

## The UK Government's three-pronged strategy for "CFS/ME"

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From the sheer extent of their published output on "CFS/ME" over almost three decades, the influence of the Wessely School is apparent for all to see. Not as immediately apparent is the degree of their dissemination of disinformation about ME/CFS: those who have carefully analysed their publications claim to have found evidence of selectivity in use of the available evidence, suppression and dismissal of evidence that vitiates their ideological beliefs, multiple methodological flaws in their "research", breaches of research ethics and vociferous accusations of harassment by those who disagree with them to an extent that is mind-blowing.

The Wessely School refuse to accept the WHO's 1969 formal classification of ME as a neurological disorder and despite at least four warnings from the WHO, they insist that it has dual classification in the ICD, once as a neurological disorder but again as a mental/behavioural disorder, when the WHO unequivocally states that: *"it is not permitted for the same condition to be classified to more than one rubric as this would mean that the individual categories and subcategories were no longer mutually exclusive"*. Professor Peter White is a persistent offender over this issue.

The Wessely School often fail to declare fully the extent of their vested interests (ie. their work for the permanent health insurance industry and their work as advisors on "CFS" to Departments of State); they ignore elementary rules of procedure; they defy established research principles that require new research to be grounded on what is already known and published about the disorder in question and they proceed as if this substantive body of mainstream knowledge did not exist. Some would regard that as professional misconduct.

The Wessely School repeatedly uses a well-thought-out strategy: first they actively ignore the extant biomedical evidence base, failing to reference it in their papers and websites (leading people to believe it does not exist), then they diligently promote the notion that the biomedical model of ME/CFS is merely a "view" or a "belief" held by a few misguided clinicians, patients and activists, yet the existence of ME as a neuroimmune disease is not a "view" or a "belief" but a fact.

A "view" is a belief firmly held but with no proof of its truth, whereas a fact is a concept whose truth can be proved.

By referring to the biomedical model as simply a "view", they instantly downgrade its validity in public perception. This "view" or "belief" held by patients is further degraded to a symptom of the disorder, the more strongly the view is held being "proof" of the need for "cognitive restructuring" to change these "aberrant illness beliefs" (the Wessely School advises that there is no need for any biomedical testing, claiming that this would increase the wrong illness beliefs).

At the same time, aided by the lazy and unquestioning media, the Wessely School promote as fact the psychosocial model, when in reality it is nothing more than their own “view”, a view which is invalidated by the scientific evidence. Undaunted, they disseminate the impression that there are these two divergent points of view, as evidenced by the Judgment of Mr Justice Cranston – see below.

Distressingly for patients, the top echelons of the UK Establishment, including science editors, senior BBC reporters, the Medical Royal Colleges, the Royal Society and the Judiciary have been taken in by the Wessely School’s assertions about “CFS/ME” and are all convinced by them (hence the award of the inaugural John Maddox prize to Wessely for his “*courage*” in “*standing up for science*” and for “*facing difficulty or hostility in doing so*” – see “Professor Simon Wessely’s award of the inaugural John Maddox Prize for his courage in the field of ME and Gulf War Syndrome”. Malcolm Hooper. 12<sup>th</sup> November 2012).

As a direct consequence of the Wessely School’s false belief system, biomedical research has been side-lined and starved of funding, and a whole generation of doctors has been brought up believing ME/CFS to be a psychosomatic condition, with patients being disparaged accordingly.

The PACE trial is but one arm of a three-pronged strategy and thus needs to be viewed in context. The results appeared to be a foregone conclusion in favour of CBT/GET because of the “integrated plan” of the New Labour Government to roll out CBT and GET across the nation for those with ME/CFS (Department of Health, 2004, Statement of Information released via the Welsh Assembly Disclosure Log 2296).

The other two prongs of the three-armed strategy are the NICE Clinical Guideline 53 published in August 2007 and the national “Fatigue” Clinics that cost taxpayers £8.5 million to deliver interventions shown to be ineffective in ME/CFS (CBT) and to have made at least 50% of those who have undertaken it significantly worse (GET).

The “integrated plan” was designed to ensure compliance, so it was never in doubt that the PACE Trial results would conform to it (as indeed is the case, albeit after numerous departures from clinical research probity including multiple breaches of national and international codes of ethics).

**Without knowledge of what actually occurred in the production of (i) the MRC Research Advisory Group’s Report on “CFS/ME Research Strategy”, (ii) the NICE Clinical Guideline on “CFS/ME” (CG53) and (iii) what occurred in the Judicial Review that sought to challenge that Guideline, it is not possible to get a proper grasp of the enormity of the PACE trial travesty.**

**1. The MRC Research Advisory Group (RAG) Draft Report on “CFS/ME Research Strategy”**

David Sainsbury of the supermarket family is known to have donated over £16 million to the Blair New Labour Government and in 1997 was rewarded by being made a life peer (he is now Lord Sainsbury of Turville). Neither an MP nor a scientist (although he has been awarded two honorary science degrees), in 1998 he was appointed Minister of State for Science and Innovation, giving him responsibility for the Office of Science and Technology, as well as all the research councils, including the MRC. The Office of Science and Technology monitors all Government funding of research and controls policy on the direction of that research. It has been officially confirmed that it is “policy” which determines the research that is funded: *“The Department (of Health) funds research to support policy”* (Hansard: 11<sup>th</sup> May 2000:461W-462W).

