain exactly why the MRC so resolutely rejects grant applications for biomedical funding into ME/CFS (see http://www.nationalarchives.gov.uk/search/quick_search.aspx?search_text=myalgic).

10. **The UK Medical Journals and Medical Trade Journals**

The prodigious published output of Wessely School members promoting their own belief about ME/CFS is unparalleled and has flooded the UK medical literature for the last two decades.

Various surveys of the medical journals have been carried out and the ill-informed bias of the Wessely School is there for all to see.

It was in 1993 that AfME commissioned a report on the coverage of ME/PVFS in the medical press ("ME/PVFS and the Press" compiled by Dr Cathy Read – possibly a pseudonym; 29th October 1993).
This looked at the coverage of ME/CFS in the medical press over the period from March 1992 to August 1993; the publications reviewed included the British Medical Journal and the Lancet, plus three medical trade journals: General Practitioner (GP), Pulse and Doctor.

The review found that ME/CFS sufferers were often portrayed in a bad light or were not taken seriously. Despite the growing evidence of abnormal brain and immune function, there was a tendency to "psychologise" the illness, in that psychological features were exaggerated over others. Overall, the recommended treatments were antidepressants and graded exercise.

In a literature search of the Lancet for papers published on "CFS/ME" between 1995 and 2000 and in an analysis of those papers, Ellen Goudsmit PhD and others found a clear bias towards one particular school of thought and a lack of papers on the immunological or viral aspects of ME/CFS, noting that this lack of balance contrasted with the mainstream American journals. The review examined covert editorial policies, about which the authors said: *"Biased editorial policies are not benign. Editorial freedom is important but should not undermine the scientific process"*. Whilst experts around the world were discussing the limitations of the current case definitions and the need for subgrouping of "CFS", many British clinicians were unaware of these issues, or of the evidence that disproves the psychiatric model of "CFS/ME" which the UK journals promote. This loss of information, and the continued emphasis on the alleged role of inactivity (without any evidence that it is a perpetuating factor), as well as the recommendations for behavioural interventions, has undermined the UK medical profession's understanding of ME/CFS.
(ellengoudsmit@hotmail.com).

In a further review of the BMJ for the same period (1995-2000) that looked to see if the nature of the published papers on ME/CFS reflected the global research, Goudsmit found that, as in the Lancet, most of the papers emphasised the role of inactivity, mood disorders and / or maladaptive beliefs. There was no attention drawn to the immunological or viral research that had been published elsewhere. The BMJ claimed to publish "best evidence" but Goudsmit found such a claim difficult to reconcile with the journal's uncritical support of studies promoting CBT and GET and its disregard of the notable flaws in the "successful" trials (ie. the only symptoms assessed were fatigue and emotional distress and all the trials had included patients with psychiatric disorders). Goudsmit noted that a former Editor of the BMJ claimed that patients with CFS had manipulated the WHO and persuaded them to include "ME" under diseases of the nervous system in ICD-10, a claim that was patently false. Goudsmit also noted that in the five-year period under review, the BMJ had published only one paper linking CFS

with a non-psychological aetiology. She concluded: "*There remains little doubt that the editorial policy of the BMJ is uncritically supportive of the psychiatric view of CFS. This has seriously compromised the quality of the information provided on CFS to readers of the BMJ*".

The BMJ's record in relation to accurate reporting of ME/CFS is regrettable. It is widely accepted that in 2002, it was Professor Wessely who orchestrated a poll in the BMJ to identify "non-diseases" in which readers were asked to vote on what they considered were not valid diseases and that he proposed ME; such "non-diseases" were to be selected from a list suggested by the BMJ. The poll found ME – along with feckles, big ears and bags under the eyes -- to be a non-disease that is best left medically untreated.

For the Editor of a major UK medical journal to have approved and sanctioned such a poll at the expense of desperately sick people is deplorable.

As a direct consequence of this BMJ poll, numerous patients suffering from ME were summarily removed from their GP's practice list and were unable to register with any other GP: having approached a potential new GP's practice and having truthfully answered questions about any existing condition, ME/CFS patients were frequently informed that the list was full. In one case, a severe ME sufferer was tersely informed that "*this practice does not treat non-diseases*".

In August of that same year, the BMJ published an article by two Wessely School supporters, Richard Mayou (Professor of Psychiatry at Oxford) and Andrew Farmer (Senior Research Fellow at the Department of Public Health and Primary Care at Oxford). It was a Clinical Review entitled "ABC of Psychological Medicine: Functional somatic symptoms and syndromes" (BMJ 2002:325:265-268) and was replete with misinformation in that it specifically included "*Chronic fatigue (myalgic encephalomyelitis)*" in the descriptors "*somatisation, abnormal illness behaviour, medically unexplained symptoms and functional symptoms*", thereby ignoring the fact that "chronic fatigue" is not synonymous with ME/CFS. The article stated: "*Persistent symptoms may be described as functional syndromes. Although different medical and psychiatric classifications of functional syndromes exist, these are simply alternative ways of describing the same conditions*". Perpetuating factors were asserted to be the effect of immobility, the fear of worsening pain, avoidance of activity, over-solicitous care, and focusing solely on somatic problems. Doctors were warned against "*excessive investigation*" and that "*the provision of disability benefits can be a financial disincentive (and) may maintain a focus on disability rather than recovery*". The authors then stated: "*the more somatic symptoms a person has, the less likely it is that these symptoms reflect the presence of disease*". Recommended "treatments" were CBT, GET and anti-depressants. This article claimed to be "evidence-based".

In December of that year, the BMJ continued its campaign of misinformation about ME/CFS in an article co-authored by Michael Sharpe ("What should we say to patients with symptoms unexplained by disease? The 'number needed to offend' ". Jon Stone, Alan Carson, Michael Sharpe et al. BMJ 2002:325:1449-1450). The authors calculated

an '*offence score*' of descriptions pertaining to patients who are deemed to have no disease; those descriptions included '*putting it on'; being 'mad', or 'imagining symptoms'*. The authors noted that the term '*hysterical'* was the only one on their list that specifically excluded malingering. The conclusion was that many of these labels did not pass the 'offence' test, so the best label was 'functional' disorders, as this label *"provides a rationale for pharmacological, behavioural and psychological treatments aimed at restoring normal functioning"*.

The electronic responses to this article included one from Douglas Fraser, a professional violinist unable to work due to ME/CFS: (*"The very fact that you are reduced to implementing yet another euphemism should alert readers to the reality that the concept hiding behind it is as ludicrous as it is offensive"*); Tom Kindlon from the Irish ME Support Group: (*"if the BMJ is going to publish papers like this, it should also publish information about how patients with many currently-recognised diseases would have been told in the past that their symptoms were 'medically unexplained' or 'hysterical', (and) then some doctors might be more willing to say 'I don't know what is wrong with this patient' rather than to conclude 'this patient's symptoms are functional / hysterical / all in the mind' (or whatever euphemism is in fashion at the time");* Paul Lynch: (*"Question: What should we say to patients with symptoms unexplained by disease? Answer: You probably have an illness caused by chemical exposure or contaminated vaccines, but we can't possibly admit that, so we will give you some test that we know will come back 'normal' so we can legally ignore you until you start feeling frustrated and depressed, then say 'here's some antidepressants'. If you are still fit enough to complain after that, we send you for some CBT to patronise and incapacitate you even further"*); Barbara Rubin, New York: (*"The patient who is prematurely judged to have a psychiatric disorder or to be 'malingering' will face medical, social, legal and financial penalties that can destroy them and their families");* Lisa Blakemore-Brown, psychologist: (*"False diagnosis, based on ignorance, combined with arrogance, is a potent mix. Yet Governments have backed these errors to the hilt and put in place extraordinary guidance about methodologies which prevent real illnesses / disorders from ever being recognised, never mind treated").*

Nothing, it seems, will persuade or require the anti-ME psychiatric lobby to treat such patients with respect, let alone compassion, or to keep up-to-date with the literature about the biomedical disorder they so disparagingly dismiss.

