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Case No: CO/10408/2007 and CO/10435/2007

**IN THE HIGH COURT OF JUSTICE**  
**ADMINISTRATIVE COURT**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 13 March 2009

**Before : Mr Justice Simon**

**Between :**

**The Queen** (on the application of)  
**(1) Douglas Fraser**  
**(2) Kevin Short**

**Claimant**

**and**

**National Institute For Health and Clinical  
Excellence**

**Defendant**

**and**

**BB**  
**(by his mother and litigation friend JB)**

**Interested  
Party**

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**Mr Jeremy Hyam** (instructed by **Leigh Day & Co**) for the Claimants  
**Mr Charles Béar QC** and **Mr Tony Child** (instructed by **Beachcroft LLP**) for the  
Defendant  
**Mr Conrad Hallin** (instructed by **the Bar Pro Bono Unit**) for the Interested Party

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Hearing dates: 11 and 12 February 2009

**Approved Judgment**



**Mr Justice Simon:**

### **Introduction**

1. On 22 August 2007 the National Institute for Health and Clinical Excellence ('NICE') published Clinical Guideline 53 ('the Guideline'). This was a national guideline on patient care for those suffering from Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME); and was published in a number of versions, including the full version (317 pages) and a 'Quick Reference Guide' (23 pages).
2. The clinical need for the Guideline was explained in §1.2 of the full version.

CFS/ME comprises a range of symptoms that include fatigue, malaise, headaches, sleep disturbances, difficulties with concentration and muscle pain. A person's symptoms may fluctuate in intensity and severity, and there is also a great variability in the symptoms different people experience. CFS/ME is characterised by debilitating fatigue that is unlike everyday fatigue and can be triggered by minimal activity. This raises especially complex issues in adults and children with severe CFS/ME.

CFS/ME, like other chronic conditions for which the causes and disease processes are not yet fully understood, poses significant problems for healthcare professionals. It can cause profound, prolonged illness and disability, which has a substantial impact on people with CFS/ME and their carers. Uncertainties about diagnosis and management, and lack of clinical guidance for healthcare professionals have exacerbated this impact.

3. The preface to the full version sought to explain the reason for the difficulties in treatment of those with CFS/ME.

In the past their needs have to often been overlooked and this situation needs to change.

Several factors have contributed to the neglect of CFS/ME. Firstly, the illness is poorly understood. There is no generally accepted theory about its cause or causes, and the symptoms can be diverse, with wide variations both between individuals and in each person over time. This creates further difficulties when attempting to define CFS/ME for the purpose of making a diagnosis. Secondly, there is only limited epidemiological evidence on the numbers of people who develop CFS/ME and on the natural history of the illness. As a result, the available therapies are few, evidence of effectiveness is limited to people with mild or moderate CFS/ME, and access to expert therapists had often been difficult.

4. The Guideline considered and rejected a number of treatments (specified drugs, vitamin supplements and complementary therapies) on the basis that there was not enough evidence that they were effective; and recommended a range of approaches to treatment including offering Cognitive Behavioural Therapy (CBT) and/or Graded Exercise Therapy (GET) to those with mild or moderate CFS/ME on the basis that these were interventions for which there was the clearest research evidence of benefit.
5. The Quick Reference Guide described CBT and GET.

[CBT] An evidence-based psychological therapy that is a collaborative treatment approach. When it is used for CFS/ME, the aim of CBT is to reduce levels of symptoms, disability and distress associated with the condition. The use of CBT does not assume or imply that the symptoms are psychological or 'made up'. A course of CBT is usually 12-16 sessions.

[GET] An evidence-based approach to improving a person's CFS/ME symptoms and functioning, aiming towards recovery. The first step is to set a sustainable baseline of physical activity, then the duration of the activity is gradually increased in a planned way that is tailored to the person. This is followed by an increase in intensity, when the person is able.

6. There was a significant body of opinion which disagreed with this recommendation of CBT and/or GET, particularly among members of CFS/ME patient groups. Part of the complaint was directed to what was perceived to be an over-emphasis on a 'psycho-social approach' as to the nature, cause and treatment of the condition, to the prejudice of a 'bio-medical approach'.
7. The 'psycho-social approach' describes the view that CFS/ME is a somatisation (psychiatric) disorder, which needs to be recognised and treated as such. In contrast, the 'biomedical approach' describes a view that CFS/ME is an organic, neurological disease, whose pathogenesis (disease process) and aetiology (cause) may be unclear, but which produces identifiable physical symptoms of fatigue and neurological disturbance.
8. There is disagreement as to whether categorisation into these two approaches can properly describe subtle gradations of scientific opinion, which will (or at least should) respond to research and advances in knowledge about a condition whose aetiology is still not understood.
9. The World Health Organisation (WHO) includes ME as a physical/organic neurological disorder in section G93.3 of the tenth edition of the International Classification of Diseases (ICD.10), and gives an alternative name, Post Viral Fatigue Syndrome (PVFD). However, in this field even the use of some of the terms in common currency may be controversial. In 1988 the US Centres of for Disease Control introduced the term, Chronic Fatigue Syndrome. However, a witness statement deployed by the Claimants from Jane Colby (Executive Director of the

Young ME Sufferers Trust) plainly draws a distinction between ME and, what she describes as, 'the artificial construct called Chronic Fatigue Syndrome.'

### **The Claimants**

10. The First Claimant, Douglas Fraser, was formerly a professional violinist who was diagnosed as 'post-viral' in March 1994 following what was thought to be a viral infection. In 1997 he was diagnosed as having ME. Like many others with ME/CFS both his ability to work and his social life have been severely affected.
11. The Second Claimant, Kevin Short, is now in his late forties and developed the physical signs of CFS/ME in his twenties. A formal diagnosis was made in 1992. He is concerned that, as a consequence of the Guideline, the only treatments to which he will be entitled will be CBT and GET.
12. Underlying the present claim are two concerns. The first, which is expressed by the Claimants, is that CBT and GET are treatments that they neither want nor need, and which may be detrimental to their health. In recommending these treatments the Guideline has the practical effect of preventing them obtaining what they consider may be more effective treatment, since it would only be in exceptional circumstances that a Primary Care Trust would fund a treatment which was not recommended by the Guideline. The second is an implicit concern that they may be regarded by health professionals and the wider public as suffering from a mental health condition. Pauline Sykes, whose witness statement is also deployed in support of the Claim, expresses the point in §14.

ME/CFS is a deeply misunderstood (and controversial) condition and as such medical practitioners who are not experts in the condition are naturally unwilling to step out of line with the Guideline. The damage done by the Guideline to ME/CFS sufferers is inestimable as it had firmly bracketed the condition in the minds of the medical profession, whether intentionally or not, as a mental health condition.

### **NICE**

13. NICE is an independent body responsible for providing national guidance on the promotion of good health, and the prevention and treatment of ill health. As part of its functions NICE provides guidance and guidelines. NICE guidance assesses whether particular drugs or specific treatments are sufficiently cost effective to be recommended for use in the National Health Service. NICE guidelines are broader in their extent and relate to particular illnesses.
14. It is common ground that while NICE Guidelines help health professionals in their work, they do not replace their knowledge and skills, or override their clinical judgment. Nor do they detract from the right of a patient to be involved in his or her particular treatment. Decisions as to the implementation and monitoring of the NICE recommendations are for NHS Trusts and the Healthcare Commission respectively.

