Preview of the NICE Judicial Review.

Margaret Williams & Horace Reid. 3rd February 2009.

May be reposted.

The Judicial Review of the NICE guidelines on CFS/ME will be held on Wednesday & Thursday 11^{th} & 12 of February 2009. The case is being brought by two adult patients living in the UK.

The constraints of this type of legal challenge (Judicial Review) have already been indicated by the judge who initially granted leave to proceed. Mr Justice Cranston made it clear in June 2008 that a court is not an appropriate forum for medical debate. Arguments will therefore centre on technical issues, such as whether NICE followed its own prescribed procedures.

Much to the disappointment of many patients, there will be no debate on the aetiology, definition, or biomedical status of ME. However in an intense two-day hearing, other crucial issues will be addressed.

Guideline Development Group Bias.

It has been the practice of the psychiatric lobby to attempt to pack important CFS/ME committees with their own supporters, to achieve their desired outcomes of CBT & GET. They did this successfully in 1996 with the Royal Colleges report, repeating the trick with the CMO's committee in 2002. With NICE the liaison psychiatrists have been more subtle. Instead of personally serving on the Guideline Development Group (GDG), it seems that they have managed to stack the group with sympathizers, whilst biomedical ME specialists critical of their approach were excluded. A Freedom of Information request has revealed that Professor Anthony Pinching among others was deeply involved in the GDG selection process.

The many competing interests of the individuals on the GDG (declared and undeclared) may now be subjected to the scrutiny of a High Court judge.

Failure to Declare Conflicting Interests.

Take for example the case of Dr. Fred Nye. Incredible as it may seem, as a member of the GDG he was allowed to adjudicate on the quality and relevance of his own research. His RCT, co-published with Powell and Bentall, constituted 25% of the positive evidence base supporting the NICE recommendation on GET. It is difficult to understand how the chairman and fellow members of the GDG could regard him as a neutral and objective participant when the value of GET was being debated.

At some stage Dr. William Hamilton, another GDG member, did declare his

connection with the Liverpool Victoria and Exeter Friendly insurers. But NICE failed to appreciate that his appointment gave him an opportunity potentially to import an inappropriate commercial agenda into the clinical area. Many health insurers have subjected ME patients to sharp practice; their notoriety came to the attention of Dr. Ian Gibson's committee in 2006. His Parliamentarians condemned the "blatant" conflicts of those individual researchers who mingled their commercial and clinical interests. In its appointment of Dr. Hamilton, NICE failed to heed these warning voices.

A number of other prominent GDG members failed to declare their close connection with interested parties such as Professors Simon Wessely, Peter White, and Trudie Chalder. Their names and multiple omissions may soon be disclosed.

Scrutiny of the CBT/GET Evidence Base.

The Wessely School continually boast that their favoured treatments CBT & GET are "evidence based"; but their claims lack objective validation. All too often they peer review their own work. In the 2006 NHS Plus exercise, for instance, on Occupational Health guidance for CFS/ME, Professors Chalder and White sat in judgment on their own research, without declaring a competing interest. Their fellow NHS Plus participant, Professor Michael Sharpe, apparently noticed nothing amiss.

It is clear that the court cannot entertain clinical arguments on the merits of NICE-endorsed treatments for any disorder. However the Judge may be asked to consider whether NHS recommendations for 240,000 UK ME patients can justifiably be based on the miniscule amount of evidence supporting CBT & GET. The much-vaunted Wessely School evidence base will be subjected to impartial public scrutiny.

As AYME has hinted in its website post of 19/1/09, the case has the active support of many leading biomedical researchers, at home and abroad. Dr. Bruce Carruthers, lead author of the Canadian national ME guidelines, plans to be present in court throughout the two day hearing.

AYME & NICE.

AYME contemplate two outcomes: the 2007 NICE CFS/ME guideline could be struck down altogether; or it might survive, and be subject to routine revision in due course.

Routine revision, already envisaged, would simply give NICE an opportunity to repeat past errors. The psychiatrists would likely get their way once more, and the legitimate concerns of ME patients would be ignored as usual.

NICE Must Begin Again.

Striking down Clinical Guideline 53 is the more desirable option. The present guideline would cease to have effect, and NICE would have to begin again from scratch. Those who allegedly manipulated the composition of the CFS/ME GDG would be exposed and discredited. No-one would dare to resort to such tactics again. If it is proved that the GDG was infiltrated by the commercial interests of the medical insurance industry, and became a pawn of a clinical special interest group, then NICE will be much more circumspect next time. And the CBT/GET research bubble will be definitively burst.

Patient & Media Support Needed.

It is important that ME patients and their families come in person to London next week. The presence of large numbers inside the building, and outside along with TV cameras, will impress upon the court the importance of this issue to a quarter-of-a-million UK ME patients. (Observer spaces inside the designated courtroom will be extremely limited).

National and local ME charities in the UK and abroad should alert the media to the global significance of this court case, in the long-running medical controversy about ME.