The medical trade journals

The medical trade press is widely distributed free to doctors, especially to GPs, and to hospital libraries by the drug companies. It is demonstrable that, since the advent of Simon Wessely in the late 1980s when fellow HealthWatch member Caroline Richmond (a journalist infamous for her published invective against patients with ME/CFS) lost no opportunity to promote Wessely's latest published views by echoing them in the medical trade journals. These trade magazines have made a point of promoting psychiatric interventions for those with "CFS" and of mocking and denigrating sufferers from

ME/CFS in a way they would not dare do about patients with multiple sclerosis or other neurological disorders.

For example, on 1st April 1994 GP Medicine carried a bold banner headline proclaiming: "*GPs despise the ME generation*"; on 27th May 1994, reporting on the Dublin International Meeting on (ME)CFS, GP was particularly disparaging: "*Hundreds of hangers-on joined dozens of researchers for a conference which gave ME a little more credibility. Most of the papers were from those who measured and pampered the afflicted*"; on 12th January 1995 Doctor magazine ran a feature called "Bluffer's Guide" by Dr Douglas Carnall, in which he wrote: *"Investigations have their own hazards – it is possible to reinforce the patient's somatising behaviour. This has all kinds of risks, especially that the patient will run off to join a self-help group, membership of which is itself an adverse prognostic factor. Modern bluffers prefer the term chronic fatigue syndrome….if they really insist on a physical diagnosis tell them chronic fatigue syndrome is a complex disorder in which multiple biopsychosocial factors are mediated via the anterior hypothalamus ---in other words, it's all in the mind. Or, if you're feeling tired, you could always refer*"; Doctor magazine also ran a quiz by Dr Tony Copperfield (known to be the pseudonym of a GP in Essex) in which GPs were asked to choose from four possible answers to the question: *"What would be your initial response to a patient presenting with a self-diagnosis of ME?"* The correct answer was: *"For God's sake pull yourself together, you piece of pond life"*.

One of the worst examples was published on 20th October 2001 in Pulse in a series called "Choices for the new generation of GPs". The item on which three GPs provided their approach was entitled: "ME patient with litigation history demands inappropriate therapy" and the approach provided by Dr Mary Church (this is her real name: she is a Principal in a practice in Blantyre, Scotland and most disturbingly, she is a member of the British Medical Association medical ethics committee) was particularly contemptuous but is not untypical: *"Never let patients know you think ME doesn't exist and is a disease of malingerers. Never advise an ME patient to make a review appointment. At the end of the consultation, I say goodbye, not au revoir. Always refer ME patients to a local expert. It's a wonderful way of passing the buck*".

This crusade of poking fun at ME/CFS patients continues unabated: following the publication of the NICE Guideline on 22nd August 2007, the following appeared on Britain's second most popular doctor-blog:

"*In surgery today, several of Dr Rant's punters referred to recent NICE guidelines that they had read about in this morning's newspapers. After a morning of punters quoting these guidelines, Dr Rant decided to have a look. And he is glad that he did. Because he's got a disease that is as bad as multiple sclerosis, systemic lupus erythematosis (sic) and other chronic conditions. After all, looking at the guidelines: Knackered all the time – yup. Seeing patients frequently leaves him knackered. Difficulty sleeping – yup, got that too. Headaches – yup -- called 'patients'. Palpitations – yup. Normal blood tests, urine, etc – yup. He's had those checked and they all come back as normal. So there you have it. Whereas Dr Rant previously had negative feelings about anyone who declared*

that they had CFS/ME, he shall be far more lenient. He shall become far more understanding about their need to wear soft collars, wear tinted glasses and shall empathise with their need to spend all day on a sofa in a darkened room in a house full of cats. He will even understand their desire to argue with any health professional who disagrees with the diagnosis of CFS/ME and suggest that they may simply (have) a shit life".

Although some of these items are doubtless intended to be amusing, it is not appropriate for a doctor to write with such contempt about **any** illness, physical or psychiatric, which ruins lives and quite frequently causes death.

These items are damaging because they lend credence to what many doctors privately admit they still believe (ie. Wessely's view that ME does not exist and that "CFS" is a psychiatric disorder).

The ramifications of the Wessely School assertions about ME/CFS are uncontainable, extending throughout the NHS to Consultant level.

On Sunday 15th June 2003, Clare White, a university graduate who had been severely affected by ME for many years, became very ill with acute renal colic and vomiting. She was taken to the Accident and Emergency Department of a famous London hospital. She was in great distress. On arrival she was seen by a very helpful, polite, considerate and conscientious junior doctor who examined her and found that she had many abnormalities, including blood in her urine. He asked her if she had any other diagnosis, so she told him she suffered from ME. He began organising various investigations, including an IVP. The woman then heard him discussing her case with a Consultant just outside her cubicle and distinctly heard the Consultant instruct the junior doctor to do nothing because ME was a "personality" problem that did not need further investigation. The junior doctor stated that the abnormalities he had found needed investigating. The two doctors had a heated argument, the outcome being that the junior doctor, although clearly very angry, was pressurised into not investigating further. This patient was sent home without medical intervention, in great suffering and with no-one to look after her as she lived alone. She subsequently died.

In 1989, when the UK charity ME Action Campaign (now Action for ME) represented those with ME as distinct from those with chronic fatigue, its journal InterAction carried the results of 1500 professionally conducted questionnaires that had been sent out and some of the responses are provided here. Although this survey was conducted 18 years ago, there is little sign of change in medical attitudes today.

Comments of doctors to ME patients:

- "Throw away your crutches – it's your head that needs them, not your legs"
- "Women of your age imagine aches and pains – are you sure you're not attention-seeking?"

- “I’m not prepared to do any tests, they cost money”
- “Shut up and sit down”
- “You are a menace to society – a pest. I wish you’d take yourself away from me”
- “You middle class women have nothing else to worry about”
- “Its one of those things you silly young women get”
- “Hypochondriac, menopausal, you have the audacity to come here and demand treatment for this self-diagnosed illness which does not exist”
- “Stop feeling sorry for yourself – I have patients with real illnesses, patients who are dying from cancer”
- “ME is a malingerer’s meal ticket”
- “Your inability to walk is in your mind”
- “I’m not going to further your career of twenty years of being ill”
- “Nothing at all wrong with this woman – Put her on valium” (to GP from Consultant).