15. Since it is not possible for NICE to employ experts in every field of healthcare, it contracts with National Collaboration Centres ('NCCs') to assist in the development of guidelines.

### **Chronology**

16. The origin of the Guideline was a request from the Secretary of State for Health and the Welsh Assembly to NICE in February 2004:

To prepare for the NHS in England and Wales, guidance on the assessment, diagnosis, management of adjustment and coping, symptom management, and the use of rehabilitation strategies geared towards optimising functioning and achieving greater independence for adults and children with CFS/ME.

There was no requirement to investigate the cause of CFS/ME.

17. On 1 March 2004 NICE commissioned the National Collaboration Centre for Primary Care ('the NCC-PC') to draw up the Guideline. The NCC-PC in turn entrusted this task to a Guideline Development Group ('the GDG').
18. In April an initial list of registered stakeholders was published. This was a list of organisations representing patients, carers and health professionals who were consulted throughout the guideline development process.
19. In the summer of 2004 the Chair of the GDG, Professor Baker, was appointed; and nominations were sought for membership of the GDG.
20. The NCC-PC subsequently prepared a draft Scope (or terms of reference) for the Guideline, with contributions from registered stakeholders, NICE and an independent Guideline Review Panel. This draft was then put out for consultation, before being published in its final form on the NICE website on 21 February 2005.
21. In the meantime, in December 2004, the NCC-PC commissioned the Centre for Reviews and Dissemination at York University to conduct a systematic review of published material relating to the diagnosis, management and treatment of CFS/ME. This review was carried out by a team led by Anne Marie Bagnell, and is referred to as the York Review.
22. On 24 February 2005 the names of the members of the GDG were published on the NICE website. As part of its guideline development methodology, NICE had issued a document dated February 2004 entitled, 'Declaration of Interests on Appointment and at Meetings' ('the 2004 Code'). It will be necessary to consider this and a later version issued in April 2007 ('the 2007 Code') later in this judgment. The date on which the names of the members of the GDG were published is important since NICE contends that much of what the Claimants complain about in these proceedings, in particular the membership of the GDG, was known from February 2005.
23. The GDG under the Chairmanship of Professor Baker had 18 members. Among these were 3 patient representatives. The remaining 14 came from the medical and health-care professions:

Ms Jessica Bavinton (a physiotherapist, nominated by the Chartered Society of Physiotherapists),

Dr Esther Crawley (a Consultant paediatrician, nominated by the Royal College of Paediatrics),

Dr Tony Downes (a General Practitioner, nominated by the Royal College of General Practitioners),

Dr Richard Grunewald (a Consultant Neurologist, nominated by the Association of British Neurologists),

Dr William Hamilton (a General Practitioner and researcher, nominated by the Royal College of General Practitioners),

Ms Judith Harding (a Dietician, nominated by the Dietetic Association),

Dr Frederick Nye (a Consultant Physician, nominated by the British Infection Society),

Ms Amanda O'Donovan (a Clinical Psychologist, nominated by the Psychological Society),

Dr Alastair Santhouse (a Consultant Psychiatrist, nominated by the Royal Society of Medicine),

Dr Julia Smedley (a Consultant Occupational Health Physician, nominated by the Association of Occupational Health),

Dr David Vickers (a Consultant Paediatrician, nominated by the Royal College of Paediatrics),

Ms Gillian Walsh (a nurse, nominated by the Royal College of Nursing),

Ms Carol Wilson (an Occupational Therapist, nominated by the College of Occupational Therapists) and

Dr Philip Wood (a Consultant Immunologist, nominated by the Association Clinical Pathologists).

Eighteen meetings of the GDG were held between March 2005 and September 2006.

24. In October 2005 the York Review (488 pages) was made available to the GDG. The York Review identified relevant Randomised Clinical Trials ('RCTs'), and ranked them according to a validity score. The trials were classified as having either 'positive', 'negative' or 'no effect', under the classifications of 'overall effect' and 'any effect'. The York Review categorised the RCTs under various headings:

Behavioural,

Immunological,  
Pharmacological,  
Alternative/Complementary,  
Supplements, and  
Other.

Under the heading 'Behavioural' the York Review noted,

In the behavioural category, cognitive behavioural therapy showed positive results. Four of the five RCTs evaluating CBT found a positive overall effect of the intervention and these studies also scored highly on validity assessment. ... [GET] also showed promising results: four of five RCTs found an overall beneficial effect of the intervention compared to the control groups. Two of these scored highly in the validity assessments.

The York Review concluded that the RCTs of other treatments did not demonstrate similar positive effect or score highly in the validity assessments.

25. The GDG also sought and received a significant amount of information from patients and patient groups by questionnaires and surveys. The Full Guideline explained at §2.6.1

Patient stakeholder organizations were invited to submit evidence on the 'patient experience' and the GDG reviewed and discussed the summaries of these.... However, information gathered through patient surveys is generally considered as relatively low-level evidence for several reasons [ in particular bias].

26. On 29 September 2006 a draft Guideline (with the York Review) was issued for public consultation. The consultation period ended on 24 November 2006; and comments from the public were tabulated, together with a response to such comments. This document, consisting of 575 pages, was described as the 'CFS/ME Consultation Draft'. It will be necessary later to consider one aspect of this document.
27. Following this there were four further meetings of the GDG to consider the extensive comments received during the public consultation, and to finalise the Guideline.
28. On 1 June 2007 the Guideline was reviewed by NICE's Guideline Review Panel under the Chairmanship of Professor Drummond; and by NICE's Guidance Executive on 27 June.
29. On 16 July, one of the Patient members of the GDG (Tanya Harrison) wrote to Professor Baker saying that she was,
- unable to sign-up to the NICE Guidelines on ME/CFS with their current content

Part of her letter, relied on by the Claimants, foreshadowed a complaint in the current proceedings.

... I do believe that the GDG was biased towards the psycho-social approach. I do believe that the GDG has ignored patient and bio-medical evidence, because if it hadn't, then the guidelines would not be recommending the widespread use of CBT and GET, against patient and bio-medical research evidence. Given the controversy in the medical population, and the paucity of quality of the RCTs I feel that it was vital to listen to patient evidence, and give it more credence ...

30. On 22 August 2007 the Guideline was published.
31. On 21 November 2007 the current proceedings were issued. Some of the grounds originally advanced are no longer pursued: for example, the argument that the recommendations in respect of CBT and/or GET were so contrary to the views of a strong body of medical opinion as to amount to being irrational.
32. Permission to bring the Judicial Review proceedings was given by Cranston J on 17 June 2008; and on 19 September NICE served its evidence in response, including witness statements from Professor Baker and Professor Littlejohns (the Clinical and Public Health Director of NICE).
33. On 8 December 2008 the Claimants served a further witness statement from Mr Beagent (a solicitor at Leigh Day). Mr Beagent's evidence was the basis of a number of new arguments. First, that there was either actual bias or a perception of bias among members of the GDG; and secondly, that there was a failure to declare specific conflicts of interest which should have precluded some members of the GDG from joining the GDG or participating in discussions about its recommendations of CBT and/or GET.
34. As part of the new case the Claimants subjected the selection and the background of members of the GDG (apart from the patient members) to close scrutiny, in order to demonstrate an impermissible preference for the socio-psychological approach. These allegations were (a) not prefigured by any correspondence, (b) contained grounds for challenge of the Guideline for which Permission had not been given, and (c) were advanced in a highly contentious form. Since allegations had been made in relation to the selection of every professional member of the GDG, NICE unsurprisingly felt the need to serve detailed evidence in response. This evidence consisted of twenty new witness statements.
35. In §46 of his witness statement Mr Beagent made an attack on the process by which the members of the GDG were selected, and the involvement in that process of Professor Anthony Pinching,

A Freedom of Information Act request made by a concerned member of the public, revealed in July this year the involvement in the selection process of an individuals (*sic*) who is known to the Claimants to be sympathetic to the psycho-social school and a proponent of CBT and GET: Professor

Anthony Pinching. Professor Pinching's published views are particularly strident.

