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PROOF POSITIVE ? (REVISITED)

Margaret Williams 14th September 2016

The PACE trial was instigated and carried out mostly by a group of psychiatrists well-known for teaching that ME/CFS does not exist other than as an aberrant belief: their assumption was that ME/CFS is a behavioural disorder that is amenable to behavioural interventions. The Investigators had no evidence for their assumption and despite abundant scientific evidence to the contrary, it remained their firmly-held belief. They favoured two interventions in particular: cognitive behavioural therapy (CBT), which was to *"change the behavioural and cognitive factors assumed to be responsible for perpetuation of the participant's symptoms and disability"* and graded exercise therapy (GET), which was to correct the assumed deconditioning resulting from avoidance of activity.

The original (selective) results on the PACE trial were published in The Lancet in early 2011; they were accompanied by press releases from The Medical Research Council, King's College London and Queen Mary University of London, all of which proclaimed: "*Two effective treatments benefit up to 60 per cent of patients with CFS/ME".* Importantly, this figure was achievable only because the Investigators used a much less demanding definition of improvement than they had stated in their published protocol.

Following lengthy Freedom of Information (FOIA) requests, all of which were refused until the final one, the raw data from the PACE trial had to be released, following which the Investigators re-analysed their data according to their own published protocol.

Those results were different from what had been published in The Lancet to such loud acclaim (orchestrated by the Science Media Centre, of which Professor Sir Simon Wessely, one of the PACE team, was a founder member).

It revealed that the improvement figure was only 21% for the GET group and 20% for the CBT group versus 10% for those who received usual medical care alone, meaning that for every ten people treated with CBT or GET, only one person would show protocol-defined improvement. All participants received what was described as standardised "specialist" medical care (SSMC), but those receiving SSMC alone may have seen the Fatigue clinic doctor only three times for 30 minutes each time during their participation in the trial, a total of 90 minutes throughout the trial.

Hence the protocol-specified figures are that CBT and GET helped only an additional 10% of participants over usual medical care and not the widely reported 60%.

So far, only the "improvement" statistics from the PACE trial original protocol have been made public; although the promised "recovery" statistics as per the original protocol have been released to the Respondent following a Freedom of Information request, they have not yet entered the public domain.

Given that Professor Peter White, psychiatrist and Chief Principal Investigator of the now-infamous PACE trial, appears to have looked at the data before re-defining "recovery", if (as widely expected) there are no group differences according to the protocol definition of "recovery", there could be no argument that, despite the fanfare of success, the PACE trial failed.

Of importance is that – despite glowing reports of the PACE trial's claimed success -- two major institutions in the US have gone on record stating their concerns about the interventions used in the PACE trial: the Centres for Disease Control (CDC) has archived its toolkit that recommended CBT and GET as interventions for ME/CFS (http://www.cdc/gov/cfs/toolkit/archived/html) and the National Institutes for Health (NIH) have advised that the Oxford criteria used in the PACE trial (see below) are flawed: *"Specifically, continuing to use the Oxford definition may impair progress and cause harm…Thus, for needed progress to occur we recommend that the Oxford definition be retired"* (http://annals.org/article.aspx?articleid=2322804). Their conclusions were based on comprehensive reviews of over 9000 peer-reviewed research papers and testimony from expert researchers and clinicians.

Furthermore, in March 2015 a landmark case in the UK courts (the Montgomery case) became a new legal test for consent to medical treatment: hiding behind a "*reasonable body of opinion"* is no longer an option for clinicians – a patient must be informed of **all** material risks found in **all research**, and ignorance of the facts is no excuse. Even before this change in the law, the General Medical Council's Guidance on consent to medical treatment was clear that patients must be advised of all risks. All clinicians, researchers and health professionals who for years have prescribed CBT/GET for people with ME/CFS without fully informing them of the risks have thus been in breach of these GMC guidelines on consent. This includes those involved with the PACE trial. The empirical evidence collated by UK ME charities from over 5,000 patients are that CBT is ineffective and GET may be – and often is – actively harmful, resulting in relapse that may be lifelong.

<u>The role of Professor Peter Denton White OBE</u>

In 2004, Professor Peter Denton White was awarded an OBE for *"services to medical education"*; notices circulating at the time proclaimed him as leading the research into "CFS/ME" and said his OBE was *"a well-deserved honour and acknowledgement of his contribution to work on CFS/ME"*.

He was born in November 1952: aged only 64, he suddenly retired from clinical practice just before he was compelled by an order of the court to release the raw data from the PACE trial, so any investigation by the General Medical Council for alleged professional misconduct is unlikely to be pursued, but is he guilty of misfeasance in public office?

According to the Crown Prosecution Service (CPS) website, misfeasance in public office is a cause of action in the civil court against the holder of public office, the allegation being that the office-holder has misused or abused their power: such misuse or abuse is an affirmative act that causes harm to another party without reasonable justification. The NHS is a State body as it provides public health care, so this matter is one in which the public has a significant interest.

Facts to be considered

1. Peter White has used his own money, as well charitable money and public money, in order to lobby support for his belief that ME/CFS is a psycho-behavioural disorder that can be overcome through "cognitive restructuring" and graded aerobic exercise

2. he has egregiously used large sums of public money (£250,000) to prevent the disclosure of data that would falsify his belief

3. for nearly 30 years, he has ignored evidence that disproves his belief, including evidence from his own trials

4. he has failed to correct errors of fact after being alerted to them

5. he has consistently failed to disclose significant financial, institutional and ideological conflicts of interest

6. he has been in breach of his NHS contractual obligations in that he has persistently ignored mandatory directives and has wilfully encouraged other clinicians to do the same

7. as a consequence of his actions:
    - money which should have been used for biomedical research into the aetiology of ME/CFS has been diverted to fund studies into therapies which were already known to be ineffective and even harmful
    - patients have been stigmatised as sociopaths and malingerers who refuse to accept they have a behavioural disorder
    - patients have been denied financial support from private insurers for whom Peter White and his colleagues work (for example, he was Chief Medical Officer for the giant re-insurer Swiss Re and was also CMO to Scottish Provident) and from the Department for Work and Pensions (where he was lead advisor on "CFS/ME" and was a prominent member of the group who re-wrote the chapter on "CFS/ME" in the DWP's Disability Handbook used by Examining Medical Practitioners, by DWP decision-makers and by members of the Appeals Services Tribunals); he also works for the US Centres for Disease Control, and for defendants in legal actions (BMC Health Services Research 2003:3:25)
    - patients with ME/CFS have been wrongfully sectioned and detained under the Mental Health Act

- clinicians who oppose his views about ME/CFS have been sanctioned by the General Medical Council and prevented from working.