Comments of ME patients about their doctors:

- “I was told I was lazy and laughed at”
- “(he said) the illness was a load of trollop, he laughed me out of the surgery”
- “(he) laughed when I told him I could only visit him if I felt fit enough”
- “I was called ‘stupid’ and shouted at on more occasions than I care to mention…one neurologist said he ‘couldn’t care less’ whether I ever got better”
- “I was told I was a disgrace”
- “My illness started with a sudden, severe collapse. The doctor said that it was due to ‘attention seeking’”
- “(I was) told that I was a nutter”
- “(I was) told I was selfish and introverted and it was nothing but hysteria”
- “(the) doctors said to me ‘if you go on like this you will be struck off the register’”
- “(the doctor) said my symptoms / signs ‘didn’t exist’”
- “It was suggested ‘a good man’ was all I needed”.

That same year, a severely affected patient, a former professional woman, was informed by her GP that ME *“is a condition developed by the patient for what they can get out of it”*.

In 1991, researchers at Southampton University asked 140 local GPs to refer patients with ME/CFS to take part in a trial; only 60 bothered to reply, of which 40 made it clear that they did not believe in ME/CFS (“*GP doubts hamper new treatment*”: GP Magazine, 6th April 1991).

In April 1994, GP magazine, in the item entitled “*GPs despise the ME generation*” referred to above, stated that nationwide, only 10 to 30% of GPs believe that ME is a real disease.

Perhaps GPs are not entirely to blame for such an attitude when the information digest that is so repeatedly provided for them in the medical trade publications (such as Pulse, GP and Doctor) and in major medical journals such as the BMJ is provided virtually exclusively by Wessely School psychiatrists and their supporters.

Despite considerable advances in biomedical understanding of the disorder, ten years after the ME Action Campaign questionnaire, professional perception had not changed much.

On 18th February 1999, Adrian Furnham, Professor of Psychology at University College, London, wrote an article in the Daily Telegraph in which he suggested that there was *"a wealth of conditions that can be fashionable excuses for lack of success*" in which he included ME/CFS. In the ME Association's magazine (Perspectives, Summer 1999, page 3), Dr Charles Shepherd, the Association's Medical Adviser wrote: "*Professor Furnham's view that ME/CFS is nothing more than a fashionable medical excuse for people who are otherwise lazy, mediocre or incompetent is not only insulting, but totally inconsistent with published scientific findings*". Dr Shepherd made a formal complaint to the Disciplinary Committee of the British Psychological Society, claiming that Professor Furnham had broken the Society's Code of Conduct given that their Code of Conduct required that members "*shall value and have respect for scientific evidence when making public statements"*. After four months, the Investigatory Committee of the BPS concluded that Professor Furnham had not committed any form of professional misconduct.

Commenting on a paper in the Journal of the Royal Society of Medicine about children with ME/CFS, Dr Keith Hopcroft, a GP in Basildon, Essex, wrote in Update, 6th April 2000, page 522: *"In more than three-quarters of a group of children with chronic fatigue syndrome, the illness began at the start of the school year. An adult version of this – recurrent brief chronic fatigue—affects me every Monday morning"*.

On 23rd March 2001 in an article entitled "*Top 100: the many faces of fatigue*", GP magazine afforded Dr Marko Bogdanovic (research registrar, Merton College, Oxford, and a Wessely School adherent) a platform to "attack" ME/CFS sufferers: "*The provision of disability services and benefit payments is controversial because illness beliefs may be reinforced (and) services and benefits constitute a secondary gain"*.
The tradition of shameful diatribes and invective against ME sufferers still abounds. Doctors seem to vie amongst themselves to produce jibes at ME sufferers' expense but they do not jibe with equal disdain and derision at those with other classified neurological conditions.

The situation does not improve, as was aptly demonstrated by Joan Crawford at the MERUK International Conference in Edinburgh on 25th May 2007. Ms Crawford, a chemical engineer, noted that in the last seven years there had been six surveys on the attitude of primary care physicians towards those with ME/CFS and she presented disturbing evidence from those surveys, commenting: "*We find a pretty corrosive attitude (amongst) healthcare people"*.

Ms Crawford considered those surveys of GPs' attitudes, mentioning that in the Bowen et al study of 2005, 28% of UK general practitioners did not recognise ME/CFS as a clinical entity on a sample of more than 1,000 GPs. She commented that a negative attitude by GPs can have profound implications.

She mentioned the 2005 study of Thompson and Smith, which stated that the level of specialist knowledge of ME/CFS in primary care remains low, and that only half of the respondents believed ME/CFS exists, commenting that there are huge numbers of medical doctors in primary care who have no understanding of the implications of this illness, and who are quite dismissive towards such patients.

In the Raine et al study of 2004, Ms Crawford noted the finding that: "*GPs tend to stereotype ME/CFS patients as having certain undesirable traits*".

She looked at an Australian study carried out in 2000 (Stevens et al) on over 2,000 doctors: *"31% did not believe that ME/CFS was a distinct syndrome, which is just under one third, which is quite extraordinary, and 34% stated that ME/CFS 'is a convenient diagnosis that enables patients to avoid their psychological problems' "*.

Ms Crawford said that many GPs viewed ME/CFS patients in moralising terms – they were ambitious, or illness-focusing, or demanding, or medicalising: *"The stereotypical ME patient is still very much alive and well in primary care"*.

She concluded by observing that ME/CFS is seen as trivial, when the reality in the literature is that the SIP (sickness impact profile) is higher in ME/CFS than in multiple sclerosis and rheumatoid arthritis. (Two DVDs of this Conference are available from MERUK at 01738-451234, and a transcript of the DVDs is available at http://www.meactionuk.org.uk/Defiance_of_Science.htm).

It is abhorrent that vulnerable and desperate patients should still be forced to justify their illness because of ill-informed but influential doctors who so persistently dismiss the reality and severity of ME/CFS.

The incidence of psychiatric co-morbidity in ME/CFS has been greatly over-emphasised: a study in the Journal of the Royal Society of Medicine (2000:93:310-312) found that of patients in a tertiary referral centre who had received a psychiatric diagnosis, 68% had been misdiagnosed, with no evidence of past or current psychiatric illness.

Notwithstanding, the ill-informed views of the Wessely School about ME/CFS continue to be over-represented in the UK literature and the impact of this has been the degradation and destruction of almost the entire ME/CFS research environment in the UK, yet Wessely School beliefs about ME/CFS continue to be supported by editorial bias and by compliant peer-reviewers, a system that has come under serious public scrutiny and found to be wanting, but which the psychiatric lobby and their paymasters are at pains to support.

Apparent attempts to control the peer-review system for corporate advantage

On 18th June 2005 The Times carried an item by Tracey Brown that extolled the virtues of the peer-review system in the protection of the public ("Review by peers is vital to ensure accurate science"). It was notable that this article promoted a link to a document authored by Ms Brown called "Peer Review and the Acceptance of New Scientific Ideas" (available free online at www.senseaboutscience.org).

Here things become interesting, because Ms Brown turns out to be a member of a Working Party convened in November 2002 by an organisation called "Sense about Science" that proclaims (and is apparently designed) to equip the public with an "understanding" of peer-review, especially on controversial issues including MMR and autism, genetically modified crops, fluoridation and mobile phones in relation to children's health. In other words, it seems that its aim is to "educate" the public to accept industry's agenda, although the message is nicely gift-wrapped: "*an understanding of peer review might help the public to weigh the relative merits of different research claims*".