In 2006 Lord Sainsbury became the first Government Minister questioned by police in the cash for peerages inquiry and resigned as Science Minister but whilst in office he seemed a devout Wessely supporter and one of the Sainsbury family trusts (the Linbury Trust, run by his brother John, now Lord Sainsbury of Preston Candover) funded Wessely to the tune of over £4 million to research chronic “fatigue”.

The Linbury Trust ascribes the perpetuation of “CFS/ME” to *“the effect of medical behaviour”* in legitimising it as a disorder. The Trust’s published views are that: *“Searching for causes is not only futile but may prevent recovery”* and that: *“We can state confidently that CFS...is not an inflammation of the brain...or a muscle disease”* (A Research Portfolio on Chronic Fatigue edited by Robin Fox for The Linbury Trust, Royal Society of Medicine Publications 1998). It boasts that: *“The Linbury Trust...began funding research into CFS in 1991”* and, untruthfully: *“Before the Linbury initiative, much of the knowledge base in this area was...erroneous”* (Second Linbury Portfolio: New Research Ideas in Chronic Fatigue; co-edited by Simon Wessely; RSM Publications 2000).

Under Lord (David) Sainsbury, in 2002 the MRC set up a Research Advisory Group (RAG) to consider the direction of future research into “CFS/ME”. Before the final Report was to be published, there was to be a public consultation process and a draft Report was to be issued for consideration and comments.

Although referring to NICE (where an identical process took place over its Clinical Guideline for “CFS/ME” -- see below) and not specifically to the MRC RAG, Christopher Booker noted that “consultation” processes are 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, 20<sup>th</sup> June 2004). That is certainly true in the case of ME/CFS.

Before the MRC RAG released its draft Report and during the public consultation period, evidence submitted to the RAG of international research findings underpinning the serious organic nature of ME/CFS included proof of 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, and the involvement of the liver, pancreas and heart, plus much more.

So desperate were some people to ensure that their input and evidence of the biomedical pathology that had been demonstrated to occur in ME/CFS were received safely by the MRC RAG that they chose to pay extra postage costs and sent their submissions by Special Delivery, which guaranteed next-day delivery and the signature of the person at the MRC who signed for receipt.

Many people (over 16,000) signed a petition organised and submitted by Research into ME (RiME) calling for the RAG to consider the biomedical evidence; it was handed in to the MRC on 2<sup>nd</sup> September 2002 but the MRC jubilantly announced that it would be ignored, with Elizabeth Mitchell of the MRC claiming that it would be *“too overwhelming”* to consider it.

The day after it received that petition, the MRC awarded an initial £2.6 million (later to become £5 million via other co-funders) to the Wessely School for the PACE trial.

The MRC RAG was chaired by Professor Dame Nancy Rothwell and it released its draft Report on the direction of future research on “CFS/ME” on 17<sup>th</sup> December 2002. The draft Report was authored by Dr Chris Watkins, MRC Programme Manager for Research on Mental Illness (who later appeared to play an interesting role concerning the curious changes in registration of the PACE trial). Key issues of concern about the RAG draft Report that were raised at the time included the following:

- RAG members were said to have been selected because they did not specialise in CFS/ME and were said to be fresh to the field. This was untrue and two names in particular stood out: Professor Alan McGregor (from King’s College, London) and Philip Cowan (Professor of Psychopharmacology at Oxford). Professor McGregor had co-authored papers on “CFS” with Simon Wessely and was a member of the Linbury Trust Advisory Panel that had funded Wessely; Professor Cowan held strong views on “CFS” and had co-authored a paper entitled “Abnormalities of Mood” published in the second Linbury Trust Portfolio on Chronic Fatigue; he had also co-authored papers on “CFS” with Professor Michael Sharpe (later to be one of the Principal Investigators of the PACE trial) and other key members of the Wessely School. Another RAG member was Professor Til Wykes who, like Simon Wessely, worked at The Institute of Psychiatry and who was known for her view: *“If you encourage them (ME/CFS patients) 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”* (The Observer, 2001).