Although in the UK both the Department of Health and the Department for Work and Pensions have confirmed – in writing – that they accept ME/CFS as a neurological disorder, this is not borne out in practice: undoubtedly as a result of the pervasive influence of Professor White and his colleagues, only the most basic NHS investigations are carried out and there is no treatment or support for this group of patients other than behavioural modification interventions. It is indisputable that many patients with ME/CFS have died and that a larger than average number have been driven to suicide.

On 11th January 2002 the Chief Medical Officer's Working Group (from which Peter White and Trudie Chalder – another PACE PI – resigned because they did not get their own way about classifying "CFS/ME" as a behavioural disorder) published its Report. Speaking in support of those with ME/CFS at the launch of the Report, Professor Sir Liam Donaldson, Chief Medical Officer, said on the record: "*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: 11th January 2002). He was immediately vilified by GP Dr Mike Fitzpatrick of "spiked": ***"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. The effectiveness of the ME lobby reflects its middle-class base."*** Proponents of psychosocial model insist that ME does not exist as a disease and that it is caused by aberrant beliefs, deconditioning and "*hypervigilance to normal bodily sensations"* (The Cognitive Behavioural Management of the Post-viral Fatigue Syndrome; S Wessely, T Chalder et al; In: Post-Viral Fatigue Syndrome, ed. Rachel Jenkins and James Mowbray, John Wiley & Sons, 1991, page 311).

That same month, on 31st January 2002, a company called One Health (company number: 04364122) was incorporated to act as a lobby group in order to achieve Professor Peter White's lifetime goal. He was Chairman of One Health and his fellow Directors included Trudie Chalder. It was described as a company that (quote): "*was established in order to promote a system of healthcare based on the biopsychosocial model of ill-health".*

Of significance is that One Health's registered address was 100 Fetter Lane, London, the same address as the company's lawyers -- Messrs Beachcroft, the same lawyers who acted for NICE in the 2009 Judicial Review of the NICE Clinical Guideline on "CFS" and who threatened the Claimants' lawyers with a massive wasted costs order unless most of the Claimants' evidence was withdrawn. (The evidence was that members of the Guideline Development Group were carefully selected because of their support for the psychosocial model of ME/CFS, even to the point that the Medical Advisor to the ME Association was rejected as a member, so the outcome – the recommendation of CBT and GET -- was a foregone conclusion). Sadly, the threat was so substantial that, without discussing it with their clients, the Claimants' lawyers capitulated: they withdrew their evidence and apologised to the Court, but the Judge still imposed a £50,000 fine on them. As Peregrine Simon QC, the Judge, the Rt Hon

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

One Health was supported to the tune of at least £100,000 by the Andrew Mitchell Christian Charitable Trust, based at The Grange, St Peter Port, Guernsey (a significant financial interest which it seems Peter White has never declared). This is confirmed in the auditors' statement of financial activities from 31.01.2002 to 31.12.2002. The Patron of One Health was Greville Mitchell, a multi-millionaire businessman and father of the late Andrew Mitchell, who was tragically killed and in whose name the charitable fund was set up.

The Memorandum of Association of One Health stated:

1. *The name of the Company is 'One Health'*
2. *The registered office of the Company will be situated in England and Wales*
3. *The objects for which the company is incorporated are to carry on all business associated with the establishment and promotion of a system of healthcare based on a biopsychosocial model, being a model that incorporates thoughts, feelings and behaviour with a physiological approach to health and illness; such establishment to include, without limitation:*

3.1 research into the biopsychosocial model of healthcare by active promotion of the biopsychosocial model amongst healthcare professionals, patients and others, using evidence and influence;

3.2 the education of healthcare professionals in relation to the biopsychosocial model; and

3.3 publicising, through any medium thought appropriate by the Company, the biopsychosocial model.

LEGAL STATUS

The organisation is a charitable company limited by guarantee, incorporated on 31 January 2002.

Members of the One Health company 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 is "*a blind alley*" and that the correct approach to illness – whatever its provenance -- is the psychosocial one, in which thoughts, feelings and behaviour can be modified by cognitive behavioural therapy with graded exercise, resulting in restoration of health and productivity.

Many people believe that it is a retrograde step to reject the hard-earned scientific evidence -- gained over centuries -- that ill-health is directly caused by disease and its pathological processes and to revert to blaming ill-health on aberrant beliefs instead of pathogens.

Supported by the company One Health, Professor White's pervasive influence has been immense, extending even to some members of the Judiciary. One professional woman developed ME after being involved in a road traffic accident and, supported by extensive and robust medical evidence, brought an action for damages in the High

Court. That evidence was rejected by the court and the Claimant was informed that (quote): *"Judges regard ME as psychological self-indulgence"*.

Peter White's influence also encompasses the General Medical Council; the Medical Research Council; the Department of Health; the Department for Work and Pensions; the Scottish Chief Scientist's Office, NICE; the Medical Royal Colleges; the Royal Statistical Society; the Royal Society; the Science Media Centre; The Lancet and other medical journals; the mainstream media; the (supposedly impartial) Cochrane Review (that found in favour of GET, a review which Peter White appears to have partly funded himself, just as he part-funded the Oxford criteria used in the PACE trial) and The Houses of Parliament, where there is a misleading record in Hansard about the outcome of the PACE trial: on 6th February 2013 there was a "debate" on the PACE trial in the House of Lords for which, on his own admission, Peter White briefed all those who spoke in support of it, with the intended result that the study was enshrined in Hansard as an officially-recorded success story:

"I have had to provide responses to Parliamentary Questions from members of both Houses of Parliament to allow them to understand the nature and findings of the PACE trial. In particular, I had to recently brief several members of the House of Lords so that they might speak in a critical debate about the Pace trial held on 6th February this year (exhibit C)" (Peter White's evidence to FOI Tribunal on 28th June 2013).

Knowingly misleading Members of Parliament is a serious offence.

<u>Background</u>

There is a group of (mostly) psychiatrists known as the "Wessely School" (Hansard: Lords: 9th December 1998:1013) who, over the last 30 years, have devoted their careers to "eradicating" ME/CFS and their efforts have been relentless. Most of them work not only for the NHS but for the permanent health insurance (PHI) industry and a medical statistician calculated (from evidence set out in the member's CV) that one member of the Wessely School augmented his income by about £4,000 per week through his work for the insurance industry.

These psychiatrists often fail to declare fully the extent of their vested interests; 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 that body of mainstream knowledge did not exist. Some would regard that as professional misconduct.

There is hard evidence that these social constructionists were bent on indoctrinating politicians and Government agencies worldwide – and in the UK were not averse to publicly side-lining even the Chief Medical Officer (indeed, psychiatrist Michael Sharpe said in the BMJ that doctors would not accept a particular strategy just because the CMO's report recommended it: BMJ:2002:324:131) – and on imposing their own ideology onto an unwitting public and an unconvinced medical profession.