Of relevance to the ME/CFS issue is that apart from Tracey Brown, other members of the Sense about Science Working Group included Professor Colin Blakemore, currently Chief Executive of the MRC that is supporting and funding the psychiatric PACE trials on "CFS/ME" (with which AfME has joined forces with Simon Wessely, Peter White, Michael Sharpe and Trudie Chalder) and Fiona Fox, Director of the Science Media Centre, whose Science Advisory Panel includes Professor Simon Wessely.

Some editors, however, seem to turn a blind eye to the many documented concerns about the bias that permeates the peer-review system.

Those editors ill-serve both the scientific and clinical communities, let alone the patients, the alleviation of whose suffering used to be paramount in medicine but which now seems to have been replaced by the dictates and corporate interests of multi-national industries who dominate and control not only governments but also medical and research institutions.

As confirmed by a member of the Medical Research Council and noted above, referees and peer-reviewers are chosen in the expectation that they will deliver the desired outcome, and the media are briefed accordingly: UK national newspapers have frequently run headlines such as: "*ME's mainly in the mind---Study reveals yuppie flu can be cured by positive thinking*" (Daily Express, 5th January 1996, about one of Michael Sharpe's studies) and: "*ME is just a myth, sufferers told*" (Sunday Telegraph, 20th November 1994, about the conclusions of 150 British psychiatrists attending a pharmaceutical conference in Jersey).

The machinery of the psychiatric lobby is in perfect running order and no furrow is left unploughed, including the libraries in the Palace of Westminster.

The House of Commons Library

It is known that MPs are provided only with information on ME/CFS which endorses a psychiatric aetiology, in particular, with a Research Paper prepared for MPs by Dr Alex Sleator of the Science and Environment Section of the House of Commons Library (98/107, December 1998) which was simply a re-hash of the discredited Joint Royal Colleges' Report of 1996. Many letters exist from MPs which testify to this. This is despite the fact that medical textbooks, papers, journals and international conference reports which demonstrate an organic basis for the disorder are known to have been placed in the House of Commons Library for the use of MPs. It has been ascertained that the information supporting an organic basis has been removed to the Library archives, so unless MPs are sufficiently well informed to know precisely what to ask for on ME/CFS, it is difficult for them to access such material.

The tactics of denial used by the Wessely School

It is not only upon ME/CFS patients that Wessely School psychiatrists seek to impose their preferred but unproven psychotherapy regimes; other related conditions for which these particular psychiatrists promote their own regime include almost any syndrome for which medicine does not yet have a definitive explanation of the exact, confirmed pathoaetiology, for example, fibromyalgia, multiple chemical sensitivity, chronic low-dose organophosphate poisoning, Gulf War syndrome, pre-menstrual tension, irritable bowel syndrome, and atypical chest pain. Psychiatrists of the Wessely School deny the physical reality of all these conditions, asserting that they are all one and the same somatic (ie.psychiatric) syndrome. (In the case of irritable bowel syndrome [IBS], it has now been shown not to be a "psychological" disorder at all: American researchers have demonstrated molecular alterations in serotonin signalling in the gastro-intestinal tract and that IBS is caused by altered gut biochemistry).

Denial of the known and available evidence

Denial of existing evidence is currently popular with those who see themselves as "revisionists", and such people are extremely dangerous, as they seem to believe that they and their like-minded colleagues alone have the prerogative to define reality.

On 29th April 2000 Channel Four transmitted a programme entitled "Denying the Holocaust" which revealed the tactics used by "deniers" of the truth (in that case, the reality of the Holocaust).

Whilst in no way comparing the suffering and atrocities imposed upon Holocaust victims with the suffering imposed upon those with ME/CFS by doctors who do not believe in it,

it may nevertheless be salutary to examine the similarities in the tactics and methods used by “deniers” and “revisionists” of whatever discipline.

Referring to David Irving (the subject of a lengthy legal action involving Penguin Books and Professor Deborah Lipstadt, who was also the subject of the programme), the narrator said: *“familiar with (the) evidence, he bends it until it conforms to his ideological leanings and political agenda”*.

Such allegations have been made about Wessely in relation to what he has published about ME/CFS.
Tactics used by “deniers” were identified in the programme as including the following:

manipulation, distortion, deliberately portraying things differently from what is known, falsifying facts, invention, misquotation, suppression, illegitimate interpretation, political re-modelling, exploiting public ignorance and intimidation.

Deniers take liberties with facts, and what is omitted is often more significant than what is included.

A falsifier uses many different means but all these techniques have the same effect --- falsification of the truth and denial of reality.

Other tactics include the following :

- deniers aggressively challenge others’ views, claiming that others have no proof, and challenge them to validate the established facts and to produce proof to standards specified by the deniers themselves but to which they do not require their <u>own</u> “evidence” to subscribe

- deniers claim that “pressure groups” are active against them and are attacking both them and the truth

- deniers claim that there are “orchestrated campaigns” against them

- deniers agree, prepare and organise as a matter of policy a systematic strategy amongst themselves

- deniers show a readiness to jump to conclusions on every occasion

- deniers endeavour to rationalise their own ideology and for their own ideological reasons they persistently and deliberately misrepresent and manipulate the established evidence

- deniers fly in the face of the available evidence
- deniers engage in “complete deniability” which has nothing to do with genuine scholarly research.

Tactics of denial used in relation to ME/CFS as a physical disorder

Revisionism and denial of established evidence in medicine is nowhere more apparent than in the case of ME/CFS, and the choice of Government medical advisers is a matter of great economic impact.

To policy makers and commissioning officers in a cash-strapped NHS, the advantages of denial must seem attractive. The last thing needed is a chronic disease which affects hundreds of thousands of people, so accepting advice which promotes the view that the condition in question is neither new nor particularly disabling (and that the disorder is largely self-perpetuated) makes instant economic sense, especially if the advice also recommends that granting state benefits to those affected would be not only inappropriate but counter-productive.

In ME/CFS, denial is directed at undermining the experience and expertise of doctors who hold different views from Wessely School psychiatrists.

In medicine, denial ought to be very rare due to the peer-review system but, as noted above, in the case of ME/CFS, many peer-reviewers and editors of journals appear to share the same views as the deniers, so that articles and research papers which show a lack of objectivity, which misrepresent the existing literature and which make unsubstantiated claims abound, with the consequence that readers are deliberately misled.

In the UK ME/CFS literature (mostly as a result of the assiduous activities of psychiatrists of the Wessely School), there is evidence of a systematic attempt to deny the severity of the symptoms, the role of external causes and the nature of the illness. Such is the profusion of articles, reports and research papers produced by this group of psychiatrists that there is now a widespread belief that ME/CFS is not a disorder which requires money to be spent on specialist tests or on expensive virological, immunological, vascular or gene research, let alone on long-term sickness benefits.