There is then what appears to be a quotation from one of Professor Pinching's publications. At §47 Mr Beagent concluded,

It is notable that Professors Baker and Littlejohn, in their detailed description of the selection process neglect to mention the involvement of these individuals (*sic*).

36. Mr Beagent's allegation was that a man who was said to be 'sympathetic to the psycho-social school' was involved in the selection process, with the implication that his involvement in the process was concealed by Professors Baker and Littlejohns.
37. Although the quotation from Professor Pinching's publication might suggest that he held views favouring the psycho-social model, the citation consisted of sentences or part sentences which were not connected, and which had been carefully selected from 5 pages of the original article. Furthermore, the article from which selected parts had been extracted contained a detailed discussion of potential causes of ME/CFS which, if anything, tended towards the bio-medical approach. At the time of the publication Professor Pinching was Professor of Immunology at St Bartholomew's and the Royal London School of Medicine and Dentistry.
38. In his witness statement made in response to these contentions Professor Pinching complained that the quotation deployed by Mr Beagent was 'selective' and 'totally misleading'. I agree with those descriptions. Having compared the extract in Mr Beagent's witness statement with the original article, it is plain that the extract was an unfair and misleading summary, and there was no proper basis for describing Professor Pinching as sympathetic to the psycho-social approach. On the contrary the evidence suggests a much more nuanced and balanced approach.
39. Three further points may be noted in relation to the position of Professor Pinching. First, I note and accept NICE's un-contradicted evidence that Professor Pinching's involvement was limited to informal comment on the mix of specific nominations received from the nominating professional bodies. Secondly, in a second witness statement made on the second day of the hearing Mr Beagent disavowed an intention to mislead the Court in relation to the position of Professor Pinching. Thirdly, Mr Hyam specifically abandoned any challenge to the Guideline on the basis of what had been said about Professor Pinching.

#### **The issues**

40. At the heart of the claim is the Claimants' concern that the recommended treatments stigmatised patients. In their view CBT is ineffectual save in circumstances where there is a secondary co-morbidity, and may be positively harmful if patients are misled as to the level of their underlying physical pathology. They are also concerned that GET may be dangerous to certain types of patient, for example those with cardiac problems.
41. In opening the case Mr Hyam drew attention to the support for the Claimants' view from a significant body of medical opinion. Malcolm Hooper, emeritus Professor of

Medicinal Chemistry at the University of Sunderland, and patron of the Sunderland and South Shields ME Association, summarises this view in §41 of his witness statement.

In the full version of the Guideline, NICE acknowledges the heterogeneity of 'CFS/ME', yet the recommendations ignore this and advocate a blanket implementation of CBT/GET for all patients with mild or moderate 'CFS/ME'. This is irrational and potentially dangerous.

42. Although Mr Hyam referred to these matters in his opening submissions, he confined the claim to two particular contentions.
43. First, he submitted that the decision to recommend CBT and/or GET to the exclusion of other treatment was irrational and perverse, since (a) it was based on inadequate material (the insufficiency of the York Review and the countervailing view of patients); and (b) it overlooked the dangers of these therapies. He further submitted that the consequence to patients was sufficiently serious to call for the intervention of the Court. I shall refer to this as the 'Irrationality Issue'.
44. Secondly, he submitted that the constitution and membership of the GDG would lead the objective observer to conclude that there was an appearance of a pre-determination (i.e. more than a mere predisposition) in favour of the psycho-social approach to the treatment of the condition. I shall refer to this argument, which was further defined during the course of argument, as the 'Pre-determination Issue'.
45. For the Defendant Mr Béar QC submitted that the entire claim was misconceived. The Irrationality Point amounted to an invitation to the Court to override a specialist advisory body on matters of expert judgment supported by misleading assertions that relevant matters had been disregarded. So far as the Pre-determination Point was concerned, he submitted that the Claimants' case was founded on factual misrepresentations and a failure to analyse the relevant legal principles. In any event he submitted that this point was to a greater or lesser extent time barred, and that it would plainly be against the public interest to grant any remedy.

### **The Law**

46. It is convenient to summarise the legal principles under 2 headings: first, the proper approach to decisions of public bodies which are charged with exercising judgment on the basis of evidence; and secondly, the principles to be applied where there is an allegation of apparent bias in a public decision-making body.
47. The following cases were cited in relation to the Irrationality Issue: *Tesco Stores Ltd v. Secretary of State for the Environment* [1995] 1WLR 759, *R (London and Continental Stations and Property Ltd) v. The Rail Regulator* [2003] EWHC 2607, (Admin), *R (Khatun and others) v Newham LBC* [2004] EWCA Civ 55 [2005] QB 37 and *R (Western Riverside Waste Authority) v. Wandsworth BC* [2005] EWHC 536 (Admin) [2005] Env. LR 41. These cases support the following applicable principles.
  - i) When a decision is made by a public body in good faith, following a proper procedure and applying conscientious consideration, a claimant must show

more than that a mistake has occurred. It must be shown that the decision was one that could not reasonably have been reached on the material or was otherwise irrational, see Lord Templeman in *R v. Independent Television Commission, ex.p TSW Broadcasting Ltd* [1996] JR 185, cited in the *Western Riverside* case at §52.

- ii) Facts which have been found by a body charged with making decisions based on their findings of fact are not readily susceptible to challenge. The principle was expressed by Lord Brightman in *Puhlhofer v. Hillingdon LBC* [1984] AC 484 at 515E

Where the existence or non-existence of a fact is left to the judgment and discretion of a public body and that fact involves a broad spectrum ranging from the obvious to the debatable to the just conceivable, it is the duty of the court to leave the decision of that fact to the body to whom Parliament has entrusted the decision making power save in a case where it is obvious that the public body, consciously or unconsciously, are acting perversely.

The principle of proper weight being attached to the decision-maker's conclusion is echoed in an observation of Lightman J in *R v. Director General of Telecommunications, ex p Cellcom* [1999] ECC 314 at §26, referred to in the *Rail Regulator* case at §29,

The court must be astute to avoid the danger of substituting its views for the decision makers and of contradicting ... a conscientious decision maker acting in good faith and with knowledge of the facts.

