The NICE CFS/ME: full guideline DRAFT was published in September 2006 and recommends CBT or GET as the therapies of first choice for CFS/ME (Appendix 3 - 1). Detailed critiques of the draft are appearing on the internet (Appendix 3 - 2) and already the guideline has been declared unfit for purpose (Appendix 3 - 3).

This paper seeks to show that failures and omissions in the draft guidelines highlight a human rights issue with regard to the application of psychological therapies, with implications for society as a whole.

The failures this paper examines are:

- the failure to explain the biopsychosocial theory on which NICE recommendations for treatment are based;
- the failure to address the scientific and medical dispute with regard to the safety and appropriateness of the use of the biopsychosocial theory and the use of CBT and GET in ME/CFS;
- the failure to address the moral, ethical and safety issues arising from its recommended therapies.

By ignoring these serious issues with regard to CBT and GET, we believe that as currently drafted the NICE Guidelines violate the right of clinicians and patients to the highest, safest standards of Medical practice and care, amounting to a violation of their Human Rights.

Turning first to the issues of the failure to explain the biopsychosocial theory and the scientific and medical dispute with regard to the safety and appropriateness of the use of the theory and CBT and GET in CFS/ME:

Carruthers and van de Sand in an Overview of the Canadian Consensus Document on CFS/ME state:

‘A hypothesis underlying the use of Cognitive Behaviour Therapy (CBT) for ME/CFS is based on the premise that the patient’s impairments are learned due to wrong thinking and “considers the pathophysiology of CFS to be entirely reversible and perpetuated only by the interaction of cognition, behaviour, and emotional
processes. The patient merely has to change their thinking and their symptoms will be gone. According to this model, CBT should not only improve the quality of the patient’s life, but could be potentially curative”.

‘Proponents ignore the documented pathophysiology of ME/CFS, disregard the reality of the patients’ symptoms, blame them for their illness, and withhold medical treatment. Their studies have often included patients who have chronic fatigue but excluded more severe cases as well as those who have other symptoms that are part of the clinical criteria of ME/CFS. Further, their studies fail to cure or improve physiological impairments such as OI, sore throat, IBS, etc. Dr. A. Komaroff, a Harvard based world authority, stated that the evidence of biological process “is inconsistent with the hypothesis that (the syndrome) involves symptoms that are only imagined or amplified because of underlying psychiatric distress. It is time to put that hypothesis to rest.” (Appendix 3 - 4)

Hooper (2006) writing in the August Journal Of Clinical Pathology states:

‘The challenge of these syndromes to modern medicine is in accord with the growing understanding of the neuroendocrineimmune (NEI) paradigm, sometimes referred to as the psychoneuroimmune (PNI) paradigm. This has emerged as a result of the identification of complex biological messenger molecules that serve to communicate between these NEI systems.’

‘This understanding, supported by extensive human and animal studies, provides an extensive intellectual foundation for the biological approach to investigating these complex and challenging syndromes of uncertain origin.’

‘In contrast, the alternative and controversial claims of some psychiatrists that all these syndromes are expressions of somatisation or covered by the biopsychosocial (BPS) theory lack any sound intellectual basis and spell the failure and possible imminent extinction of modern psychiatry.’

‘Undoubtedly the perverse use of chronic fatigue syndrome, to impose a psychiatric definition for ME/CFS by allying it to fatigue syndromes, has delayed research, the discovery of effective treatment(s), and care and support for those suffering from this illness ‘

‘Any activities associated with increased free radical production should not be recommended to sick ME/CFS patients as this will intensify the damage. This is why GET is so damaging for many ME patients since exercising muscle is known to generate increased oxidative stress.’ (Appendix 3 - 5)

Hooper and Reid (2006) published a critique exposing the inadequacy of the evidence base of RCTs relied upon by NICE, which include inter alia the following:

‘There is no objective evidence that CBT & GET are effective, nor that claimed improvements are sustained long term. These treatments are not tolerated by a
large minority of patients. Internationally, a number of prominent researchers have strong reservations about GET. ‘(Appendix 3 - 6)

In a presentation to the Group on Scientific Research into Myalgic Encephalomyelitis (Gibson Parliamentary Inquiry) ME Research UK Chairman Dr Vance Spence (2006) said:

‘The evidential basis of the CBT model for ME/CFS, consists of 8 discrete RCTs, 3 "negative" for the intervention and 5 "positive". While there are arguments for and against each of these trials, I think we can agree that this constitutes a far-from-impressive evidence base, particularly when set beside other evidence bases and beside patients' reports and surveys.’ (Appendix 3 - 7)

Marshall, Williams, Hooper (2001), give the opinion of an eminent Leading Counsel (a member of the House of Lords) which states:

‘On the document you have sent me there is an overwhelming case for the setting up of an immediate independent investigation as to whether the nature, cause and treatment of ME (biopsychosocial theory and the use of CBT and GET) as considered by the Wessely School is acceptable or consistent with good and safe medical practice.