- The draft RAG Report was replete with misinformation and skewed thinking. It claimed 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”*.
- Given this claim that their strategy reflected the current state of knowledge about CFS/ME, it was illogical for the RAG also to state that they had purposely not considered the current level of scientific knowledge on the aetiology or pathogenesis of CFS/ME; instead, they chose to rely on the Wessely School’s published articles.
- The draft Report advised that studies researching 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 asserted that predisposing factors for “CFS/ME” include female gender, personality and previous mood disorder.
- It further asserted: *“Many reported findings in the area of pathophysiology are not published in the peer-reviewed literature, or are not well described.....the lack of methodological rigour and independent replication mean that many of these claims find little support from the wider medical community, but may have strong currency among some patients and practitioners”*. Such deprecation was not only patronising and arrogant, it was ludicrous. Evidence was promptly submitted to the MRC RAG listing 65 international peer-reviewed journals (some of high impact factor rating) that had published scientific findings about the pathophysiology of ME/CFS. Authors of those papers included world-renowned experts including Professors of Medicine and Professors of Immunology.
- Journals that were perfunctorily dismissed and denigrated by the RAG included, for example: The New England Journal of Medicine; JAMA (Journal of the American Medical Association); Annals of Internal Medicine, Reviews of Infectious Diseases; Biological Psychiatry; Clinical Infectious Diseases; Archives of Internal Medicine; CRC Critical Reviews in Neurobiology; Journal of The Royal Society of Medicine; European Neurology, Biologist; Postgraduate Medical Journal, Quarterly Journal of Medicine; Journal of the Royal College of General Practitioners; Journal of Neurology, Neurosurgery and Psychiatry; Journal of Infection; Infectious Diseases in Clinical Practice; Journal of Psychiatric Research; Annual Reviews in Medicine; American Journal of Medical Science; Journal of Investigative Medicine; Journal of Clinical Pathology; Journal of Psychosomatic Research; Journal of Clinical Endocrinology; Current Therapy in Endocrinology and Metabolism; Proceedings of the Royal College of Physicians of Edinburgh; Annals of the New York Academy of Sciences; Acta Neurol Scand; Psychoneuroendocrinology; Clinical Autonomic Research; Applied

Neuropsychology; American Journal of Roentgenology; Psychiatric Annals; Journal of Virological Methods; Journal of General Virology; Journal of Medicine; Journal of Medical Virology; Immunopharmacology & Immunotoxicology; Journal of Clinical Virology; Journal of Immunology; International Archives of Allergy and Applied Immunology; Journal of Clinical Microbiology; Clinical Experimental Immunology; Journal of Clinical Investigation; Clinical Immunology and Immunopathology; Clinical and Diagnostic Laboratory Immunology; Annals of Allergy; Journal of Allergy and Clinical Immunology; European Journal of Medical Research; Toxicology; Clinical Physiology; Nuclear Medicine Communications; Journal of the Neurological Sciences; International Journal of Neuroscience; Journal of Virological Methods; Archives of Neurology; Journal of Clinical and Experimental Neuropsychology; International Journal of Molecular Medicine; British Journal of Clinical Psychology; Arthritis and Rheumatism; Seminars in Arthritis and Rheumatism; Journal of Rheumatology; European Journal of Medical Research; Advances in Neuroimmunology; Angiology. (*This list is not comprehensive but merely illustrative*).

- In addition, there was the (now defunct) Journal of Chronic Fatigue Syndrome which, although derided by some UK “CFS” investigators, carried impeccably referenced papers, for example “Review: Immunology of Chronic Fatigue Syndrome” by Professors Roberto Patarca-Montero, Mary-Ann Fletcher and Nancy Klimas, a major review which lists 212 references.
- The draft RAG Report rejected 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 many international experts who were highlighting the urgent need for the study of subgroups.
- Inevitably, the draft RAG Report recommended that there should be no research into the biomedical aspects of ME/CFS and that future research should focus on CBT and GET.

(For a more detailed account, see: “Response to the MRC Research Advisory Group (RAG) Draft Document for Public Consultation on ‘CFS/ME’ Research Strategy dated 17<sup>th</sup> December 2002”: M Hooper, EP Marshall, M Williams); see also “Corporate Collusion?”, September 2007 by the same authors).

### The finalised MRC RAG Report

The MRC RAG final Report was released on 1<sup>st</sup> May 2003 (“MRC CFS/ME Research Advisory Group: CFS/ME Research Strategy”).

It retained much of what had been in the draft Report, continuing to assert: *“Many reported findings in the area of pathophysiology are not published in peer-reviewed literature”*; once again it claimed that in those studies which had found evidence of abnormalities: *“the lack of methodological rigour means many of these claims find little support in the wider medical community, but may have strong currency among some patients and practitioners”*.

That was misleading, but in the UK, “policy” was to take precedence over patients. This was confirmed two years later when, on 22<sup>nd</sup> June 2005, Laurie Taylor presented a programme called “Thinking Allowed” on the UK’s Radio 4. He ended 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 (ie. New Labour’s) approach to research in the following manner: 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 community knew to its considerable cost: it had been saying so for many years but had been systematically denigrated and ignored.

That quotation was momentous because it exactly encapsulated the reality: forces intent on “eradicating” ME and the medical stalwarts who support them were (and still are) at work that are beyond belief.