It may be informative to compare the tactics of denial listed above as identified in the TV programme with a selection of methods and tactics used by those engaged in denial activity relating to ME/CFS:

- Deniers consistently ignore existing evidence which contradicts their own preferred theories: they disregard evidence, they misconstrue findings, they distort figures and they speculate

- Deniers apply a double standard to the evidence --- they support their own claims with a select choice of studies, with flawed research (ie. with research which has been shown to be flawed in the medical literature), and with a mass of generalisations, whilst insisting that the opposition provides irrefutable proof. These authors down-play and attempt to overlook inconsistencies in their own

research. (Indeed, on one spectacular occasion, when challenged, Simon Wessely actually blamed his peer-reviewers for allowing his own indisputable "mistake" to evade rectification)

- Deniers challenge the expertise of those with whom they disagree, implying that their own claims are based on balanced scientific scholarship whilst those of others are based only on myth

- Deniers portray sufferers as victimisers, claiming that it is patients who are guilty of targetting psychiatrists; who then portray themselves as the vulnerable and wronged group. There is reference to "vicious campaigns" organised by "pressure groups" and to unreasoned hostility on the part of the patients

- Deniers minimise or trivialise the distress and suffering of those with ME/CFS, alleging that patients exaggerate their symptoms and suffering

- Deniers promote the view that patients have only themselves to blame, and that the problem is therefore not external but internal

- Deniers often include a totally reasonable and uncontroversial supposition (for instance, that decisions must be based upon the best evidence), which gives the impression that their other arguments must be equally reasonable and valid

- Deniers often suggest or imply that patients are motivated by financial or secondary gain (even though there is not a shred of evidence to support such a claim), and that their claims for state benefits are unjustified

- Any negative characteristics of a minority of patients are typically generalised and ascribed to all ME/CFS patients, without any supportive evidence

- Deniers suggest or imply that patients have formidable powers, for instance that they are able to influence certain institutions; that they get the media on their side and even that they have managed to influence the World Health Organisation. It is also alleged that patients use such tactics to misrepresent the situation to lead others astray

- Deniers even re-write medical history and alter it so that it appears to support their own claims (this is certainly demonstrable in the psychiatric interpretation of the early ME literature)

- Deniers may attempt to rename or reclassify the condition (for example claiming it as a modern form of an old (psychiatric) illness)

- Deniers make inappropriate comparisons between syndromes, suggesting that they are all simply the same (psychiatric) syndrome, ignoring or downplaying any specific and / or unusual features which are present.

Illustrations of denial by the Wessely School

In the case of ME/CFS, it seems apparent that the tactics of denial which were exposed in the Channel Four programme mentioned above are indeed being implemented by the psychiatrists of the Wessely School; out of the many available illustrations, just the following are provided:

On 25th April 2000, Dr Michael Sharpe of Edinburgh wrote a letter to Mrs Ann Crocker in which he stated: *"I understand your desire to have the condition classified as a Neurological Disorder (but) trying to change doctor's (sic) behaviour by altering classification probably will not work and might even provoke a paradoxical response"*. The reality is that ME was formally classified by the World Health Organisation in the ICD as a neurological disorder in 1969, and it is Wessely School psychiatrists (not patients) who are actively trying to "alter the classification" ***from*** neurological ***to*** psychiatric.

In April 2002, Wessely agreed to answer questions put to him by various members of the UK ME/CFS community. The questions and Wessely's answers were posted on the internet. One such question was: *"Why do you continue to ignore the ICD-10 and why do you classify (ME)CFS as a somatoform disorder?"*

In an apparent denial of the facts, Wessely stated: *"I don't classify (ME)CFS as a somatoform disorder"*. This answer did not accord with the published evidence, since many Wessely School papers, including Wessely's own, specifically refer to ME/CFS as a somatisation disorder.

From just a 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*" appears to deny reality:

- (1995) Dr Adrian Furniss from the Disabled Living Allowance Advisory Board / Benefits Agency Medical Services / 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' (*somatoform)* word"; Michael Sharpe gave a lecture entitled "Management of somatoform disorders in primary care" and Trudie Chalder 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", Wessely's frequent 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 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) that are to be called "MUS", or "medically unexplained symptoms". In 2003, Wessely asserted: "*This term (MUS) is now used in preference to 'somatisation' "* (JRSM 2003:96:223-227). Importantly, the definition of MUS is already published: "*Physical symptoms without organic basis will be referred to as 'medically unexplained or functional symptoms'. These terms are used synonymously with somatisation*" (Assessment and Treatment of Functional Disorders in General Practice: the Extended

Reattribution and Management Model. Per Fink et al. Psychosomatics, March-April 2002:43:2:93-131)

- (2004) In a debate that was reported in the British Journal of Psychiatry (There is only one functional somatic syndrome. Simon Wessely / Peter White. Brit 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"*

- (2004) On 15th November 2004 in an email to Connie Nelson which he sent whilst he was in the US, eight years after the Joint Royal Colleges' Report had been so severely criticised, Simon Wessely still denied the reality that the Report was heavily biased, writing (verbatim): "*The royal college report was written back in 1995. Back then the way these things were done was to ask the top 10 or 15 names in the field, get them into a room and tell them to come up with some conclusions, so we had, i forget how many, but i think it was something like 15 or 20 experts representing those who had published the most. I don't think we came up with anything at all to be ashamed off – rather the opposite, and i think it reads pretty well now even a decade later. Yes, i probably do wish that I hadn't been on the committee, cos then people like "Margaret williams" wouldn;t be able to make that criticism of the process. (On the) york review..just about every tom dick and harry in the world of ME would have received a draft copy of the york review and asked for comments – it was a forerunner of the NICE system now in use. I can't recall if I replied or not. The rigour of their methods would not have left much to say. if the only criticism people can make of report A or paper B is that in some way it was tainted by some connection with the svengali figure of the great satan himself, then it is a sad day indeed for science and all of us. It is one of the reasons that I moved away from ME, because i could tell that despite having given ten years of my life to it, and knowing about as much about it as most folks in this country, my involvement on the national stage was getting counter productive because of my symbiotic reputation"*. This would seem to illustrate (a) that Wessely still supported the Report's recommendation that ME/CFS is a somatisation disorder; (b) his pride in something that others condemned as biased and (c) his avowal that he had "moved away from ME", a statement that does not accord with the facts.

Illustrations of threats issued by Simon Wessely

In 1994, following publication of an article in the CFIDS Chronicle which quoted Wessely's own published views about ME/CFS patients (The Views of Dr Simon Wessely on ME: Scientific Misconduct in the Selection and Presentation of the Available Evidence?. CFIDS Chronicle, Spring 1994:14-18), Wessely was incensed. He threatened the UK distributors of the CFIDS Chronicle with an injunction unless they defaced every

copy by removing the article before sending it out. The distributors were intimidated by Wessely's threats and they acquiesced. Subscribers in the UK who had paid in advance complained that they received defaced copies even though there was no injunction in place. Copies that were distributed world-wide from the US were not affected, and Wessely's threats simply served to draw more attention to the article than might otherwise have been the case.

On 18th January 2000, Simon Wessely wrote to the Countess of Mar that the *"ad hominen* (*sic*) *attacks"* upon him *"may have the unforeseen outcome of reinforcing unhelpful stereotypes of sufferers held by some in high office"*. Again, this seems to be nothing less than a threat using an intimidation technique made, it must never be forgotten, against very sick human beings who, since Wessely came to such prominence in 1987, had been trying to redress the wrongs perpetrated upon them by these powerful medical deniers.