- iii) There is an important distinction to be drawn between the question of whether something is a material consideration and the weight which should be given. The latter is a matter for the decision maker, subject to questions of *Wednesbury* irrationality; and, providing the decision-maker has taken into account, the fact that it has given it no weight is not a ground for review, see the observations of Lord Hoffman in the *Tesco* case at 780F-H and 784C and Laws LJ in *Khatun* at §34-35.
  - iv) The Court should be wary of invitations to engage in detailed analysis of the phraseology used and drawing fine distinctions between different parts of what may be long and complex reasoning. This is to say little more than that a Court of Review is, in this context, concerned with rationality, rather forming its own view on part of the material available to the decision-maker.
48. It is right to note two points at this stage. First, these principles are not in issue. On the first issue the Claimants base their claim squarely on the basis of irrationality. Secondly, the Claimants' criticism is focussed on a confined, albeit important, part of a lengthy guideline. They have advanced no challenge on any wider basis. The question is whether they have made good their claim on what are now relatively narrow grounds.

49. Two cases were relied on in relation to the Pre-determination Issue: *Flaherty v. National Greyhound Racing Club Ltd* [2005] EWCA (Civ) 1117 and *Lewis v. Redcar and Cleveland Borough Council* [2008] EWCA (Civ) (2009), 1 WLR 83. These cases indicate the following:

- i) The test for apparent bias will involve the Court conducting a two stage process. The first requires the Court to ascertain all the circumstances which have a bearing on the claim of bias. The second requires the Court to consider whether those circumstances would lead a fair minded and informed observer to conclude that there was a real possibility of bias: see Scott Baker LJ in *Flaherty* at §27, citing Lord Phillips of Worth Matravers MR in *Re Medicaments and Related Classes Goods (No.2)* [2001] 1 WLR 700, 726 §83.
- ii) The relevant circumstances are those apparent to the court at the time of the hearing of the Claim.
- iii) The context is critical.

The principles of natural justice or fairness must adapt to their context and can be approached with a measure of realism and good sense,

see Mance LJ in *Modahl v British Athletic Federation Limited* [2002] 1 WLR at §128, cited in *Flaherty* at §29.

- iv) A Court of Review adopts a particularly critical eye in cases of judicial or quasi-judicial proceedings, where appearances are important, see for example *Lewis v Redcar* (at §§71 and 98/99).
- v) Where the context is the decision of a body whose members may be expected to have prior views, the requirement is that the members approach the issue fairly and on the merits.

So the test would be whether there is an appearance of predetermination, in the sense of a mind closed to the planning decision in question ... [what needs to be shown is] is something which goes to the appearance of a predetermined, closed mind in the decision-making itself,

see Rix LJ in *Lewis v. Redcar* (at §96): a case where the allegation of bias related to the decision of Local Government Planning Committee. In this context the Court of Appeal approved the statement of Collins J in the case *R (Island Farm Development Ltd) v. Bridgend County Borough Council* [2006] EWHC 2189 (Admin) at §31,

The reality is that councillors must be trusted to abide by the rules which the law lays down, namely that, whatever their views, they must approach their decision making with an open mind in the sense that they must have regard to all material considerations and be prepared to change their views if persuaded that they should...[U]nless there is

positive evidence to show that there was indeed a closed mind, I do not think that prior observations or apparent favouring of a particular decision will suffice to persuade a court to quash the decision...It may be that, assuming the *Porter v Magill* test is applicable, the fair-minded and informed observer must be taken to appreciate that predisposition is not predetermination and that councillors can be assumed to be aware of their obligations.

50. In the present case, the context is the recommendation of an independent expert body, whose members had been chosen for their knowledge and expertise. In such a case, the law does not, in my view, call for a more rigorous test than was expressed in *Lewis v Redcar*. It is not enough for the Claimants to demonstrate the expression of prior views. They have to show (at least) predetermination: a closed mind at an early stage. This, as Longmore LJ stated in *Lewis v Redcar* at §109, is a difficult test to satisfy.

#### **The 2004 and 2007 Codes**

51. The 2004 Code was published as an appendix of NICE's Guideline Development Manual, and was primarily directed to identifying interests arising from direct or indirect financial payments received from the Healthcare Industry (i.e. companies or organisations which were involved in manufacture, sale or supply of goods or services to the NHS). It envisaged the possibility of interests, which were not covered specifically by the Code.

If members or employees have interests not specified in these notes which they believe could be regarded as influencing their advice on their role they should declare them.

The 2004 Code required that:

Members with conflicts that are regarded as substantial should be excluded from the Group at the beginning of the Guideline Development Process.

52. On 1 April 2007 a new Guideline Development Manual was published, which replaced the 2004 Code with the 2007 Code. The 2007 Code extended the definition of the Healthcare Industry to include,

... individuals who are involved in the development, manufacture, promotion, sale or supply of ... services which are advertised, promoted or marketed as contributing to the promotion or maintenance of good health.

53. There was a category of 'personal pecuniary interest' which included (paragraph 3.3)

... a current personal payment, which may relate to the manufacturer or owner of a product or service being evaluated ...

This was also a category of personal non-pecuniary interest, described at paragraph 3.5

A personal non-pecuniary interest in a topic might include but is not limited to:

i) a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review.

54. So far as advisory body meetings were concerned, the issue of how these declared interests should be dealt with was addressed at paragraph 4.5. A person declaring a personal specific pecuniary interest should (in general) take no part in the proceedings. A personal non pecuniary interest was treated differently,

When someone declares a non-pecuniary interest the chair of the advisory body shall determine on a case-by-case basis, whether he or she should take part in the proceedings.

55. In October 2007 NICE published the GDG members' Declarations of Interest, which had been made under the 2007 Code. The Declarations of Interest were introduced by a short statement of intent.

During its development the CFS/ME guideline development group complied with [NICE's] policy on Declarations of Interest. Personal and non-personal pecuniary interests were reviewed and considered by the chairman. The guideline was nearing completion when the new policy came into effect. Following the policy revision, all GDG members have reviewed, and where appropriate amended, their declarations in the light of the new policy.

When the request by NICE to place these on the website was received, the current declarations were sent to GDG for a last review. Several members have added or amended in the interests of transparency which may have previously been viewed as not relevant. Disclosure is based on the individual's assessment of the policy in consultation with the NCC-PC.

## **Discussion and conclusion on the Claimant's claim**

### **The Irrationality Issue**

56. The starting point for the Claimants' argument is the NICE Guideline Development Manual. The 2006 edition of the Manual contained 90 pages of material and a further 76 pages of appendices. Chapter 7 was concerned with reviewing and grading evidence; and paragraph 7.3.3 dealt with levels of evidence. Table 7.1 contained a weighting system which categorised evidence from the highest levels of reliability to the lowest. At the highest level was 'High-quality meta-analyses, systematic reviews of RCTs, or RCTs with very low risk of bias.' At the lowest level was 'Expert opinion, formal consensus.'

57. The advice in the Guidelines Manual was to use the system for evidence in table 7.1 until such time as a decision was reached on the most appropriate system.
58. As I have already noted, the Consultation Draft set out a large number of comments which had been received on the draft Guideline. Many of the comments were critical of the York Review. Among these was one particular comment,

This document is the primary building block on which these Draft Guidelines have been based ... We concurred with the detailed critique of the [York Review] 'Inadequacy of the [York Review] Medical Evidence Base' by Malcolm Hooper and Horace Reid, January 2006 ...

59. The Consultation Draft set out a response to this point under the heading 'Inadequate foundation for definitive guidelines,'

We too agree that by itself the RCT/controlled trial evidence base is not an adequate foundation of definitive guidelines, which is why the GDG also considers the experiences of both patients and clinicians.