Physicians who genuinely try to help those with ME/CFS are themselves victimised, in some cases being reported to the General Medical Council. This “policy-based evidence-making” has now reached such an extent that it has been likened to a cancerous metastatic spread. 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 ME/CFS of the “Wessely School” psychiatrists have spread throughout the medical profession, the media (aided by the activities of the Science Media Centre), Government, and even some of the patients’ support organisations (see: “Politically-modified Research?”: Margaret Williams: 25<sup>th</sup> June 2005).

The RAG Report advocated the use of *“broad inclusion criteria”* for all future research that was -- allegedly -- into a specific WHO-classified neurological disorder, an approach that many considered to be lacking in scientific exactitude.

The RAG Report stated: *“there is good evidence that muscle strength, endurance and recovery are normal”* and *“The general opinion is that there is no physiological basis to the weakness and/or fatigue”*; it also stated: *“Clinical neuroimmunological studies...are likely to be of limited value”*.

Although the RAG conceded that it had not undertaken a detailed review of the current level of scientific knowledge about ME/CFS, it continued to refer to *“the effects of gender”*, *“mood disorder”*, *“the effects of suggestibility”*, *“personality factors”*, *“sickness behaviour syndrome”* and to abnormalities induced by *“immobility”*; it re-iterated that *“studies investigating causal pathways and*

*mechanisms would not have immediate impact on increasing understanding of CFS/ME”.*

Plainly, the agenda and results were pre-determined, because the Report stated that the RAG members had “*chosen to consider how the evidence-base for potentially effective management options (ie. CBT and GET) can be strengthened*”.

This indicated a disturbing narrowness of approach that was not in patients’ best interests, given the amount of documented information recording how patients with ME/CFS have been actively harmed by graded exercise regimes.

Unsurprisingly, the RAG Report promoted as “centres of excellence” the “Fatigue” clinics (which cost UK tax-payers £8.5 million and where unsupervised non-medical staff delivered a one-size-fits-all programme of “brain-washing” to convince sufferers that they were not physically ill, together with incremental aerobic exercise) that formed one arm of the three-pronged “integrated plan”.

These “Fatigue” clinics were usually housed within psychiatric units, since clinics for “pure” ME patients in NHS hospitals such as Preston were 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 long-established ME clinic at the Royal Free Hospital that was run by Dr Ramsay’s successor-in-post (Dr William Weir) was perfunctorily closed, with patients being referred to a “Fatigue Clinic” run by a GP and then referred on 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, with the inevitable result that its conclusions did not sit squarely on the foundation of existing knowledge about ME/CFS.

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. Certainly it did nothing but a grave disservice to those with ME/CFS, but it did conform to “policy”, so all was well in the State of Science.

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#### The NICE Guideline on CFS/ME (CG53)

In its First Report of Session 2007-2008, the House of Commons Health Select Committee was clear: “*NICE should not recommend interventions when the evidence*

*is weak*" (Volume 1:29) but that is exactly what NICE did in its Clinical Guideline on "CFS/ME" (CG53).

In alleged support of the PACE trial and prior to selective results being published in February 2011, the MRC conceded about CBT/GET that: *"there was a lack of high quality evidence to inform treatment of CFS/ME and in particular on the need to evaluate treatments that were already in use and for which there was insufficiently strong evidence from random controlled trials of their effectiveness"* (Dr Frances Rawle, Head of Corporate Governance and Policy, 6<sup>th</sup> January 2011).

That is a astonishing admission, since the NICE Clinical Guideline on "CFS/ME" of 22<sup>nd</sup> August 2007 relied upon the pre-PACE Wessely School "evidence-base" to recommend the use of CBT and GET nationally as the intervention of choice, yet the MRC confirmed – in writing -- that there was insufficient evidence for the implementation of this nationwide programme of CBT and GET recommended by NICE in its Clinical Guideline, so NICE jumped the gun by four years.

#### The draft NICE Guideline

The same scenario of "policy compliance" as existed in the RAG pertained throughout the public consultation process and production of the NICE Guideline on "CFS/ME" (CG53), but to a far greater and more sinister degree:

- A "policy decision" was taken by NICE not to consider any biomedical evidence that disproved the psychosocial model. The NICE Guideline Development Group (GDG) was specifically instructed not to consider the totality of the published evidence on ME.
- GDG members who would support "policy" were carefully chosen, and there was not a single medical expert on ME/CFS on the GDG (an unheard-of situation in the production of other NICE Guidelines, where GDGs are replete with experts in the disease in question). ME/CFS experts who requested to be on the GDG were dismissively brushed aside, and even the application of the Medical Advisor to the ME Association to be a member of the GDG was refused.
- GDG members included doctors who work for the permanent health insurance industry (PHI) and who had a long track record of refusing legitimate claims by asserting that "CFS/ME" is a behavioural (mental) disorder and thus excluded from benefit; one such GDG member, Dr William Hamilton, had spent 15 years working for insurance companies and during production of the NICE Guideline on "CFS" was Chief Medical Officer for at least three such companies including Exeter Friendly Society, Friends Provident and Liverpool Victoria Friendly Society. Further, Hamilton had been funded by the Linbury Trust for his work on "CFS/ME" (£58,992 to collaborate with Peter White).