This was to be done by means of a co-ordinated strategy that the Wessely School intended to be implemented not only by the Government agencies to which they have been advisors, but also by "educational" campaigns in the media (including using the internet), starting with the indoctrination of children at school (ie. before their critical faculties are sufficiently developed to enable them to be discriminating, which seems particularly morally repugnant).

That Peter White and his like-minded colleagues really were intent on changing medicine from biomedical to psychosocial is illustrated by a chilling comment in 2002 from one of the PACE PIs (Trudie Chalder):

"Rather than start with the physicians, which might be quite a difficult task, we could make a start with youngsters in schools. My experience is that they are much easier to educate. The only barrier is the parents. Once we have the child on our side we are in a very good position" (see below for context).

Such determination to change people's beliefs by means of *"cognitive restructuring"* may result not only in the removal of a person's right to receive appropriate medical care but may further distort the social structure of what was once a decent British society in which respect was afforded to the sick as of right, because the nature of State institutions such as the DWP are being changed by social constructionists from supportive to punitive.

Such behaviour is not dissimilar to that of a cult, whose members in this case have a great deal invested in their own beliefs.

No-one, especially Ministers and Secretaries of State, should be in any doubt about the goal of those engaged in the truly sinister social engineering that is intent on replacing medicine and welfare with institutional control of peoples' thoughts and behaviour.

Historical Perspective

Since 1969 myalgic encephalomyelitis (ME) has been listed by the World Health Organisation (WHO) International Classification of Diseases (ICD) as a neurological disease and since 1992 it has also been listed synonymously as Chronic Fatigue Syndrome.

Professor Peter White and his like-minded colleagues do not agree with the WHO classification and insist that "CFS/ME" is a behavioural disorder, so for decades they have taught and advised clinicians and medical students not to use the formal WHO classification.

This is a serious breach of their NHS contractual obligations, because adherence to the WHO ICD is mandatory in England.

On 10th September 2002 the Communications Director (Anne-Toni Rodgers) of the National Institute for Clinical Excellence (NICE) Special Health Authority issued a

Communications Progress Report which, at section 2.7.1.5 is clear: *"The ICD-10 classification is used for the recording of diseases and health related problems…The WHO produces the classifications and ICD-10 is the latest version…**the classification codes are mandatory for use across England**".*

Because Peter White saw no reason to comply with that directive and continued to insist that there was dual classification of ME/CFS in ICD-10 (once in the neurological section but again in the mental health section), advice was sought from the WHO headquarters in Geneva; on 23rd January 2004 the WHO stated in unequivocal terms:

"This is to confirm that according to the taxonomic principles governing the Tenth Revision of the World Health Organization's International Statistical Classification of Diseases and Related Health Problems (ICD-10) it is not permitted for the same condition to be classified to more than one rubric as this would mean that the individual categories and subcategories were no longer mutually exclusive".

However, Peter White ignored this directive from the WHO, just as he ignored the directive from NICE.

The intensity of his dissatisfaction with WHO classification of ME/CFS in ICD-10 was evident in his presentation to the Royal Society of Medicine's conference on "CFS" in April 2008 (Power Point slides: http://www.roysocmed.ac.uk/chronicfatigue08/white.pdf) in which he was unequivocal in advising clinicians not to use the ICD-10 classification of ME/CFS as a neurological disease; his words *(verbatim*) were:

" I'm going to review the ICD-10 criteria for the illness and see if they're helpful. The answer will be, they are not helpful…..This meeting is about clinicians making the diagnosis and helping patients…..Then we come to the three clinical criteria to see if they're useful, and two of them actually do have help to us: the NICE Guidelines criteria and the Royal College of Paediatrics and Child Health criteria I would commend to you".

The NICE Guideline CG53 recommends CBT/GET and very limited investigations, whilst the RCPCH Report of December 2004 (Evidence-based Guidelines for the Management of CFS/ME in Children and Young People) bears little relationship to children and young people with ME/CFS. The College's view of ME/CFS was that it is a behavioural disorder. The RCPCH report emphasised behavioural interventions: "*Children and young people with CFS/ME should be considered for graded exercise or activity programmes"* and stated: *"The overarching aim of CBT is to help patients modify their behaviour for their own benefit".*

White continued his presentation and in flagrant denial of his obligations he said: *"Does the ICD-10 help us? Unfortunately not; **there are at least five ways of classifying CFS using the ICD-10 criteria.** What are they? We start off well: myalgic encephalomyelitis is in the neurology chapter of ICD-10…and helpfully, "chronic fatigue syndrome, postviral". So it starts off well. What if the viral illness is not a clear trigger for the illness? Well, you've got alternatives: in the Mental Health Chapter, you've got Neurasthenia…if you think that somehow, psychological*

factors have some role to play….you somehow have to guess that psychological factors have an important role to play in their aetiology".

He concluded his presentation: *"It's confusing, isn't it?….ICD-10 is not helpful* ***and I would not suggest, as clinicians, you use ICD-10 criteria. They really need sorting out, and they will be in due course, God willing".***

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

As a direct consequence of these psychiatrists' false belief and influence, biomedical research into ME has been side-lined and starved of funding in the UK, and a whole generation of doctors has been educated to believe ME/CFS to be a behavioural disorder, with sufferers being disparaged and dismissed accordingly.

Key questions that Professor Peter White must be required to answer

- why were patients attending a "fatigue" clinic of which Peter White was in overall charge coerced onto the PACE trial on pain of being discharged from a consultant's care if they declined (support from a consultant being necessary to authorise claims for state benefits)?
- why on 14th July 2006 did Peter White seek approval from the West Midlands Multicentre Research Ethics Committee (MREC) to write to GPs asking them to refer patients with "fatigue" to the PACE trial (*"If you have a patient… whose main complaint is fatigue (or a synonym)…please consider referring them to…one of the PACE trial centres")*?
- why, having obtained financial and ethical approval to study "CFS/ME", did Peter White write to the editor-in-chief of The Lancet in March 2011 claiming not to have been studying ME? He wrote: "*The PACE trial paper refers to chronic fatigue syndrome (CFS) which is operationally defined; it does not purport to be studying CFS/ME"*
- why was trial data not kept securely (as promised to all participants) and allowed to be stolen, being then lost to analysis (theft reported to Southwark police on 22nd March 2006; crime number 3010018-06)?
- why, in the Minutes of the Joint Trial Steering Committee and Data Monitoring Committee held on 27th September 2004, are no conflicts of interest recorded by the three PIs (who all worked for the PHI industry and did have financial conflicts of interest) and why did some members of the TSC fail to declare significant financial conflicts of interest?
- why did Peter White refuse to release the raw data for so many years when it does not belong to him but to UK tax-payers?
- why did the PIs change the primary outcomes of the trial after they received the raw data?
- was that decision known about, approved and recorded in Minutes by the trial data monitoring and ethics committee?
- was that decision known about and approved by the West Midlands MREC?