60. In §61 of his witness statement Professor Baker responded to a broad criticism that the GDG did not take into account relevant evidence.

Broadly speaking there were five sources of evidence considered by the GDG: [1] the York Review, which was commissioned to independently review the randomised controlled trials (RCTs) and controlled trials relevant to the Guideline, and evaluate the evidence identified ... [2] evidence submitted to the GDG by the stakeholders, which consisted primarily of the results of patient surveys conducted by stakeholders but also references to other evidence (e.g. study papers) that the stakeholders wished the GDG to consider, [3] the experience and expertise of the GDG and co-opted experts, [4] responses from the wider group questionnaire, [5] work done by a health economist to support GDG's considerations.

61. The Claimants' argument proceeded as follows. The most reliable evidence according to weighting system in Table 7.1 of the Guidelines Manual should have been the systematic reviews of RCTs carried out by the York Review; and the least reliable should have been expert opinion. The Consultation Draft acknowledged that the RCT evidence base in the York Review was not an adequate foundation of definitive guidelines; and, according to Table 7.1, the experience and expertise of the GDG (source 3), should have been given the least weight according to Table 7.1. It followed that the only sources of evidence which remained were sources 2 and 4. These would have been antipathetic to the recommended treatment. It therefore followed that there was no adequate basis for the recommendation of CBT/GET.
62. Although it was presented attractively by Mr Hyam, the argument was, in my view, unsound.

63. The purpose of the Guideline was to provide practical advice for practitioners. In the words of Professor Baker,

To put it in simple terms, the purpose of the Guideline (along with clinical guidelines in general) was to evaluate what works in practice, rather than speculate on what should work in theory.

64. It is clear that the GDG looked at a considerable amount of material before making its recommendations. The York Review was one of the sources available to the GDG, but it was not the only one. It was for the GDG and not the York Reviewers to assess the weight of the evidence. The GDG also considered the experiences of patients and clinicians, as well as the experience and expertise of members of the GDG and the co-opted experts. The weighting system set out in table 7.1 of the Guidelines Manual as to how evidence should be assessed was advice: it was not a prescriptive rule. On the clearest and highest authority it was for the GDG to decide what weight to attach to evidence, and it cannot be said that the decision to make the recommendations on the basis of what was available to the GDG was irrational. Decisions of fact are for those entrusted to make those decisions.

65. I am also very doubtful as to whether the phrase,

we too agree that by itself the RCT/controlled trial evidence base is not an adequate foundation of definitive guidelines,

in the Consultation Draft, carries the weight which the Claimants attach to it. The GDG was not saying that the RCT's carried no weight. On the contrary, on the basis of the table 7.1 weighting, the York Review analysis supported CBT as a treatment at a level described as A-.

66. I also reject the contention that the Guideline overlooked the risks involved in GET (or CBT) treatment. There is simply no basis for the contention.
67. Finally on this point, even if I had been persuaded that the recommendation of CBT and/or GET as treatment for those with mild or moderate CFS/ME was flawed on the limited grounds advanced, I would not have made an order quashing the recommendation. Such an order would have resulted in no recommended treatment for those suffering from CFS/ME; and this result could not be justified on the confined grounds of complaint.
68. In my judgment the challenge on the Irrationality Issue fails.

#### **The Pre-determination Issue**

69. During the course of the hearing the Claimants' argument, the Pre-determination Issue was confined as follows:

- i) In respect of Dr Fred Nye, Dr William Hamilton, Ms Jessica Bavinton and Dr Alastair Santhouse a conflict of interest existed which, in the light of the 2004 and 2007 Codes, should have resulted in them
- a) not being appointed and/or

- b) not participating in discussions in respect of the recommendations in respect of CBT/GET.
- ii) In respect of the remaining 11 non-patient representatives, viewed as a group, they lacked appropriate balance because of 'the absence of views representing bio-medical opinion'.
- iii) If the Court were to determine that any of the 4 identified personnel had conflicts of interest which ought to have been declared, or gave rise to a real risk that the decision of the GDG was made with a real risk of closed minds, then the decision as whole should not in the public interest be upheld.

70. In confining the argument as outlined above, the Claimants abandoned what they had belatedly come to recognise were inaccurate criticisms of 11 non-patient representatives on the GDG and unjustified allegations of bias. The change in approach was summarised in §10 of the Mr Beagent's 2nd witness statement.

It is quite plain, following service of the witness statements from the professional GDG members that some of those perceptions of bias held by the Claimants are demonstrably false, or premised on a false basis.

71. The GDG was selected on the basis of extensive public consultation. The professional members were the nominees of the Royal Colleges and equivalent professional societies. The GDG process was supervised by NCC-PC and NICE whose neutrality is not challenged, assisted by Professor Pinching whose neutrality is no longer challenged. Ms Turnbull (the Chief Executive of the NCC-PC) addressed an earlier criticism that GDG members were not asked for their views about the nature and cardinal symptoms of CFS/ME in §9 of her witness statement.

What we were interested in was having GDG members with day to day experience of treating CFS/ME, who would be open-minded about where the evidence would take them. This was why [we] tried to avoid inviting anyone who had had widely publicised involvement with the CFS/ME community that meant they were likely to strongly promote a particular theory of the condition. Provided members were open-minded and had experience of dealing with CFS/ME, it was not considered of particular importance what their views on the origins of CFS/ME were. The GDG would be conducting a fresh review of the relevant evidence and all the views brought to the table would be informed of this.

I consider that this approach is consistent with legal principle and good practice.

72. After they were selected, the membership of the GDG was made known to the public without any contemporary objection. Mr Beagent's explanation for the delay in raising this complaint is set out in §69 of his 1st witness statement.

Although the Claimants were deeply concerned about the make up of the GDG throughout the development process, they did

not, until after proceedings were afoot, become fully aware (and could not reasonably have been aware) of the disposition of so many members towards the psycho-social model, the complete absence of proponents of the biomedical model and the more serious instances of conflict of interest among the GDG members. Over the course of these proceedings, more and more information has come to light which raises serious questions about the make up and balance of the GDG and reinforces this ground of challenge.

73. So far as the general balance of the GDG is concerned, the Claimants' explanation is unconvincing; not least because so much of the information in Mr Beagent's 1st witness statement is now shown to be unreliable. I agree with Professor Pinching's observation (at §7 of his witness statement):

The result was a skilled, experienced and well balanced GDG and the statement paragraph 69 of the witness statement of Jamie Beagent to the contrary is unfounded and untrue.

74. I am satisfied that the broad criticism of 'lack of appropriate balance', which was not pursued by Mr Hyam with enthusiasm, is entirely without merit.
75. I turn then to the specific criticisms of 4 members of the GDG.
76. Chapter 4 of the Guideline Development Manual was entitled, 'Forming and running at Guideline Development Group'; and emphasised the importance of convening an effective GDG. Paragraph 4.2 was concerned with identifying interests and conflict of interest.

#### 4.2.1 Declaring Interests

Potential members of the GDG ... should provide a formal written declaration of personal interests ...

Any changes to a group member's declared conflicts of interests should also be recorded at the start of each GDG meeting. The Group leader, in discussion with the NCC Director, should determine whether these interests are significant.