- One GDG member was paediatrician Dr Esther Crawley, a committed Wessely School supporter who was subsequently proven to exaggerate the success of the PACE trial, publishing a paper in which she claimed a success rate of up to 40% (when challenged, she was unable to provide any evidence for her claim).
- Another GDG member was an Occupational Health physician, Dr Julia Smedley, who confirmed in writing that: *"I do not treat patients with CFS/ME"*. Why was Dr Smedley even considered for the GDG? She clearly had no day-to-day experience of the disorder under discussion (a stated requirement for election to the GDG).
- Other GDG members included a dietician and a reflexologist/hypnotherapist, who were chosen in preference to dedicated medical practitioners who had devoted their whole career to the disorder.
- It was confirmed that advisors to the GDG included Simon Wessely, Peter White and Michael Sharpe.
- The Questionnaire sent out for public consultation contained a serious "misprint" relating to questions 29-61 (out of a total of 90 questions), making a nonsense of responses to those questions and meaning that over one third of answers would be likely to achieve results that respondents did not intend but which would support the pre-determined outcome.
- The GDG relied on the York Systematic Review of the CBT/GET literature, which was shown to be flawed (see: "Inadequacy of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base: Comments on Section 3 of 'The diagnosis and management of CFS/ME in adults and children: Work to support the NICE Guidelines' " by Professor Malcolm Hooper and Horace Reid, January 2006 – this academic review exposed the ineffectiveness of CBT and the potential dangers of GET as recorded by international researchers from the US, Canada, Australia and New Zealand).
- Patients' own evidence was ignored, which perpetrated and even sanctioned the culture of contempt surrounding CFS/ME; this was embedded in the GDG's decision not to accept CFS/ME as a physical disorder (which was in defiance of the WHO international classification of ME/CFS as a neurological disorder) and GDG members even went so far as to state that if a patient displayed abnormal neurological or cardiovascular features, they did not have "CFS/ME".

- The draft Report stated categorically that *“some will recover fully”* and that *“there are no objective abnormalities”*.
- *“CFS/ME”* was portrayed as a somatisation disorder and the advice was that *“the concept of CFS (should be considered) through a biopsychosocial model”*, even though ME/CFS is a formally classified nosological entity that is organic, not psychosocial, in aetiology and nature.
- Of particular concern was that the draft NICE Guideline stated: *“Terminology used by doctors such as ‘functional syndrome’ and ‘medically unexplained symptoms’ are part of common usage in clinical practice today”*, thereby sending out the clear message that any doctor who did not subscribe to this would run the risk of being ridiculed by his/her peers and might even face sanctions.
- As anticipated, the draft Guideline effectively proscribed laboratory testing and focused only on CBT/GET as the interventions of choice.
- There were important technical anomalies in the draft Guideline, including the GDG’s failure to comply with the AGREE Instrument (Appraisal of Guideline Research and Evaluation Instrument), especially GDG members’ failure to declare any conflicts of interest; the GDG’s failure to describe precisely the patients to whom the Guideline was meant to apply, and the GDG’s absolute failure to include individuals from all relevant professional groups (the AGREE Instrument requires that NICE was obliged to give equal weight to three main sources of data: random controlled trials; 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).

In its response to the draft Guideline, the ME Association said they were unwilling to endorse it; that it contained numerous recommendations which were based on opinion rather than on evidence-based medicine which normally dominates a NICE guideline, and that it was not fit for purpose: *“We find it hard to imagine another situation where a group of people, many of whom have little or no direct experience in the clinical care of an illness they are advising on, have produced such a poor quality guideline”*.

Also commenting on the NICE draft Guideline, in his Stakeholder Comments on 26<sup>th</sup> November 2006 Dr Neil Abbot, Director of Operations at the charity ME Research UK (MERUK) said: *“The draft produced by the GDG is unsafe and unsatisfactory because it does not engage with key issues involved in the diagnosis and management of ME/CFS....It would be preferable for NICE and the GDG to recognise that...evidence-based recommendations for treatment cannot be made at present than to incorporate an inadequate evidence base into...guidelines which feed into clinical care and government policy to the detriment of people with ME/CFS”*.

Many other Stakeholders submitted cogent criticisms (for more details, see “Corporate Collusion?” by Malcolm Hooper, Eileen Marshall and Margaret Williams, September 2007).

### The finalised NICE Guideline on “CFS/ME”

In contravention of usual practice, GDG members did not declare their competing interests until two months after the final Guideline was published.

The final Guideline was like the proverbial Curate’s egg: good in parts. It was clear that, to its credit, the Guideline Development Group took heed of many submitted representations but that the Wessely School retained control of the recommended management strategies, although to nothing like the extent they sought, and that even those management strategies (CBT and GET) were 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, about which Dr Ellie Stein – herself a psychiatrist -- said at the ME Research UK International Conference in Edinburgh on 25<sup>th</sup> May 2007: “*I would never in my practice use the Wessely model of CBT – I find it disrespectful to try to convince somebody they don’t have an illness they clearly have*”).