- why was "recovery" re-defined (this meant that someone could enter the trial with a certain score, become more disabled with a lower score during the trial, but still be counted as "recovered")?
- why was the re-definition of "recovery" not specified in the statistical analysis plan?
- why was the statistical analysis plan published two years after selective (ie. adjusted) results had been published?
- why has funding been awarded for an even longer term follow-up, given that at the two-year follow-up there were no group differences between those who had received "treatment" and those who had not?
- why did Peter White ignore the warning sent by Adrian Baldwin, who wrote to the journal Psychological Medicine to warn them that there was a significant error in the recovery paper (ie. this was not a dispute over interpretation – there is a provable and significant error that they were made aware of but did nothing to correct)?
- why did Peter White use his own money to fund the Cochrane Review of GET (which, unsurprisingly, given that Peter White himself was instrumental in that Cochrane Review, found that it was effective)?
- why were the PACE PIs allowed to use their own "Oxford" criteria for entry to the trial (without informing participants that Peter White himself had co-funded those criteria: JRSM 1991: 84:118-121) and when one of the PIs (Michael Sharpe) stated in 1997 that the Oxford criteria *"have been superseded by international consensus"* (Chronic fatigue syndrome and occupational health. A Mountstephen and M Sharpe. Occup Med 1997:47:4:217-227)?
- why did Peter White and his co-PIs fail to declare their vested financial interests to PACE participants (in particular, that they worked for the PHI industry, advising claims handlers that no payments should be made until applicants had undergone CBT and GET)?
- why did Peter White permit such misleading media reporting at the press conference convened by the Science Media Centre, resulting in false reporting to and by the media?

<u>How did the PACE trial come to be funded by over £5 million, when the PIs themselves already knew that CBT and GET did not work in ME/CFS?</u>

Long before the PACE trial started, Peter White warned – in fact he virtually threatened -- the MRC that he would be applying for major funding because he had long been determined to carry out such a trial: on 2nd March 1989 he wrote to Dr DA Rees, the then–Secretary of the MRC, saying: "*RESEARCH ON POST-VIRAL FATIGUE. I understand that the Medical Research Council may be considering special grant awards for research in this area. If this is the case, I would like to forewarn you that I shall be looking for funding for substantive projects to test various hypotheses regarding the physical and psychological aspects of this putative diagnosis…I will be seeking funding…(for) a treatment trial of a graduated return to*

physical activity and exercise". On 10th April 1989 Dr Katherine Levy from the MRC replied on behalf of Dr Rees, informing Peter White that he had been misinformed.

However, Peter White persisted, and the PACE Trial was the result, even though the PIs and others connected with it (including Professor Sir Simon Wessely) have known for years that a key intervention used in PACE (CBT) does not work for people with ME/CFS and they had publicly conceded that CBT confers no lasting benefit and that there is no evidence of objective, measureable increase in activity levels in ME/CFS patients after a course of CBT.

For example:

- at the American Association for CFS (AACFS, now the IACFS/ME) International Conference at Cambridge, Massachusetts on 10-11th October 1998, 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 began 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)

- Wessely himself stated in 2001 that CBT is *"not remotely curative"* and that: *"These interventions are not the answer to CFS"* (Editorial: JAMA 19th September 2001:286:11)

- the authors of the York Systemic Review (upon which NICE relied for supposed evidence of clinical effectiveness) themselves conceded the methodological inadequacies of the studies upon which NICE based its management recommendations and that after a course of CBT, there is no objective evidence of improvement 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)

- 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 Peter White's own discussions in 2002, Professor Robert Lewin from the Department of Health Sciences at the University of York said on the record: *"As we all know, CBT gains tend to fade over time"* (see below)

- 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 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)

- 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 I:29) but that is exactly what NICE did in its Clinical Guideline on "CFS/ME" (CG53). However, 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, 6th January 2011: personal communication). That is a astonishing admission, since the NICE Clinical Guideline on "CFS/ME" of 22nd 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, with Peter White at the helm (albeit behind the scenes), NICE jumped the gun by four years by relying on "evidence" which the MRC described as "*insufficiently strong"*

- referring to the PACE trial itself, PI Michael Sharpe said on 18th April 2011 on Australian ABC radio: "**What this trial wasn't able to answer is how much better are these treatments than really not having very much treatment at all"**

- of over-riding importance is the fact that at two-year follow-up of PACE participants, there was a null result, with no difference at all between the groups (which bore out the existing evidence)

- according to Co-Cure (17th September 2016) Peter White's co-PI Professor Michael Sharpe has disclosed that results of the PACE trial were substantially poorer when evaluated with the originally-declared scoring of primary outcome variables. The unanticipated revelation demonstrated the need to share the PACE data for independent re-evaluation, particularly given the clinical and public health importance that has been attached to it.

Given that such an evidence-base already existed, why was the PACE trial ever funded? Was it funded because of Peter White's obsessional determination to change the face of modern medicine?

A sign of maturity is said to be the ability to learn from experience, but these "behavioural" psychiatrists seem to persist in exhibiting a disturbing inability to learn from experience.

Background to Peter White's determination to stop medicine going down *"a blind alley"* and to replace medical science with a psychosocial cult

It was in 2002, about seven months after One Health was formed, that Professor Peter White applied to the West Midlands MREC for ethical approval for the PACE trial.

One Health was dissolved in 2010, just before the first (modified) PACE results were published in The Lancet in early 2011.

As is now clear, One Health seems to have been a breeding ground for psychosocial constructionism, whose proponents, by programmed brain-washing using multi-media, intended to exert control not only over State institutions and policy but also over the entire medical profession (including medical schools), over children, their parents, and over all sick people, no matter what the cause of their disease (see below).

Before any of the questions posed above can be addressed, it is necessary to be aware of what was actually said at the One Health conference held on 31st October and 1st November 2002.

The ME community has for decades urged UK Government bodies to fund research into both the epidemiology and the biomedical abnormalities that are known to exist in myalgic encephalomyelitis, almost always to no avail, to the extent that the ME community realised that there were powerful vested interests at stake.

Now there is hard evidence of the reason for the Establishment's apparent resistance to acknowledge ME/CFS as an organic disorder and it does indeed involve psychiatrists of the Wessely School.

The evidence is contained in a book entitled "Biopsychosocial Medicine: An integrated approach to understanding illness" edited by Peter White, Professor of Psychological Medicine at St Bartholomew's and the London, Queen Mary School of Medicine, published by Oxford University Press (2005).