If a member of the GDG has a possible conflict of interest with only a limited part of the guideline development or recommendations, that member may continue to be involved in the overall process but should withdraw from involvement in the area of possible conflict. This action should be documented and be open to external review. If it is considered that an interest is significant in that it could impair the individual's objectivity throughout the development of a guideline, he or she should not be invited to join the group.

**Dr Hamilton**

77. There are 3 criticisms of Dr Hamilton. (1) He had a 'direct pecuniary interest' arising out of his relationship with the Liverpool Victoria Friendly Society and the Exeter Friendly Society whose life policies excluded those with CFS/ME. (2) His relationship with insurance companies should have been disclosed. (3) He was a committed proponent of the psycho-social approach and of CBT as a treatment of CFS/ME.
78. It is common ground that before Dr Hamilton joined the GDG he completed a personal statement in his nomination form stating that he was the Chief Medical Officer and a Board member of the Exeter Friendly Society; and that he was the Chief Medical Officer of the Liverpool Victoria Friendly Society. This was also specifically referred to in his October 2007 declaration of interests. It is also accepted that he was paid a fixed *honorarium*, plus an hourly fee for attendance.
79. The Claimants rely on the views of 'the Gibson Inquiry.' This was a report of a Parliamentary group on Scientific Research into ME chaired by Dr Ian Gibson MP. The report, dated November 2006, defined its purpose at §1.2

Our task is to highlight the ongoing struggle of the CFS/ME community and to ensure that the voice of the patient is heard. We have examined the available evidence, as far as we can in the time available to us.

At §6.3 the Gibson Inquiry drew attention to a potential conflict of interest where advisors to the Department of Work and Pensions also had consultancy roles in medical insurance companies.

Given the vested interest private medical insurance companies have in ensuring CFS/ME remain classified as a psychosocial illness there is blatant conflict of interest here.

80. Mr Beagent was forthright in his attack on the position of Dr Hamilton.

Most egregious in the view of the Claimants (and the wider ME Community) is the fact that Dr William Hamilton is Chief Medical Officer of two medical insurance companies: he is CMO of the Exeter Friendly Society which specifically excluded ME sufferers from its policy; and also of the Victoria Friendly Society ... The insurance companies have a direct financial interest in supporting the psycho-social model and do so. The fact that the Dr Hamilton receives no bonus related payments does not mitigate his direct pecuniary interest and the perception of bias in the ME/CFS community.

It is unclear how Mr Beagent and the Claimants came to believe they could speak on behalf of 'the CFS/ME community'.

81. The allegation that the Exeter Friendly Society 'excludes' ME sufferers from its policies is wrong. Dr Hamilton's evidence is clear and is now unchallenged,

A policyholder healthy at application who later developed CFS/ME would have a valid claim.

Those who suffer from CFS/ME at inception of the Policy would have that condition excluded, as is customary with any pre-existing disease.

82. The Liverpool Victoria Friendly Society has no policy exclusions for CFS/ME; and pays out on CFS/ME claims in the same proportion (93%) as it pays other claims. Neither of the insurance companies with which Dr Hamilton is associated classifies CFS/ME as a mental disorder.
83. As noted above, Dr Hamilton declared his connection with these insurance companies in his nomination form. He also made a further declaration under the 2007 Code.
84. The first and second points are without merit.
85. The evidence cited by Mr Beagent in support of the assertion that Dr Hamilton was a committed proponent of the psycho-social model consisted of an extract from a 2001 joint paper in the British Journal of General Practice. This publication was drawn to the attention of NICE in his Personal Statement, as evidence of Dr Hamilton's interest in the subject. In his witness statement Dr Hamilton denied that he has a committed position in relation to CFS/ME or that he is a proponent of any kind. He contended that the quotation cited by Mr Beagent was not a single direct quotation from the joint paper, but two sentences which appear four paragraphs apart with a number of material omissions which made Mr Beagent's quotation misleading.
86. In his second witness statement Mr Beagent revised his evidence. He accepted that Dr Hamilton,

does not regard himself as a committed proponent of any particular view, and that such a suggestion cannot be sustained before this Court.

However, he continued,

That said, his published views as expressed in the article when read as a whole (as opposed to citation in the statement) are, in the Claimants' view, such as *might* preclude him from participating in the discussions of the GDH in relation to GET and CBT (emphasis added).

87. The Claimants' opinion that Dr Hamilton's views 'might' preclude him from participation is plainly insufficient to ground a challenge on the basis of pre-determination.

### **Ms Bavinton**

88. There were 4 criticisms of the involvement of Ms Bavinton. (1) She had a pecuniary interest in the recommendation of GET since she had written a manual which would lead to 'a benefit in career terms.' (2) She had advertised a fee-charging course she was now 'running off the back of the Guideline.' (3) She worked 'on a regular basis' for insurers, who had a vested interest in a psycho-social model. (4) She had worked

with Professor White, who was a leading proponent of the psycho-social approach. In his oral submissions Mr Hyam focussed on what he contended was a failure to make the appropriate declaration under the 2004 and 2007 Codes.

89. Ms Bavinton had set out in her nomination form her interest and experience of GET, and her authorship of a manual on GET. In my view there was no obligation to make any further disclosure under the terms of the 2004 Code which, even if one were to assume Ms Bavinton had a 'a personal interest', was concerned with payment for work rather than incidental remuneration. So far as the 2007 Code is concerned, her October 2007 declaration of interests described her research work and the publication of a GET manual 'which may be published sometime'. Both the Chair of the GDG and NICE were aware of her expertise in GET. As Ms Turnbull (of the NCC-PC) explained in her witness statement,

This expertise was one of the reasons why Ms Bavinton was invited to join the GDG in the first place. Other GDG members with experience of other ways of managing the condition were selected for similar reasons (e.g. Carol Wilson for her knowledge of activity management, Gill Walsh for her experience of relaxation therapy, Fred Nye for his knowledge of investigations). Applied consistently, the Claimants' argument is that no-one on the GDG should have had any expertise in any of the treatments being considered by the GDG nor should they work in the field for payment.

90. The challenge to Ms Bavinton's involvement on the basis that she was subsequently involved in implementing the recommendation is unsound in law; but in any event, on Ms Bavinton's evidence, the implied accusation that she is somehow profiteering from the Guideline recommendation is incorrect on the facts.
91. So far as the third point is concerned, the allegation of vested interest is highly generalised; and, when particularised, is shown to be without foundation in fact. In any event, Ms Bavinton's evidence as to her duties when employed as an independent consultant by insurance companies does not suggest that there has been a conflict of interest and duty.
92. The final allegation in relation to Ms Bavinton's association with Professor White is set out in §9(1)(iii) of the Reply.

This was not all. She had worked extensively alongside Professor Peter White who is a leading psycho-social proponent in relation to CFS/ME, and is the author of the current physiotherapy page on the AYME website recommending GET.

AYME is a charity which supports the Guideline's recommendations that CBT and/or GET should be offered to people with mild or moderate CFS/ME.

93. It is common ground that Professor White is a clinical colleague of Ms Bavinton at St Bartholomew's Hospital; but it is not accepted by NICE that Professor White is a 'leading proponent' of any particular view. It appears that his interests extend to the

biology of the illness and that he has undertaken studies into the virology, immunology and physiology of CFS/ME.