However, reference was 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 CBT would include “*identifying perpetuating factors that may maintain CFS/ME symptoms*” and would address “*any over-vigilance to symptoms*”.

Research that indicates potential dangers of the recommended management regime was ignored and there was continued dismay that NICE again highlighted CBT and GET as the most effective forms of treatment.

Note: despite all the biomedical evidence contained in the above documents and the compelling scientific evidence that continues to mount since they were written, NICE has still got CFS/ME listed under mental health/behavioural conditions: <http://www.nice.org.uk/guidance/CG53/chapter/1-Guidance>

### The Judicial Review of the NICE Guideline on “CFS/ME”

The process of bringing a Judicial Review (JR) is costly and complex. Permission to bring a JR has to be sought and obtained from the High Court, which in itself is a significant hurdle. Obtaining bullet-proof evidence to withstand rigorous legal scrutiny is just the start. Finding suitably interested, competent and committed

lawyers to act for Claimants who are effectively challenging a Department of State is a Herculean task. Ensuring that those lawyers are fully briefed and that they understand every aspect of the case is an almost insurmountable undertaking before the case even gets to Court. When the topic is ME/CFS, it is virtually impossible. However, after an inordinate amount of effort by many people, in 2008 Legal Aid was granted for this to proceed.

Reasons for a JR of the NICE Guideline included what has been addressed above in relation to the NICE Guideline on CFS/ME, especially:

- NICE's failure to identify the disorder to which its Guideline purported to apply
- the GDG's refusal to accept the WHO classification of ME/CFS as a neurological disorder, which under NICE's own protocol is mandatory in the UK. NICE's Progress Report No. 8 dated 18<sup>th</sup> September 2002 from NICE's Communications Director Anne Toni Rodgers, which at the time was specifically drawn to the attention of NICE's Board, is unequivocal:

*"2.7.1 Institute Classification System*

*2.7.1.1. Following discussions with Department of Health and other national agencies the Institute has adopted a new classification system that will be applied Institute wide*

*2.7.1.3 The previous classification system was only used by the Institute*

*2.7.1.4 The ICD-10 classification has been used as the basis for the new Institute classification directed at the informed reader*

*2.7.1.5 The World Health Organisation (WHO) produces the classification and ICD-10 is the latest version. ICD-10 is used within the acute sector of the NHS and the classification codes are mandatory for use across England".*

- the GDG's failure of procedure: because the intention of a NICE Guideline is to influence clinicians (which immediately impacts on patients), there are rigorous criteria that must be observed in the production of a Guideline, but in the case of CG53 these were ignored
- NICE's fabricated statements about cost effectiveness of CBT/GET and there were also mathematical errors in NICE's figures and statistics; (NICE's statisticians transferred data from one study to another to achieve the figures it wanted: since even NICE could not procure non-existent evidence to support its recommendations for behavioural therapy, it decided to create its own evidence by transferring data from one study and inserting that data

into a totally different study to produce what might have been the desired results if the study in question had run for five years instead of only fourteen months. The fact that the transplanted data came from a study that had used different entry criteria and whose own data had been corrupted (admitted by the authors themselves) seems not to have troubled the Institute for Clinical Excellence. Most straight-thinking people might regard such doctoring of the evidence as fraudulent

- the proscribing of testing and treatments that have been shown to help PWME
- the GDG's failure to consider the totality of the evidence, in particular, the biomedical evidence: it was charged with providing guidance on the diagnosis as well as the management of CFS/ME, so the literature which demonstrates clear biomedical pathology ought to have formed part of the GDG's literature review and not been specifically excluded from the GDG's remit (but of course that evidence would have invalidated the behavioural research on which the use of CBT/GET was based so they had to ignore it)
- the potential dangers of the recommended interventions
- the rejection of patients' views and preferences
- the deliberate refusal to have a medical expert experienced in ME/CFS on the GDG as required
- the bias of certain GDG members
- the covert conflicts of interest of some GDG members
- the fact that some GDG members were voting on studies that they themselves had authored in support of the psychosocial model
- the GDG's ignoring of the documented signs and symptoms in ME/CFS and the demonstrated pathology of major body systems
- the GDG's ignoring of the existing evidence that CBT/GET are both ineffective and harmful (especially if inflammation is present)
- the fact that even before the GDG started work, a policy decision had been taken about the outcome
- the fact that NICE is funded by and accountable to the Department of Health, which formally accepts ME/CFS as a neurological disorder yet NICE's GDG refused to accept it as such, which is inconsistent.

The Application Hearing was heard on 17<sup>th</sup> June 2008 before The Honourable Mr Justice Cranston and was successful: the Approved Judgment stated:

*“There is no doubt that ME is a debilitating condition and many of us will know of people who either have the condition, or who know of other people who have the condition.....Given that there is this obvious divide between the biomedical and psychosomatic approaches to ME, given the great public interest....it seems to me that this case ought to go forward for a full hearing”.*

The Full Hearing was held on 11<sup>th</sup> and 12<sup>th</sup> February 2009 before The Honourable Mr Justice Simon and it failed on all counts. Before he became a Judge, Peregrine Simon

QC worked out of Brick Court, a leading set of chambers that acts for the insurance industry against claimants.