Twenty eight *"international experts in the field"* were invited; twelve talks were given, followed by an equal time spent in discussion. The book includes those (edited) talks and discussions. The conference was chaired by Professor Simon

Wessely; others present included Professors Michael Sharpe and Trudie Chalder (together with Professor Peter White, they were to be the three Principal Investigators of the PACE trial).

Other "*international experts in the field*" who have featured in the fate of those with ME included Professor Mansel Aylward, formerly of the Department for Work and Pensions (which will ring bells for those with ME/CFS who have had to appear before DWP Appeal Tribunals in order to obtain or retain their State benefits) who went to Cardiff as Professor and Director of Psychosocial Disability and Research at a new Centre funded by UnumProvident, the medical insurance giant that has a lengthy and disturbing track record of refusing to pay legitimate claims, especially to those with ME/CFS, to the extent that punitive damages have been awarded against it.

Other "*international experts in the field*" included Professor Jos Kleijnen, Director of the Centre for Reviews and Dissemination at the University of York, the same Centre that carried out the systematic review of the literature that sought to show the efficacy of cognitive behavioural therapy for the Chief Medical Officer's "independent" Working Group on "CFS/ME" (to which Wessely donated his personal database of over 3,000 papers), a review which concluded that cognitive behavioural therapy was the management regime of choice for those with "CFS/ME". This was the same Professor Kleijnen who, during that systematic review of the literature, failed to acknowledge or answer correspondence that drew attention to the published peer-reviewed evidence of the organic basis of ME/CFS and of the biomedical abnormalities that have been demonstrated to exist in the disorder.

An "*international expert in the field*" of note to the ME community was Professor Peter Salmon, Professor of Clinical Psychology at Liverpool, known for his view that "CFS/ME" is somatisation of mental illness, whose Editorial in the May 2002 issue of the British Journal of General Practice stated: *"Opinion has been divided about the validity of chronic fatigue syndrome or myalgic encephalopathy (CFS/ME) as an illness. Now, in a report to the Chief Medical Officer, an expert group has concluded that the condition is indeed a chronic illness meriting significant NHS resources, including the unreserved attention of the medical profession. The approach adopted by the group became dominated by the perspective of sufferers…. The group's recognition of CFS/ME as a distinct syndrome runs counter to trends in recent research* (citing Wessely, Lancet 1999:354:936-939) *…The prevailing view in UK primary care has been that somatisation of mental illness is the basic problem. Approaches to care which focus on changing the way patients and doctors communicate about the illness and, in particular, incorporate and modify patients' beliefs within an agreed management strategy, are gaining ground…. Unless the medical profession clearly understands its role in the management of illness beliefs and behaviour in the absence of demonstrable pathology, it risks becoming both an intellectual casualty and a potent vector of this and other social epidemics".*

Yet another "*international expert in the field*" was Dr Michael Fitzpatrick, a general practitioner at Barton House Health Centre, 233 Albion Road, London N16 9JT, better known for his association with the on-line magazine "spiked" and for his public attack on the UK Chief Medical Officer when in January 2002 the latter stood up in support of ME as being on a par with multiple sclerosis and motor neurone disease.

Another such "*international expert in the field*" was Professor Adrian Furnham, Professor of Psychology at University College, London, who became famous for publishing highly derogatory comments about people with ME: in the Daily Telegraph on 18th February 1999 he wrote an article implying that some people might use "ME" as an excuse for professional under-achievement and lack of success and he implied that such illnesses were no more than a product of a *"psychobabble industry based on medicalising mediocrity"* and were not real.

Yet another "*international expert in the field*" was Francis Creed, Professor of Psychological Medicine at the School of Psychiatry and Behavioural Sciences at the University of Manchester and Director of Research and Development for the Manchester Mental Health and Social Care Trust; he was also Editor of the Journal of Psychosomatic Research. One of his research areas was the treatment of somatisation. Creed failed to acknowledge or respond to letters written to him as Editor asking that the Journal present a more balanced and less biased portrayal of ME/CFS.

Other *"international experts in the field*" included Professor Edward Shorter, holder of the Hannah Chair in the History of Medicine at the University of Toronto, Canada, whose views were so beloved by Elaine Showalter, such views being that the creation of disorders such as ME are simply *'a spiral of suggestion'*. In her article in The Independent on Sunday, 25th January 1988 (I am a Duvet woman: why are 85 per cent of ME sufferers women?) Showalter promoted Shorter's view: *"Patients are exposed to a diagnosis and assured by a sensation-hungry media that it represents the explanation of their problems (and) they are reassured that doctors do not know what they are talking about. This is a recipe for the disintegration of medical authority and a psycho-circus of suggestion"*.

So much for the known beliefs of the contributors, but what were they saying in this book? The following extracts provide the answer, but what they do not provide is the answer as to how attempts to alter the way a person thinks about such a serious neuro-immune disorder as ME/CFS can address or assist how ill a person feels (and actually is), nor how the favoured psychiatric '*management regimes'* can improve understanding of the pathological processes that result in end-organ failure that cause patients to feel (and to be) so sick and disabled.

Unless the disease itself is robustly investigated and understood -- and ultimately treated -- no amount of psychosocial 'management' will have worthwhile or lasting effects, either upon the hapless sufferer trying to cope without medical support with serious and destructive organic pathology or upon the cash-strapped and rapidly sinking NHS.

The whole concept of "biopsychosocial" intervention would seem to be a short sighted quick-fix that is doomed to pass into oblivion once the biomedical evidence falls into place: to disregard the need for (and the importance of) the bio*medical* aspects that are already known to underlie ME/CFS and to place such undue emphasis and funding only on the bio*psychosocial* aspects has, through the auspices of members of the One Health company, come to dominate UK Government policy and service provision.

The Discussions

In the context of the PACE trial and the recently-released data, of particular importance and relevance is the discussion section following the presentations at the One Health conference (chapter 12: "*What are the barriers to healthcare systems using a biopsychosocial approach and how might they be overcome?"*).