In October 2003, an article in The Scotsman (Doctor's Notes: ME sufferers have found an enemy in Wessely – so they need friends: The Scotsman, 6th October 2003) by Dr Margaret Cook, former wife of the late Robin Cook MP, accurately portrayed the significance of Wessely's role in the misperception of ME/CFS. She referred to Wessely's belief that ME does not exist at all; to his downplaying of the need for research into diagnostic markers; to his insistence that no state funding should be granted for research other than psychiatric studies and to the resultant closing down of the portals, thereby reducing the chance of the broad and open perspective needed to break through the barriers of prejudice and ignorance.

In her article, Dr Cook also referred to a revolutionary article in the BMJ (May 2003) about doctors' lavishly-generous sponsors, the pharmaceutical companies, and how the medical profession now prostitutes itself for funding, and how both treatment and research are distorted as a result. She noted Wessely's response to that article, in which he refused to countenance the possibility of his judgment being swayed by any such paymaster, about which Dr Cook commented: *"You can tell from every sentence of his letter that he is used to dictating principles and having everyone in his orbit humbly accept his gospel. If I needed persuading that the ME community merited my support, this letter and its author would convince me. When you have enemies like him, you need a powerful lot of friends"*.

It was indeed a remarkably frank article, but the point is that it was entirely factual and was fully supported by evidence.

On 8th October 2003 Wessely wrote a letter to the Scotsman in response, in which he said: *"Margaret Cook's article shows the real battle is not between myself and sufferers of ME but between your correspondent and the facts. I have never suggested that CFS does not exist. Unlike Margaret Cook, I have spent the last 15 years of my life looking after sufferers from this condition. Quite how Margaret Cook thinks that I could block research into this condition is beyond me, but if she had read the recent Lancet editorial I co-wrote with the chief executive of Action for ME, she would have seen a plea for more, not less, research into all aspects of CFS/ME"*.

Many letters were sent to the Scotsman, all supporting Dr Cook and thanking The Scotsman for publishing her article. One of them, from Tom Kindlon (from the Irish ME Support Group), said: "*As someone who has had ME for the last 14 years but was only diagnosed 9 years ago, I have devoted much of the last 9 years to reading the literature; based on this information, I feel breakthroughs are more likely if Prof Wessely (and other psychiatrists with similar views) had less influence on the area*".

Another response said: "*Wessely claims to have spent the last 15 years of his life "looking after sufferers" from ME yet for the most part, he has denied the very existence of ME(CFS). How many other caring doctors do you know who amuse themselves by orchestrating a campaign in the BMJ about 'non-diseases' and who proposed ME as one of those 'non-diseases', as happened in April 2002? Wessely's ubiquitous misrepresentation of ME/CFS as a psychiatric disorder rests on his own definition of the disorder, not on the facts: it has been endlessly pointed out to him (supported by hard evidence) that he is wrong, yet he is unmoved. Wessely's long-term denial that these patients have an organic disorder – which flies in the face of the now massive evidence that they do – essentially means that he does not believe them. If Wessely persists in seeking the withdrawal of (the) article and an apology, the ME community would welcome the opportunity to bring everything out into the open, where Wessely might be shown to be a bully who ruthlessly attempts to silence the chronically sick who are so often powerless in the face of such power as that which he wields*".

A letter from DM Jones MSc said: "*Such has been his 'help' to ME patients in his 15 years of almost supreme 'reign over their fate' that he has successfully poisoned the minds of GPs and other healthcare professionals against these patients. Take for example his '<u>History of the postviral fatigue syndrome'</u> published in the prestigious British Medical Bulletin (BMB 1991:47:919-941) – in the text he emphasises the similarities between neurasthenia and ME, citing comments on neurasthenia sufferers which include the following: 'always ailing, seldom ill'; 'a useless, frivolous, noxious element of society'; 'purely mental cases'; 'laziness, indifference, weakness of mind and supersensitiveness characterise them all'; 'the terror of the busy physician'. One can only deduce that Dr (now Professor) Wessely wished ME sufferers to be viewed in this way by these professionals. It was apparent then already that the interests of the pharmaceutical industry played a significant role; all one needed to do is read the small print acknowledgements to realise this. I know I speak on behalf of many ME sufferers when I express my thanks to Dr Cook for speaking up for ME patients*".

Another response pointed out: "*Simon Wessely publicly claims that Margaret Cook's article shows 'the real battle is not between myself and sufferers of ME but between your correspondent and the facts', so let the facts speak for themselves*".

An interesting development then occurred: on 11th October 2003 Wessely wrote to a journalist who had published articles on ME/CFS, asking the journalist's opinion about Dr Cook's article: "*This was published in The Scotsman on Monday. Do you think this is*

fair comment? I don't think I need to tell you my feelings. This seems to be rapidly spiralling out of control. Your views / advice?"

The journalist replied to Wessely, saying: "*You are obviously a hate figure (and) it might be interesting to enquire as to whether hate figures have any responsibility for the way they are perceived. The inescapable take-home message (that has been reinforced by newspaper headlines) is that this condition has a large psychological component, that these people are imagining it, making it up, being hysterical, suffering from neurasthenia etc. And that is not only seen as downgrading the reality of their condition but also has practical implications as far as benefits go. Whilst I take your point that you have looked into the physiological side and found nothing, it does seem to be the case that a number of other equally erudite / careful scientists have looked there and found something that they do think is significant. I have to admit that when you set that body of work against the conclusion of the MRC that the biological area was not worth major funding, it is hard to escape the conclusion that you and the MRC are not taking the biological side seriously and that you do regard this as a psychological condition. You may say that you do take on board the biological aspect but the inescapable fact is that you are getting £2 million plus to research more aspects of the psychological side, a degree of funding that is not matched in any way by the funding from the MRC going to the biological side. The public perception of what is going on is that your actions on the issue of definition have tended to reinforce the psychosocial basis of the disorder rather than the biological one, which is at the heart of the reason why you have been so vilified. My opinion is that you would not improve anything by attempting to take any legal or other steps – you would be further seen as a major establishment figure attempting to silence / muzzle some poor powerless and chronically ill patients. A very simple step to change the perception of your position would be for you to give encouragement for a similarly sized grant to the one you have recently received, to look into some of the biological factors. It seems rather unlikely that there is something about CFS patients that makes them especially hostile and unreasonable, as opposed to people suffering from heart disease or multiple sclerosis (which) means the level of disagreement over CFS must reflect some underlying issue. I'm sure there is a lot of psychiatric literature on how denying another person's reality triggers all sorts of deep hostile responses"*.

In his response, Wessely entirely failed to address a single one of the legitimate points raised by the journalist, but what he did say, however, was astounding.

Wessely said he <u>was</u> prepared to sue The Scotsman. He asserted that he had looked, but had found no abnormalities; incredibly, he claimed that he had carried out the same tests as the Dundee team (ie. vascular endothelial experiments) and had found nothing. It was not hitherto known that Wessely had carried out studies on ME/CFS patients using a highly sophisticated scanning laser Doppler flowmeter such as that used by the Dundee team, the central point being that if a study has not been published, it effectively has not been done.

Wessely also said he had done work on genes and all his results were negative.

He said he was against the Canadian case definition and claimed the authors were not unbiased scientists (as he was); he said there was no need for any more poor quality science.

He said the whole field had moved forward and that the "radicals" were left fighting yesterday's battles and there was now a remarkable rapprochement between the psychiatrists and the ME charities. Wessely said that it was only a coterie around the Countess of Mar who do not support his views, and that the cause that the radicals are fighting is over. He said the radicals needed a reality check and their behaviour was outrageous; he said that the radicals were crazy and were engaged in fantasies, lies and gross distortions.