The Judgment was handed down on 13<sup>th</sup> March 2009. The Judge said that the Claimants' evidence was unconvincing, unreliable, unfounded and untrue, and entirely without merit; the Claimants' contentions could not be sustained; their allegation that there was insufficient representation of the biomedical approach was misconceived; there was no conflict of interest among members of the GDG; no GDG member had a closed mind about ME/CFS and GDG members' financial conflicts of interest (eg. working as Chief Medical Officer for three insurance companies with a financial interest in keeping CFS/ME excluded from benefits) were not sufficient to preclude membership of the GDG and the claim was seen to be baseless.

The Judge said the claim contained the "vice" which was repeated against a number of members of the GDG and that there was no bias among members of the GDG (even though the known bias of the professional members of the GDG was substantial and indisputable).

The Judge found that it was not accepted by NICE that Professor Peter White was a leading proponent of any particular view, and certainly not the psychosocial model of "CFS/ME".

The Claimants' written evidence that some GDG members had misled the High Court in their Witness Statements was not heard (yet there are criminal sanctions if there is evidence that someone has made a false statement to the Court).

Furthermore, the Claimants' evidence that NICE's lawyer (Charles Bear QC) had misled the High Court was not heard (even though it was substantiated in written evidence).

The Judge accepted all NICE's evidence and their experts' Witness Statements without equivocation (not every member of the GDG provided a Witness Statement and some members provided more than one; in total, there were 24 Witness Statements on behalf of NICE).

Permission to appeal was refused.

The outcome was a grave miscarriage of justice and a legal travesty; it was also a tragedy for patients with ME/CFS.

Following the Judgment, Professor Peter Littlejohns, Clinical and Public Health Director of NICE, announced in a Press Release:

*"The Judge recognised the key role that professionals have in contributing to the development of NICE guidelines and therefore understood the vigorous approach NICE took in defending these health experts".*

What he actually meant by the term “vigorous” was that less than 48 hours before the case was to be heard, having seen the Claimants’ evidence in full, NICE’s lawyers (Messrs Beachcroft LLP, who act for NHS providers and commissioners) ambushed the Claimants’ solicitor and barrister with the threat of a career-damaging “wasted costs” order, at which the Claimants’ lawyers capitulated and – without consulting the Claimants (a gross breach which itself initiated a professional negligence claim that was upheld) they withdrew about 60% of the Claimants’ evidence and apologised to the Court and to NICE. Without the Claimants’ knowledge or permission, their lawyers themselves submitted attenuated “evidence” (which meant that the case could never have succeeded because so much of the Claimants’ evidence about the failings of the Guideline was not considered by the Court).

Notwithstanding, in July 2009 Mr Justice Simon ordered the Claimants’ solicitors to pay NICE £50,000 damages in wasted costs as compensation for what he ruled to be improper conduct of the case.

The JR challenge to NICE’s Guideline on CFS/ME was pervaded by what has been described as dishonesty, but it preserved State-sanctioned “policy” at the expense of justice.

The Claimants stood no chance against such powerful opponents who appear dedicated to silencing the evidence which does not support “policy”.

On 28<sup>th</sup> October 2006 the BMJ had carried an article and responses that pertain to ME/CFS (“Vested interests will always trump evidence”: BMJ 2006:333:912-915). One response from an NHS Consultant was especially relevant:

*“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 concerns about the situation in which an inadequate evidence-base has become canonised into established guidelines, Government policy and incentivised practice”.*

Nowhere has this been more clearly demonstrated than in the NICE Guideline on “CFS/ME”.

#### Some key documents pertaining to the JR

There was massive support for the JR, not only from most of the ME charities (excluding AfME and AYME) but also from individuals and local support groups as well as medical scientists and clinicians. The Claimant’s solicitor said : *“Since permission was granted in this case in June 2008...I have been approached by a significant number of medical practitioners and academics who are supportive of the legal challenge and critical of both the Guideline and the process which went into producing it”.* From the many received, the following professional Witness Statements were submitted but were not permitted to be considered by the Court:

- Professor Malcolm Hooper (Emeritus Professor of Medicinal Chemistry, University of Sunderland)
- Dr William Weir (Consultant Physician)
- Professor Nancy Klimas (USA – Professor of Medicine & Immunology, Miami)
- Professor Mary Ann Fletcher (USA -- Professor of Medicine & Microbiology, Miami)
- Professor Bruce Carruthers (Canada – lead author of the Canadian Clinical Working Case Definition of ME)
- Professor Julia Newton (Professor of Cellular Medicine, University of Newcastle, UK)
- Dr Terry Mitchell (consultant clinical lead of Norfolk, Suffolk and Cambridgeshire NHS ME/CFS service)
- Dr Ian Gibson MP (Biologist; former chair of the House of Common Science & Technology Select Committee)
- Dr Jonathan Kerr (Department of Cellular & Molecular Medicine, St George's, University of London)
- Dr Irving Spurr (Researcher & Lecturer in ME/CFS)
- Dr Byron Hyde (Canada – Physician specialising in ME/CFS)
- Dr Derek Enlander (New York CFS/ME Centre)
- Dr Terry Daymond (Consultant Rheumatologist; former Clinical Champion for ME in North East England)
- Dr Charles Shepherd (Hon Medical Advisor, the UK ME Association).