Professor Kate Lorig from the Stanford Patient Education Research Centre at Stanford School of Medicine provided some telling answers. When asked by Professor Mansel Aylward how did she recruit people into the biopsychosocial model, she replied: *"I'd put real marketing experts onto it. The programme is now being used in about 14 countries and the Australians found out that the way to recruit is via symptoms. Are they tired? If so, come along. We have been running the same programme with monolingual Spanish speakers. We run it in churches and community halls. This past Easter I went to mass twice, and I'm Jewish. The place to find Spanish speakers in the USA is mass on Easter Sunday. Between myself and the staff we covered 17 masses. We just take their names and addresses and then call them later. The system has to go to them, you don't ask them to go to the system. We have not focused on diseases, but on symptoms. This is what they respond to".*

Peter White then asked Professor Lorig: "*Have you seen a differential effect in outcome by diagnosis or diagnostic group? I ask this because work done in the UK under the aegis of the Department of Health suggested that a particular diagnostic group, chronic fatigue syndrome, did not do at all well".*

Professor Francis Creed asked Lorig: "*We were discussing some of the organizational barriers to instituting the biopsychosocial model more widely (but) it sounds like you have been very successful in overcoming them. What are the most telling things that have made a difference?",* to which Lorig replied: *"We have proselytised….the 'innovators' leap out in front and try everything new. These were not the people we want to reach. Instead, we wanted to target the next group, the 'early adopters' (of the regime). These are the people that need to be successful. If they are, the rest of the world will eventually come along".*

Professor Michael von Korff (Senior Investigator from the Centre for Health Studies in Seattle) then said: "*Kate Lorig outlined sources of resistance. If we want to make the biopsychosocial model work, we need to start addressing some different fields than the primary care visit and medical care".*

Mike Fitzpatrick said: *"It is interesting to contrast the approach Kate Lorig is talking about with what we are familiar with about patient campaigns, which often have a very activist feel to them, such as the ME campaign. There are vast numbers of these self-help groups. What Kate has described has a strongly top-down character (and) the nature of the training seems didactic, with master trainers. How does this sit with the existing self-help campaigns?"*

Lorig replied: *"The two master trainers in the UK both came from patient groups".*

Wessely asked: *"What would happen if (a) group started to challenge these particular treatment ideologies and said they wanted to know how to get more*

benefits from the state? You are going to come to some bits where some people in the room might say 'I tried that and it didn't work for me: in fact it made me worse' ".

Trudie Chalder said to Kate Lorig: *"It is clear that you are a very effective cognitive behavioural psychotherapist and I want to congratulate you on your programme. It sounds marvellous".* Lorig replied: *"If you are interested in it, I would suggest seeing it in action. Bob Lewin has done this".*

Professor Robert Lewin (from the Department of Health Sciences at the University of York) said*: "I went along because I got involved through the Department of Health. They wanted some disease-specific modules. I thought this was going to be done by people who had been taught by rote how to do this from a set of flip charts. Goal setting is completely different when it is done by lay people…I wonder if patient-generated goals last longer. As we all know, CBT gains tend to fade over time".*

Mansel Aylward said: *"**Today we have hit on what I think are the crucial issues. These aspects of the biopsychosocial model have had the greatest impact in developing social and welfare policy in the UK.** These techniques are simply described and one can communicate them to our colleagues, and even to our politicians, who sometime find it difficult to grasp these issues. **This sort of work will strongly influence how social policy and rehabilitation will develop over the next year or so.** Importantly, we should consider the work by Buchbinder in Australia. This showed the utility of a multi-media educational programme. We hope we will be able to repeat some of this here".*

Michael Von Korff said: "*If you take interventions that individually are modest in their effects and you have the healthcare system and the social welfare system using these approaches consistently, you end up with a larger effect. This is a very important aspect".*

Peter White said: ***"There are two ways to change beliefs. You can change beliefs first using cognitive behavioural therapy, which leads to behaviour changes (or you can) change the behaviour first, which then changes the cognition. Exposure is needed to the particularly avoided behaviour, which is exercise or physical activity in chronic fatigue syndrome".***

Wessely said: "*We are talking about barriers. The people we see just don't believe us".*

Michael Von Korff said: *"If we start with the assumption that all chronic pain patients are motivated largely by secondary gain and are difficult and demanding individuals, then we will miss the broader opportunity to fundamentally change the way (such patients) are managed in the healthcare and social welfare systems".*

Kate Lorig said: *"This is where we have to develop key messages, which the healthcare system gives consistently".*

Simon Wessely said: *"We accept that. This is what we do in treatment programmes".*

Michael Sharpe said: *"I'd like to get the word iatrogenesis on the table; doctors do cause harm by their psychological interventions: people often do not get consistent messages from their various medical attendants. In fact, in the UK at least, there are substantial numbers of doctors who give people exactly the opposite advice in terms of this evidence. When Simon Wessely is trying to tell his patients one thing, they can read something entirely different on the internet or see someone else who will tell him or her exactly the opposite. That inconsistency of apparently authoritative information is an important part of the problem".* (Is it not ironic that Mike Sharpe voiced his concern about iatrogenesis: *"doctors do cause harm by their psychological interventions"*?: presumably he was referring to non-psychiatrists without apparently being able to comprehend the iatrogenesis inflicted upon those with ME/CFS by him and his colleagues through their own psychological interventions ie. trying to brainwash sick people into believing they are not actually sick and – on pain of losing state benefits vital for very survival -- compelling them to undertake aerobic exercise when they are in a hypometabolic state and physiologically unable to do so).

Peter White said: *"**The biopsychosocial approach is important in addressing disability associated with all chronic ill-health, whatever its provenance** (but) there is an overwhelming amount of evidence for the utility of the biopsychosocial approach in both understanding and helping patients with mental ill-health and physical symptoms for which no explanation is apparent. The latter includes common disorders such as chronic fatigue syndrome. **How can barriers to making the biopsychosocial approach routine for chronic ill-health be removed? Barriers to implementing this approach exist within patients, professionals, and health-care systems. Health-care systems will routinely incorporate the biopsychosocial approach when convinced of its economic advantages**. But a more convincing case may mean considering economic costs across the whole of society, not just the health-care system….Because many patients now use the internet for information on their health, we should make greater use of this medium to get the right message across….It is probably (patients) who will drive the agenda forward, unless we take the lead ourselves".*

The one dissenting voice at the conference was that of George Davey Smith, Professor of Clinical Epidemiology, Department of Social Medicine, University of Bristol, who in a presentation called *"The biopsychosocial approach: a note of caution"* carried the torch for intellectual integrity. His contribution showed that bias can generate spurious findings and that when interventional studies to examine the efficacy of a psychosocial approach have been used, the results have been disappointing.

In the discussion that followed Davey Smith's presentation, Wessely appeared to be apoplectic: *"That was a powerful and uncomfortable paper. There will undoubtedly be many people, including those who one might call CFS activists, who would have loved every word you were saying".*

Davey Smith's response was succinct: he believed there is a need to distinguish association from actual causation.

Distinguishing between association and causation is a key issue: Wessely's confusion, especially in relation to ME/CFS, of association with causality is a criticism that has

long been directed at him and he has been reminded again and again that correlation is not the same as causation, and that he should not over-interpret results as having more practical importance than those results warrant. To do so is not only methodologically flawed, but contributes to the continued mis-perception of the disorder and consequent harm to patients.