94. This complaint contains the vice which is repeated against a number of members of the GDG. It involves a simplistic characterisation of a particular individual's views about the nature of CFS/ME; and the contention that a member of the GDG's association with that individual gives rise to 'concern'. I reject the proposition that the opinions of individuals are to be measured by those of their colleagues, even if (as is not the case here) the opinions of those colleagues can be clearly established.

**Dr Nye**

95. There are three criticisms in the case of Dr Nye. (1) He was 'effectively sitting in judgement on his own research when recommending GET'. (2) He was 'a published supporter of the bio-psycho-social (*sic*) approach and the use of CBG and GET'. (3) He failed to declare that his department received an Medical Research Council grant of £824,000 to investigate CBT/GET, which should have precluded him from being appointed to the GDG.

96. In his October 2007 declaration of interest, Dr Nye stated,

I have published (co-authored) three studies on GET for CFS/ME, a RCT, and a follow-up trial of participants and a study of risk factors for poor response to therapy.

Dr Nye's evidence is that he had been invited to join a study,

... designed to ascertain the effect of patient education and undertaking GET on the physiological symptoms experienced by CFS/ME sufferers.

The study had been set up by Professor Richard Edwards and Professor Richard Bentall. Dr Nye joined the group about a year after it began its work, when Professor Edwards left his post as Professor of Medicine at the Royal Liverpool University Hospital. The RCT was designed to identify long-term benefits of treatment and was published in the British Medical Journal in February 2001.

97. In my judgment Dr Nye's response to the first point, contained in §14-15 of his witness statement, is compelling. Published research is subject to vigorous peer review; and the 2001 Paper was further evaluated by the York Review.

I considered the research that I was involved in together with much other evidence, but did so after a rigorous external review and as part of a group of many doctors and others. Not only did I retain objectivity by virtue of my scientific and medical training but there were many checks and balances in the process. In any event, the assessments of RCTs does not really lend itself to appraisal in light of preconceived opinion but is a matter of statistical, mathematical and methodological appraisal.

The 2001 Paper relied on patient's own reports of their fatigue levels and appeared to show a clear benefit to the treatment group when compared to the control group. The Paper concluded with a summary of what the study added to the then current state of knowledge:

Patients given physiological explanations for their symptoms and encouraged to do graded exercise were significantly better than those who received standardised care at one year.

The approach may be as effective as cognitive behaviour therapy but is shorter and requires less therapist skill.

This conclusion was qualified by reference to the limitations of the study, which included the lack of a placebo control group that received equivalent therapist time and attention.

98. The evidence cited by Mr Beagent in support of the contention that Dr Nye was a supporter of the psycho-social approach is an apparent quotation from the 2001 Paper. The passages in italics (which indicate balance) were omitted from the quotation cited by Mr Beagent,

*What is already known on this topic*

No serious underlying pathology has been identified in patients with [CFS]. *Patients with [CFS] show evidence of disrupted physiological regulation, including physical deconditioning, sleep disturbance and circadian dysrhythmia.*

[CBT] targeted at changing illness beliefs and graded exercise helps some patients.

99. Dr Nye dealt with the complete quotation in §9 of his witness statement,

Read as a whole the passage is a very brief summary of what was known at the time. It sets out that CFS/ME sufferers do not exhibit obvious pathologies. (This contrasts with the way that cancer patients have visible tumours or HIV/AIDS patients have drastically reduced T-cell counts and the presence of an identifiable virus). Nevertheless there is good evidence that CFS/ME patients suffer from a number of physiological (i.e. physical) abnormalities that interfere with bodily processes and stress responses. My own view is that some of these abnormalities have a genetic basis.

100. He addressed the accusation that he is a proponent of the psycho-social approach in §10 of his witness statement. After noting that the Claimants had never asked him about his views, he said,

My expertise is in infectious diseases, an essentially biomedical speciality. I have made it clear in public statements and in my

lectures and teaching that I regard CFS/ME as a complex illness with both physiological and genetic components.

101. Mr Beagent responded to Dr Nye's evidence about his support for the psycho-social approach in §13(x) of his second witness statement

Dr Nye is considered by the Claimants to be a supporter of the psycho-social school. I accept that (i) he denies it; and (ii) that the article and/or passage quoted at paragraphs 13 is insufficient to support the suggestion that he is a 'published supporter of the psycho-social school' ...

102. So far as the Claimant's third point (the MRC grant) is concerned, the allegation (contained in §9(1)(iii) of the Reply is that,

... he neglected to declare that his department (*sic*), the Royal Liverpool University is already in receipt of part of a £824,129 MRC grant to investigate GET/CBT. This too should have precluded him from selection to the GDG

103. It appears that there has been a misunderstanding by the Claimants. Dr Nye was not involved in either obtaining or using the grant; and the funds benefited neither Dr Nye nor his department. In any event, since the MRC is a publicly funded organisation independent of the healthcare industry, any money received would not have been declarable. It was not an interest requiring disclosure.

#### **Dr Santhouse**

104. The matters of complaint against Dr Santhouse are set out in §57 of Mr Beagent's 1st witness statement.

Consultant Psychiatrist, Dr Alastair Santhouse is employed at Kings College London, CFS Research and Treatment unit where he works under the head of Service Professor Trudie Chalder and with fellow psychiatrist, Professor Simon Wessely – the foremost proponent of the psycho-social model. His own published views accord with those of his colleagues – see for instance, *The 10 Chronic Fatigue Syndrome Commandments* (16.02.04)

105. Dr Santhouse is a Consultant Psychiatrist at Guy's Hospital. His witness statement, which was not challenged on this point, makes clear that he does not work 'under' Professor Trudie Chalder (who is a senior cognitive behavioural therapist and not a medical doctor) or Professor Simon Wesseley (who is a fellow consultant psychiatrist, carrying out a similar clinical role within the CFS Research and Treatment Centre).

106. He disclosed the publication of 'Ten Commandments of CFS' in his October 2007 declaration of interests. The Claimants point to his tenth 'Commandment'.

What other treatments help.

The best research evidence is [CBT] and/or [GET]. Pacing of activities is popular with patients, and is currently undergoing trials. A huge number of other treatments have been advanced, for which research evidence is either lacking or inconclusive. This list includes use of nutritional supplements, antiviral agents, immune-suppressants and steroids.

107. Mr Hyam submitted that the expression of this opinion shows that before the GDG began its work Dr Santhouse had formed a clear view as to the efficacy of CBT and GET and the ineffectiveness of alternative treatments; and that this should have precluded him from participating in (at least) the final stage discussions and recommendations.
108. Mr Béar responded by pointing out that the Ten Commandments article has been in the public domain since well before Dr Santhouse's appointment to the GDG and caused no controversy; and that any allegation of partiality for a particular approach must be read in the light of his 'First Commandment',

Traditionally, consensus has been difficult to achieve on anything related to the topic, including nomenclature. Chronic fatigue syndrome (CFS) is the accepted name among professionals, but many patients still prefer ME. The aetiology of CFS remains elusive. Research has focused on genetic links, endocrine abnormalities, immunology, neuro-imaging, virology and infectious processes, sleep disruption, exercise, somatisation, depression and anxiety disorder. While many of these areas of research have demonstrated abnormalities in those suffering with CFS, none is able to adequately explain the illness. The current consensus would frame the illness in terms of individuals having different vulnerabilities and precipitating and perpetuating factors (both physical and psychological). However, it remains a possibility that a variety of pathological processes cause the same illness, and that fatigue is merely the final common pathway.