There were Witness Statement of GDG members (on behalf of NICE); of the 15 professional members of the GDG, no less than 7 were involved with Professor Anthony Pinching's Service Investment Programme for the implementation of the Clinical Network Coordinating Centres (CNCCs or CFS Clinics) whose remit was to deliver CBT and GET for "CFS/ME". It is therefore ludicrous to suppose that any of those 7 members of the GDG would have voted against the recommendation of CBT/GET.

Witness Statements for NICE were provided by the following: Professor Richard Baker, Dr Fred Nye; Ms Nancy Turnbull; Dr Esther Crawley; Dr Richard Grunewald; Dr Alastair Santhouse; Dr William Hamilton; Second Witness Statement of Professor Richard Baker; Ms Mary-Jane Willows, Ms Amanda O'Donovan; Mrs Jill Moss; Dr Anthony Downes; Dr Philip Wood; Dr David Vickers; Dr Julia Smedley; Ms Carol Wilson; Second Witness Statement of Ms Mary-Jane Willows; Miss Jessica Bavinton; Ms Gillian Walsh; Ms Judith Harding and by Stephen Hocking of Beachcrofts.

There was also a Witness Statement by Professor Anthony Pinching, who was responsible for selecting the GDG members. Pinching was also involved with the design the MRC PACE trial; the documentation states: "*The authors thank Professors Tom Meade, Anthony Pinching and Simon Wessely for advice about design and execution*". Thus there is evidence that Pinching advised on a psycho-social trial which had "*predictors*" that included "*mood disorder, membership of a self-help group* (such as the ME Association), *being in receipt of a disability pension, focusing*

*on physical symptoms, and pervasive inactivity. CBT will be based on the illness model of fear avoidance. GET will be based on the illness model of deconditioning”.*

It is notable that although permission had been sought and granted by the Royal Courts of Justice for the transcript of the JR Judgment to be placed in the public domain, the Judge himself, Mr Justice Simon, specifically overturned that permission and ruled that the Judgment transcript should not enter the public domain.

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### The PACE Trial

The now-infamous PACE trial was the third arm of the three-pronged “integrated plan” and followed the customary route in order to achieve the intended outcome.

It is important to be aware that, although he now strenuously denies it, Professor Peter White has in effect admitted that they’d seen the data BEFORE they changed their definition of the “normal range” (see his letter of March 2011 to Richard Horton, Senior Editor of The Lancet: the normal range analysis was *post hoc* and given in response to a (peer) reviewer's request, which indicates that this analysis was performed after the primary analysis for which he would have to have seen the data: the normal ranges that appeared in the protocol all the way from 2002 till 2007 had completely different normal ranges. It is also noteworthy that the published statistical analysis plan contained no definition of the normal range for fatigue or physical function.

### Some documents relating to problems with the PACE Trial

Magical Medicine: how to make a disease disappear. Malcolm Hooper (February 2010) (442 pages)

Complaint to The Lancet: Report: Complaint to the relevant Executive Editor of The Lancet about the PACE Trial Article published by The Lancet. Malcolm Hooper (March 2011) (46 pages)

Response by Professor Peter White (confidential letter to Richard Horton, Editor in Chief of The Lancet, sent to us by Zoe Mullan, a Senior Editor at The Lancet) March 2011. It was in this letter that Peter White wrote that the PACE trial “*does not purport to be studying CFS/ME but CFS simply defined as a principal complaint of fatigue....*”. This letter is important because Peter White denies in writing what he had written to the MREC (obtained under the FOIA from the MREC).

Initial response by Professor Malcolm Hooper to an undated letter sent by Professor Peter White to Dr Richard Horton, Editor-in-Chief of The Lancet (18<sup>th</sup> May 2011).

Professor Malcolm Hooper’s further concerns about the PACE Trial (13<sup>th</sup> June 2011).

Briefing Notes for meeting with BIS officials about incorrect answers to Parliamentary Questions re: the MRC-funded PACE Trial and ME/CFS (prepared for the Countess of Mar); Malcolm Hooper (June 2012)

Statistics and ME. Malcolm Hooper (September 2011)

Update on The PACE Trial. Malcolm Hooper. 11<sup>th</sup> July 2013

Key Concerns re: PACE Trial + Brief Summary of Key Concerns + Quotes on ME/CFS by those involved with the PACE Trial prepared for the Countess of Mar. Malcolm Hooper (September 2013).