Illuminating as these extracts have been, it was the final discussion ("*How to overcome the barriers*") that strikes the most chilling resonance because it seems to embody the social construction of their own version of reality by these influential and determined social constructivists: this is alarming because there are parallels in comparatively recent history that are forgotten at humanity's peril.

In the final discussion, Peter White thought it would be useful to outline the barriers identified in their discussion and to explore ways round those barriers. He said: *"I think we have agreed that the aetiological work is not immediately relevant to the biopsychosocial model in the healthcare system at the moment. Therefore what we need to concentrate on pragmatically is the use of the biopsychosocial model in healthcare".*

This would seem to be the clearest indication that the causation (and thus the accurate nature) of disease is of no relevance to One Health social constructionists.

Douglas Drossman (Professor of Medicine and Psychiatry, University of North Carolina, USA) said: *Is there a way to communicate these ideas to the people involved with running medical schools? Often, the problem is in changing the behaviours of physicians at practice who are 50 years old. It may be much easier to start with new medical students. We want to begin with them".*

At this point, Trudie Chalder made a truly disturbing contribution: *"Rather than start with the physicians, which might be quite a difficult task, we could make a start with youngsters in schools. My experience is that they are much easier to educate. The only barrier is the parents. Once we have the child on our side we are in a very good position".*

Wessely said: *"Mansel Aylward, you are involved with policy definitions. What have you heard here that might influence your Secretary of State?"*

Aylward said: *"I have been given a lot of information that reinforces some of the messages that I have passed on to decision makers. We had some great difficulty last year persuading certain people that the way forward in the more effective assessment of disability and its management in people on State benefits lay more with a biopsychosocial approach. There seems to be an antipathy in some parts of Government towards anything without a hard evidence base. If the biopsychosocial approach is perceived in (such a) way, it is very difficult to get the Department of Health, amongst others in Government, to favour interventions and rehabilitation adopting the biopsychosocial approach. But in recent months I'm beginning to see a change".*

Wessely: "*What made some of the policy makers change their views?"*

Aylward: *"Systematic reviews of the literature garnering evidence to support the biopsychosocial concept. Recent meetings of focus groups of key opinion makers (now) support ---with authoritative and expert opinion --- the value of biopsychosocial approaches.* ***There are going to be some developments soon. The key aspect has been effectively communicating this in a far more robust and authoritative way".***

It is noted that Aylward used the word expert "opinion", not expert "evidence".

Professor Gordon Waddell (Centre for Psychosocial and Disability Research, Cardiff) said: "***It may actually be easier to change patients and the public, and they will then force the professionals to change. Some decision makers were very jaundiced.*** *It is all about money. The main thing was to persuade the Treasury that there was an opportunity for keeping costs down".*

Professor Robert Lewin said: "*One of the things that Greville Mitchell is helping us do through One Health is an analysis that will look at the lost opportunity costs from not using cognitive behavioural therapy approaches. We are doing this in collaboration with Jos Kleijnen*".

Greville Mitchell said: "*If you go to Gordon Brown* (then UK Chancellor of the Exchequer) *and say, 'We can prove to you that if we address this issue, we can save £2 billion, then you have his full attention*".

Mansel Aylward said: "*That is the approach that has been taken*" -- which is understood to be why the DWP co-funded the PACE trial; it being the only clinical trial that the DWP has ever funded (letter dated 13th July 2007 from Dr WJ Gunnyeon, Chief Medical Adviser to the DWP).

Dr Brian Marien of the Health Psychology Unit, King Edward VII Hospital, Midhurst, West Sussex, said: *"I like Gordon (Waddell's) idea of changing patients, because I don't think we are going to change the professions. We have seen from Kate Lorig how there is a huge resistance to changing practice".*

Mike Fitzpatrick said: *"The line from the ME Association is that if you, as a GP, say you are sceptical about the ME label, the Chief Medical Officer has stipulated how this must be dealt with. This reflects the endorsement at the highest level of policy of a disease label that is not supported by the evidence --- it is a completely irrational formulation".*

Mansel Aylward's response was: "*It doesn't follow that all of that report is supported by everyone in Government service. The Department of Work and Pensions doesn't necessarily endorse all that is in the Working Party's report to the Chief Medical Officer. I am also mindful of the views of those who, as members of that group, distanced themselves from some aspects of the report"* (referring to the psychosocial lobby who had walked out of the CMO's Working Group).

Fitzpatrick said: *"Nonetheless, this is the line and it is very much promulgated that GPs should follow this. It is a consensus forged by excluding many of the people in this room who have been involved in this area. This illustrates a big problem: the*

Government are linking up with patient activist groups in relation to this very significant area of medical practice to dictate a line of approach which is not actually going to be beneficial to patients".

Professor Michael von Korff said: *"If this (biopsychosocial) field doesn't start to do definitive trials and strengthening of the research base, we are dead in the long run",* to which Wessely replied: *"There is no dispute about that. Some of the evidence doesn't translate into policy as quickly as we would like, but without evidence, I am quite sure that there would be no changes".*

Wessely then said to Greville Mitchell: *"I think you should have the last word".*

Greville Mitchell said: "*The question in the title of this meeting was whether the biopsychosocial model is a necessity or a luxury. To me, the answer from this meeting is that it is clearly a necessity. It has been a brilliant meeting".*

It may have been a "brilliant" meeting as far as most of the participants were concerned but a glaring question remained unanswered: during the meeting, Professor Robert Lewin from the Department of Health Sciences at York stated: "*As we all know, cognitive behavioural therapy gains tend to fade over time*"; this being so (and quite apart from any consideration of the appropriateness or efficacy of CBT from the outset), how could the psychosocial model that depends on the effectiveness of CBT be sold as being so attractive to the Chancellor of the Exchequer?

Was the Chancellor being deceived about the *"lost opportunity costs from not using the cognitive behavioural therapy approaches"*? If CBT has no lasting objective benefit, how can it be cost-effective? Was this self-delusion on the part of One Health company members?

In essence, the meeting exemplified an exercise in self-promotion rather than enlightenment.

In her review of Peter White's book "Biopsychosocial Medicine", US research journalist Kate Duprey hits the nail exactly on the head: ***"For the past two decades medicine has been engulfed in an ideological firestorm that is less about actual patients and their well-being than it is about professional promotion and a backlash against a medical model that does not give psychiatrists a starring role in healthcare. I didn't find (the book) to be balanced. How such polarization is helpful to patients is not adequately addressed, possibly because the well-being of patients is not the real focus.*** *When something is controversial, balance is presenting both sides, yet little or no attention was given to the large bodies of scientific research objectively refuting the stated views of the contributors. (The book) essentially remains a book of self-promotion*" (Controversial for a reason. August 5, 2005).