The opinion of the journalist was that what Wessely was saying was *"bizarre"*.

The reaction of the "radicals" around the Countess of Mar was this was pretty frightening stuff, because it was such a denial of reality.

As Dr John Greensmith from Bristol pointed out in a letter to The Scotsman: "*It is instructive to examine how Professor Wessely has raised passions to this level of fervour by, perhaps more than any other single individual, being responsible for making the area so controversial as it is"*.

Wessely demanded a retraction of Dr Cook's article and an apology, and under the onslaught of his threats, The Scotsman capitulated and the article was withdrawn. On 5th January 2004 The Scotsman afforded Wessely the right of reply to Dr Cook and stated: "*On 6th October we published an article on the controversial subject of chronic fatigue syndrome. The article contained assertions concerning Professor Simon Wessely of King's College, London. We accept that these assertions were without foundation",* and Dr Margaret Cook was sacked by The Scotsman from her position as regular columnist.

This was yet another travesty of justice for the ME/CFS community, but the matter did not end there.

In his right of reply, Wessely made assertions that caused widespread incredulity and fury. His article was carefully crafted to appear reasonable, straightforward and wholly supportive of patients, for example: "*It is a scandal that we are so in love with our high tech medicine that we are reluctant to accept suffering at face value"* and *"However, there is another scandal of even greater concern. It is the scandal of service and research – or more precisely the lack of them"*. His article went on to state: *"There are one or two units that have done sterling research over the years"* and he said that there are now evidence-based treatments, but that only a minority of patients have any chance of accessing them and this was because "*for many years CFS/ME has been a battleground. But that was the unhappy past. The publication of new reports by the Chief Medical Officer and the Medical Research Council show a new consensus emerging. The patient organisations now are active partners with clinicians, fighting on the same side for more services and more money for research"*. Wessely continued: "*But not everyone*

welcomes the new consensus and partnership. A few individuals continue to denigrate many people who have spent years studying the illness and trying to help patients. And this comes over loud and clear to those clinicians who need to commit themselves to developing new services. Too many feel the heat and decide not to enter the kitchen. Continuing to attack those few clinicians and researchers who are already engaged will achieve none of these goals".

Who could fail to be impressed by such a well-balanced and sensible article? Those who knew it not to be true, perhaps, and who at once recognised the tactics employed, including disingenuous self-promotion?

The game was, however, totally given away by his statement: *"I have been saying for 15 years that this is a real illness"*, which essentially reiterated what he had said in his first letter of 8th October 2003 to The Scotsman: *"I have never suggested that CFS does not exist"*.

There can be no question -- as there is substantial evidence -- that the Wessely School equates "ME" with "CFS": in the Institute of Psychiatry's Training Video for Physicians produced by Sir David Goldberg and Professor Trudie Chalder ("Training Physicians in Mental Health Skills: The Management of Chronic Fatigue Syndrome"), it clearly states: "*chronic fatigue syndrome is just another name for (ME). It means the same thing to the medical profession"* (Vignette 2: Assessing a tired patient). Further, in 2003 Wessely wrote: "*It may seem that adopting the lay label (ME) reinforces the perceived disability. A compromise strategy is 'constructive labelling': it would mean treating CFS as a legitimate illness while gradually expanding understanding of the condition to incorporate the psychological and social dimensions. The recent adoption by the UK Medical Research Council and the Chief Medical Officer's report of the term "CFS/ME" reflects such a compromise, albeit it an uneasy one"* (BMJ 2003:326:595-597).

If Wessely equates ME with CFS, and insists that ME does not exist, where does this leave his claim that he has been saying for 15 years that CFS is a real illness?

What Wessely has been saying for more than 15 years is that ME does not exist and that CFS is a "real" (ie. legitimate) behavioural disorder, not a classified organic disorder. Whilst no-one denies that mental and behavioural illnesses are "real", what Wessely has been saying about ME/CFS for more than the last 15 years is somewhat different and for the avoidance of doubt, a few of his assertions about ME are worth repeating:

- in 1990, Wessely wrote that ME exists *"only because well-meaning doctors have not learnt to deal effectively with suggestible patients"* (Psychological Medicine 1990:20:35-53)

- in 1990, Wessely wrote: *"It is regrettable that ME has become a 'fad' "* (The chronic fatigue syndrome – myalgic encephalomyelitis or postviral fatigue. In: Recent Advances in Clinical Neurology. Churchill Livingstone 1990)

- in 1994 Wessely said: *"I will argue that ME is simply a belief, a belief that one has an illness called ME*" and: "*The Royal Free Disease itself is part of the world of myth"* ("Microbes, Mental Illness, the Media and ME: The Construction of Disease". 9th Eliot Slater Memorial Lecture, Institute of Psychiatry, London, 12th May 1994)

- in 1994 Wessely wrote: "*Most doctors will be familiar with patients who complain about a wide variety of symptoms but whose physical examination and investigations show no abnormality. (Such) symptoms have no anatomical or physiological basis"* (J Hosp Med 1994:51:8:421-427)

- in 1995 Wessely again stated that ME was a *"belief"* (Clin & Exp. Allergy 1995:25:503-514)

- in 2002 Wessely was involved in the BMJ poll that found ME to be a non-disease that was best left medically untreated

- even in his reply of 5th January 2004 in The Scotsman, Wessely stated: "*Finding anything in CFS/ME will be seized upon by some as further proof that the disorder is genuine"*, which would seem to convey his deep belief that it is not a "genuine" disorder.

It seems that Wessely is not averse to contradicting himself.

As a consequence, in relation to ME/CFS, the term "evidence-based medicine" has become meaningless.

Illustration of Wessely's claim that *he* is being victimised

On 15th November 2004 Wessely wrote to a correspondent: "*I can't recall when i last went to an ME meeting to be honest, but no doubt 'Margaret Williams' will be able to remind me. Its a funny feeling still being stalked like this, and I can't say it's a pleasant one for either myself or my family"*. The reality is that Margaret Williams has been virtually housebound for the last 20 years; she has never "stalked" anyone and has only once referred to the fact that Wessely's wife is a senior policy adviser at the Department of Health, a position that is in the public domain. Attempting to hold Wessely to account for his own words does not constitute any form of "stalking".

Conclusion

Is it the case, as demonstrated in a TV documentary, that multi-national corporations and not governments now control the world? Are powerful and influential psychiatrists who work within the Mental Health Movement linked to the multi-national corporations that now dominate and control medical and research institutions and whose life-blood is

profit? (*Politics isn't working: the End of Politics. Cambridge academic Noreena Hertz presented evidence that multi-national corporations are taking the place of elected governments. ITV Channel 4, 13th May 2001)*

To the detriment of the sick, the deciding factor governing policies on medical research and on the management and treatment of patients is increasingly determined not by medical need but by economic considerations. Patients with ME/CFS are casualties of this corporate control.