There is substantial doubt as to whether such could be the case in view of the clear division of medical opinion.’ (Appendix 3 - 8)

There are therefore serious concerns within the scientific and medical community as to the safety of both CBT and GET with regard to CFS/ME and the theoretical basis on which they are founded. The draft maintains a deafening silence on these issues.

Turning to the moral and ethical issues with regard to the safety and appropriateness of the use of CBT and GET in CFS/ME:

Marshall And Williams (2006) draw attention to studies that show Psychological therapy brings about physical changes in the brain comparable to those brought about by drug therapy. They quote Friedman (2002) who describes three brain imaging studies, one looking at obsessive–compulsive disorder and the other two at depression, all of which showed that when patients improved, the changes in their brain, as shown on PET scans, ‘looked the same regardless of whether they had received antidepressants or CBT.’

They also draw attention to “The MRC Neuroethics Report, April 2005: Session 2 ("Altering the brain") in which Psychiatrists explain ‘a growing understanding of neurotransmission at a molecular level has allowed the design of interventions to alter specific brain functions, one such intervention being CBT: Psychological therapies such as CBT have now been shown to alter brain function. These developments may alter our view of individuality.’

The MRC Report also asks; ‘What are the risks of changing personality? Is cognitive enhancement acceptable to society? Psychological treatments also raise a number of issues about consent and coercion. How much information should patients be given about the possible effects of therapy on their brain?’ and concludes that ‘further research is needed to determine whether such therapies are reversible, or if there are persistent
adverse effects’, noting: ‘There is already evidence that in certain situations psychotherapy can do harm.’ (Appendix 3 - 9)

There are therefore serious ethical concerns about whether this type of therapy is ‘acceptable to Society’, as well as outstanding safety issues. Where are the safeguards for this form of treatment? The draft again maintains a deafening silence on these issues.

Drugs undergo exhaustive testing over an extended period of time overseen by an independent body thus ensuring their safety and efficacy. Comprehensive information on the intellectual foundation of the treatment, its effects and counter effects are provided to clinicians and patients. In the US, according to a report by Wierenga and Eaton ‘It takes 12 years on average for an experimental drug to travel from lab to medicine chest. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.’ (Appendix 3 - 10).

Similar rigorous testing processes apply to the UK under European Community regulations. The MHRA UK Regulatory Authority website states:

‘Safety, quality and efficacy are the only criteria on which legislation to control human medicines is founded. It is the responsibility of the MHRA and the expert advisory bodies set up by the Medicines Act to ensure that the sometimes difficult balance between safety and effectiveness is achieved. MHRA experts assess all applications for new medicines to ensure they meet the required standards. This is followed up by a system of inspection and testing which continues throughout the lifetime of the medicine. Safety monitoring is also continuous and the MHRA also ensures that doctors and patients receive up-to-date and accurate information about their medicines. This is achieved by ensuring that product labels, leaflets, prescribing information and advertising meets the required standards laid down by the Regulations.’ (Appendix 3 - 11).

Contrast the intellectual and scientific rigour applied in the approval process for the licensing of drugs for clinical use, with the lack of scientific and intellectual rigour applied in the NICE draft with regard to the recommendations for the use of Psychological Therapy in CFS/ME. When compared with the extensive clinical trialling over many years and the independent scrutiny a drug therapy is subjected to, the small and heavily criticised evidence base used to justify the recommendation of CBT and GET for CFS/ME in the NICE draft is seen to be totally inadequate.

In respect of informed consent, it cannot arise. There simply cannot be informed consent since there are important ethical, safety and regulatory questions arising from these treatments, to be addressed.

Ethical and safety questions such as those raised in the MRC Neuroethics Report 2005 should be paramount. It is hard to envisage any Independent authority clearing a drug for Human testing or use without ethical and safety issues, like those surrounding Psychological Therapy, being resolved.

By ignoring these serious issues with regard to Psychological Therapy, we believe that, as drafted, the Guidelines violate the right of clinicians and patients to the highest,
safest standards of Medical practice and care, amounting to a violation of their Human Rights.

This is a Human Rights issue. Without an answer to whether this type of therapy is ‘acceptable to Society’ and if it is, without an effective Regulatory framework governing its development and use, there is the serious risk that sick and vulnerable people everywhere will be vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice.

Following the consultation process, if NICE does not see the depth and breadth of the failures and omissions in the draft guidelines then a judicial review must be inevitable.

R Mitchell, V Mitchell
## References for Appendix 3:

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