It was also interesting to read the review of "Biopsychosocial Medicine" by Aziz Sheikh in the Journal of the Royal Society of Medicine, where it was promoted as book of the month (JRSM 2005:98:431-432), because Sheikh summed it up thus: *"How does "Biopsychosocial Medicine" move the subject on? Despite valiant attempts by Simon Wessely and Peter White to draw practical messages, I have to say not greatly".*

Peter White's continued lobbying and wasting of public money

In order to protect himself, Peter White has lobbied hard to prevent Freedom of Information requests from being successful, making specious arguments against the need for transparency, with the intention of curtailing the release of data to legitimate researchers and clinicians who seek to verify his own interpretation of the PACE data.

Of concern is that fact that Peter White has gone on applying for – and receiving – public money to carry out further follow-up studies of the PACE trial: would these have been funded if the objective measurement of physical function (which showed no improvement) had been known about in 2011

Not content with wasting £5 million on the PACE trial, Peter White and his colleagues have gone on wasting money with two further trials, the "GETSET" trial and the "MAGENTA" trial for children, with the possible further follow-up of PACE participants.

Given the null result of the FINE trial (a sibling of the PACE trial but involving house-bound participants) and the null results of the PACE trial at two year follow-up, there was disbelief to learn about the GETSET trial and the MAGENTA trial, and about another follow-up study of PACE. Another follow-up study of PACE participants is scientifically meaningless because there is no way of taking into account the effect of other interventions which the participants may have used after the PACE trial ended in 2009.

The GETSET trial (Graded Exercise Therapy guided SElf-help Treatment) for patients with chronic fatigue syndrome/myalgic encephalomyelitis was described as a randomised controlled trial in secondary care: *"This study will test the acceptability, effectiveness, cost effectiveness and safety of Graded Exercise Therapy guided SElf-help Treatment (GETSET) for patients with CFS/ME attending hospital clinics. GETSET has been designed to incorporate the best elements of GET provided by current and previous research trials, paying particular attention to safety and acceptability".* The methodology involved participants being given a booklet and interviewed by telephone or skype. Peter White was the Chief Principal Investigator of GETSET; originally, it ran from 1st December 2011 to 30th November 2014 (ie. before he had been forced to release the PACE trial data) and funding was £244,056.00 but Peter White changed the primary outcome measures and asked for the trial to be extended until December 2015.

The Chief Investigator of the MAGENTA trial (Managed Activity Graded Exercise in Teenagers and Pre-Adolescents) is Dr Esther Crawley, a paediatrician at Bristol who was instrumental in the NICE Clinical Guideline on "CFS" which recommended CBT and GET and who is a very vocal supporter of the psychosocial model of ME/CFS.

PACE participants put at risk

Seventeen years after forewarning the MRC of his intention to seek funding to prove his own belief that medicine was a "*blind alley*" and that all illness (whatever the provenance) is merely a dysfunctional belief that can be corrected by "*cognitive restructuring*" and exercise, the legal ruling of 12th August 2016 handed down by Brian Kennedy QC (HM Courts & Tribunals Service) that the raw data from the PACE trial must be made public has finally confirmed that Peter White has been living in a fantasy world which could no longer protect him from having to comply with an order of the court.

One question which needs to be addressed is whether his obsession with advancing his own ideology may have caused him to place PACE participants at serious risk: PACE had no serial checks on participants' immune parameters even though in 2004 Peter White himself published a paper on this important aspect (Immunological changes after both exercise and activity in chronic fatigue syndrome: a pilot study. White PD, KE Nye, AJ Pinching et al. JCFS 2004:12 (2):51-66).

In that article, White et al stated:

"We designed this pilot study to explore whether the illness was associated with alterations in immunological markers following exercise. Immunological abnormalities are commonly observed in CFS…Concentrations of plasma transforming growth factor-beta (TGF-β) (anti-inflammatory) and tumour necrosis factor-alpha (TNF-α) (pro-inflammatory) have both been shown to be raised….Abnormal regulation of cytokines may both reflect and cause altered function across a broad range of cell types…..Altered cytokine levels, whatever their origin, could modify muscle and or neuronal function.

"*Concentrations of TGF-β1 were significantly elevated in CFS patients at all times before and after exercise testing.*

"We found that exercise induced a sustained elevation in the concentration of TNF-α which was still present three days later, and this only occurred in the CFS patients.

"TGF-β was grossly elevated when compared to controls before exercise (and) showed an increase in response to the exercise entailed in getting to the study centre.

"These data replicate three out of four previous studies finding elevated TGF-β in subjects with CFS.

"The pro-inflammatory cytokine TNF-α is known to be a cause of acute sickness behaviour, characterised by reduced activity related to 'weakness, malaise, listlessness and inability to concentrate', symptoms also notable in CFS.

"These preliminary data suggest that 'ordinary' activity (ie. that involved in getting up and travelling some distance) may induce anti-inflammatory cytokine release (TGFβ), whereas more intense exercise may induce pro-inflammatory cytokine release (TNF-α) in patients with CFS".

This important information was withheld from participants and therapists alike (the Therapists' Manual on GET was dismissive of studies showing immune dysfunction in ME/CFS).

In the light of this knowledge, it is notable that there seems to have been a cavalier disregard of safety for GET participants, even though Peter White was aware that three days after exercise, TNFα remains elevated and that this probably accounts for the "*sickness behaviour"* and "*weakness, malaise, listlessness and inability to concentrate".*

It is indisputable that Peter White knew that any outcome measures should have included post-exercise immunological testing, yet no such testing was scheduled in the PACE Trial.

No matter how strongly it may be denied, PACE participants were put at unnecessary risk in order not to undermine Peter White's goal, because if such abnormalities were to have been found, it would have blown his life's work out of the water, so such testing was not carried out, thereby compromising participants' safety.

Of further significance is the fact that in his 2004 study, Peter White used the Medical Outcome Short Form (SF-36) physical function scale to measure physical disability, which showed that the median SF-36 score of the healthy controls was 100 (ie. full health) but in the PACE trial, he set his (revised) SF-36 score at 60 (which was claimed to indicate recovery ie. normal health), having reduced it from the protocol-specified score of 85.

How can "recovery" in one of his studies be set at a score of 60 when another of his studies found that healthy people had a median score of 100?

Peter White published selective results of the PACE trial in 2011 with all primary outcome measures changed from the published protocol and manipulated the data to support his own goal of proving that ME/CFS is a behavioural – not a neuro-immune – disorder.

By any standards, is that not scientific misconduct?

Are UK agencies of State content to impose on very sick people suffering from a devastating neuro-immune disease a policy that has no scientific legitimacy?

The answer appears to be yes.