It was fourteen years ago, on 18th February 1993, that Dr Paul Cheney, Professor of Medicine at Capital University USA, Medical Director of the Cheney Clinic in North Carolina, and one of the world's leading exponents on ME/CFS, testified before the FDA Scientific Advisory Committee in a testimony that has become one of the most quoted in history:

"*I have evaluated over 2,500 cases. At best, it is a prolonged post-viral syndrome with slow recovery. At worst, it is a nightmare of increasing disability with both physical and neurocognitive components. The worst cases have both an MS-like and an AIDS-like clinical appearance. We have lost five cases in the last six months. The most difficult thing to treat is the severe pain. Half have abnormal MRI scans. 80% have abnormal SPECT scans. 95% have abnormal cognitive-evoked EEG brain maps. Most have abnormal neurological examination. 40% have impaired cutaneous skin test responses to multiple antigens. Most have evidence of T-cell activation. 80% have evidence of an up-regulated 2-5A antiviral pathway. 80% are unable to work or attend school. We admit regularly to hospital with an inability to care for self*".

This is the disorder that the Wessely School denies exists, or alternatively, that they assert is a behavioural disorder and, as far as ME/CFS patients are concerned, the imperium granted to these psychiatrists is unsurmountable.

The utter arrogance of these Wessely School psychiatrists sweeps aside the abundance of medical science that has already demonstrated an organic pathology for ME/CFS: they will countenance no debate, and they continue to assert that ME/CFS is a behavioural disorder.

The Wessely School group of powerful and influential psychiatrists has a perfect set-up: by allowing no-one to oppose them and by discrediting and intimidating (with threats of legal action) those who try, they ensure nothing changes in the perception of ME/CFS they wish to promote. If the motive is not financial, what can it be? What is so appalling is that this is not ignorance, but the deliberate and determined suppression of the available international medical and scientific evidence that has demonstrated organic pathology in what is a very serious and complex disorder.

Clearly, those with ME/CFS are physically, not mentally, sick and ought therefore to be accorded the same care and support as those suffering from other long-term physical diseases such as multiple sclerosis.

Nancy Klimas, Professor of Medicine at the University of Miami and world expert in the immunology of ME/CFS, said in 2005 in her in-coming Presidential address to the International Association for CFS/ME: "*Our patients are terribly ill, misunderstood, and suffer at the hands of a poorly informed medical establishment and society*" (Co-Cure 21st March 2005: http://www.co-cure.org).

In the UK, the current circularity of misinformation about the "best" management of ME/CFS revolves around the first (2001) Systematic Review on the management of "CFS" by the Centre for Reviews and Dissemination team. This was commissioned by and produced for the Chief Medical Officer's Working Group to support its Report of January 2002. That the CRD Systematic Review was grounded on Wessely's own database has been confirmed in writing by the Chief Medical Officer himself, and Wessely was a principal adviser to the CRD team, thus it was inevitable that the Review would reflect his own beliefs.
The psychiatric lobby and its corporate paymasters have successfully engineered that in all State-commissioned Reviews, Reports and Guidelines, the remit was deliberately crafted and curtailed in order to achieve the desired outcome. By limiting the remit in each case, important biomedical evidence could be – and was -- simply disregarded, to the continued detriment of patients with ME/CFS.

It is not therefore difficult to trace the current shameful situation concerning ME/CFS in the UK back to the vigourously-held beliefs of Wessely himself, since the Medical Research Council, the National Institute for Health and Clinical Excellence, the WHO Collaborating Centre at the Institute of Psychiatry, the NHS Mental Health Minimum Data Manual, the Department of Health NHS Plus project, the Department for Work and Pensions, the Science Media Centre, the Medical Royal Colleges and many UK medical journals all uncritically accept his personal beliefs, even though his personal beliefs ignore the significant evidence-base that disprove those beliefs.

On 28th October 2006, Consultant Dermatologist Nick Hardwick from Mid-Staffordshire General Hospital summed things up accurately: "*Over the past few decades the practice of Medicine has moved from a basis of personal experience and understanding of the disease process and its treatment towards the application of authorised protocols and guidelines. (The) article raises concern about the situation in which an inadequate evidence base has become canonised into established guidelines, Government policy and incentivised practice. It takes a bold man indeed to challenge this set of Emperor's clothes. Perhaps we need a forum to build up a sufficient groundswell of opinion to challenge the court tailors*". (Vested interests will always trump science BMJ 2006:333:912-915).

In a recent interview, ME/CFS expert Dr Leonard Jason from DePaul University, USA, was blunt: when asked: "*Is it true that a particularly high percentage of patients with ME/CFS have experienced disrespectful treatment by the healthcare system?*" he replied: "*Research has found that up to 95% of individuals seeking medical treatment for*

ME/CFS reported feelings of estrangement, and one study found that 66% of individuals with ME/CFS believed that they were made worse by their doctors' care".

Jason also said that patients with ME/CFS are more functionally impaired than those suffering from Type II diabetes, congestive heart failure, multiple sclerosis and end-stage renal disease, yet healthcare professionals continue to doubt the scientific validity of the disorder. He was clear that his team's work could find no support for the psychosomatic model of ME/CFS (ie. the belief of the Wessely School), pointing out that measurements which failed to capture the unique characteristics of ME/CFS could inappropriately support the hypothetical construct of ME/CFS as a somatic (psychiatric) syndrome.
(http://www.immunesupport.com/library/showarticle/cfm/ID/8232).

The Wessely School members promote themselves as leading experts in the field of ME/CFS, yet they do not appear to take account of major international research findings in that field and appear to disregard the research that has been carried out by top academics from many disciplines including immunology, neuro-endocrinology, virology, vascular biology, cardiology, infectious diseases, biochemistry and nuclear imaging. Since these self-acclaimed top academics appear to be unaware of the general body of knowledge known about by other clinicians and researchers working in the field of ME/CFS, at what point will that body of scientific knowledge be so great that it will be considered serious professional misconduct to pretend that it does not exist?

It is salutary to recall the words of the Presiding Officer (Speaker) of the Scottish Parliament delivered at the ME Research UK international research conference on 25th May 2007 in Edinburgh; Mr Fergusson MSP said he had been contacted by a constituent asking for help: *"She's had ME for some time and been refused Disabled Living Allowance and the State support that comes along with that on the grounds that whilst she has been recognised as having ME, she has not sought or been given psychiatric treatment. Now that to my mind absolutely sums up the principal concerns of the Scottish Cross Party group on ME, which is that the cold grip of psychiatry is still far too deeply rooted in the world of ME".*
(http://www.meactionuk.org.uk/Defiance_of_Science.htm).

Many doctors and ME/CFS patients alike hold the view that the Wessely School has been responsible for over two decades of the most blatant medical abuse of ME/CFS patients. One severely affected person wrote about the involvement of Wessely School members in the MRC PACE trials: *"I think it profoundly disgraceful that any individual who has caused so much suffering to so many members of the public, including those affected by ME, is involved in this trial in any capacity".*

This particular "school" of psychiatry has, in the eyes of the ME/CFS community, caused untold damage, not only to patients but to the discipline of psychiatry, because the Wessely School perpetuates psychiatry's regrettable record of claiming unsustainable hypotheses as fact, to the harm of its victims, unknown numbers of whom have died.

As Douglas Fraser, a professional violinist badly affected by ME/CFS since 1994, has written: “When (people with ME) are subjected to (this) type of professional abuse, one realises just how out of control and irresponsible segments of the medical establishment have become. When science and rationality are so easily eschewed, you know what kind of society we are now living in”.