### **Conclusion**

109. Having ascertained the circumstances which are relied on in the support of the claim of bias I can state my conclusion on the predetermination issue as follows.
  - i) The general allegation that there was insufficient 'representation of the bio-medical approach' is misconceived.
  - ii) The nearest the Claimants came to making good the contention that the 4 members of the GDG were apparently biased was reliance on a number of selective quotations. Closer investigation demonstrated that in some cases the quotations were deployed unfairly and in others cases had to be read in their proper context. In any event, prior observations favouring a particular treatment would not be sufficient grounds for excluding a member of the GDG from participation. There was no direct evidence, or evidence from which an inference could properly be drawn, of predisposition in the sense of any

member of the GDG having a mind which was closed to the evidence; rather the contrary.

- iii) Many members of the GDG had long standing interests in CFS/ME. That is why they volunteered; and that is why, in some cases, they had published Research Papers on the subject. This did not preclude them from being appointed; nor did it require them to stand aside at the final stages of the preparation of the Guideline. Professor Baker's description of his approach as Chair of the GDG is instructive,

Firstly, given the controversy that surrounds the condition of CFS/ME we decided that it would be best to have three patient representatives rather than the usual two. Secondly, we wanted the GDG members to be those with day to day experience in treating CFS/ME, rather than, for example, those whose primary interests were research into the condition, or putting forward theories on aetiology. We also wanted the professions/specialisms regularly concerned with the treatment of CFS/ME to be represented on the group. Thirdly (and connected to the second point) while we did not ask nominees about their views on the causes of the condition, we were anxious to avoid having as a GDG member anyone whose involvement in the CFS/ME community to date (e.g. through papers they had written advancing a particular theory on the condition) made it likely that they would want to 'push' one theory of CFS/ME rather than another.

This approach was entirely appropriate.

- iv) There was a proper and effective system in place to ensure that, so far as possible, there was no conflict of interest and duty among the membership of the GDG.
- v) The interests declared were not such as to preclude members of the GDG from participating in discussions and decisions of the GDG. Professor Baker addressed this point in §28-30 of his 2nd witness statement.

28. As the selection of the GDG took place some time ago, I cannot recall in detail the consideration of the declarations of interest that were made by GDG members at the time they were first asked to participate in the Guideline's development. However, I can say that I was made aware of the declarations by the NCC and none of them led me to conclude that the involvement of any individuals who eventually sat on the GDG was inappropriate.

29. GDG members were reminded of the need to declare new interests at the start of each meeting, and also completed a regular written declaration. The declarations made at the

meetings were broad-ranging and not confined to pecuniary interests ...

30. As Chair of the GDG I was conscious that such declarations were made for a purpose and had I considered that an individual's participation in the GDG's deliberations was inappropriate at any point, I could have ruled that they should not participate in the relevant section of the meeting. I am satisfied (and was satisfied at the time) that the members of the GDG approached the development of the Guideline with an open mind.

It was both appropriate and in accordance with §4.2 of the Guideline Development Manual to leave questions arising out of the declarations of interest to the Chair of the GDG. There are no grounds for contending that Professor Baker dealt with such matters in a way that could properly be the subject of a Public Law challenge.

- vi) Many of the matters of complaint have been in the public domain for many years and were not the subject of timely complaint. Others could have been seen to have been baseless if there had been proper enquiry before the allegations were made.
  - vii) The circumstances are not such as to lead a fair minded and informed observer to conclude that there was a real risk of bias among the members of the GDG, either individually or as a group, or that they acted other than in good faith.
110. Even if the criticisms of the 4 named individuals had been fully justified, it does not necessarily follow that the recommendation for CBT and/or GET should be quashed. The recommendation was a decision of a large group; and the public interest in the need for clinical guidance would have to be considered.
111. For these reasons I have concluded that the Claimants fail in their challenge on the Pre-determination Issue.

#### **The Interested Party's claim**

112. Mr Hallin submitted that NICE was required to consider the cost-effectiveness of any healthcare intervention recommended in its Guidelines. Instead of doing so, NICE failed properly to assess the cost-effectiveness of GET; and its analysis of the cost-effectiveness of CBT was flawed and irrational.
113. Mr Béar submitted that an Interested Party whose own challenge had been stayed, as ordered by Cranston J on 17 June 2008, would not usually be permitted to advance a separate point which had not been advanced by the Claimant. However he also submitted that NICE was content to have the issue resolved at this hearing. So far as the merits of the claim were concerned, Mr Béar submitted that there was no obligation to appraise the cost-effectiveness of the treatments and that, in any event, questions of cost-effectiveness had been considered in the course of producing the Guideline.

### **Discussion and conclusion on the Interested Party's claim**

114. The first issue is the proper status of the Interested Party (BB). At the permission stage BB's claim was stayed; and Mr Hallin's argument was confined to an argument which, although contained in the Claimants' original claim, was not advanced by them in argument. It seems to me that Mr Hallin's contention that the Interested Party was entitled to advance this particular argument without the grant of permission was not self evident.
115. I am however persuaded that there are more fundamental objections to Mr Hallin's argument. In order to succeed with a claim for Judicial Review the Interested Party has to show a sufficient interest in the matter in issue. The Court recognises a sufficient interest in cases where individuals or groups seek Judicial Review and there are serious issues of public importance. Among the factors which may be relevant are the merits of the challenge, the importance of vindicating the Rule of Law, the importance of the issue raised and the likely absence of any other responsible challenger.
116. Mr Béar submits that BB has no sufficient interest in advancing what is a wholly unmeritorious challenge. If BB's challenge were to succeed, the recommendation, which is (at this stage of the argument) of benefit to those with CFS/ME, should be withdrawn. BB cannot show that he has any interest, other than the interest of a single person among the general body of citizens whose taxes contribute indirectly to the NHS.
117. For BB, Mr Hallin submitted that the challenge has substantial legal merit and that it would be wrong to exclude the claim on the grounds of insufficiency of interest.
118. BB's challenge is founded on the terms of the Secretary of State's 'Directions and Consolidating Directions to NICE 2005'. This sets out powers conferred by sections 16D, 17 and 126(4) of the National Health Service Act 1977.

Paragraph 2(1) provides that

The Secretary of State directs [NICE] to exercise the following functions in connection with the promotion of clinical excellence and the effective use of available resourced in the health service –

(a) to appraise the clinical benefits and the costs of such healthcare interventions as may be notified by the Secretary of State and make representations

(b) to develop guidelines providing advice on good practice in the management of such diseases and conditions as may be notified by the Secretary of State; ...

Paragraph 2(4) provides:

In exercising the function described in paragraphs (1)(a)-(d) and (3) above [NICE] shall have regard to the following factors:

- (a) The broad balance of clinical benefits and costs;
- (b) the degree of clinical need of patients with the condition or disease under consideration ...

119. In my judgment NICE is correct in its submission that the Secretary of State's direction was to develop a guideline under paragraph 2(1)(b) rather than to appraise the clinical benefits and costs of a healthcare intervention under paragraph 2(1)(a). It is only the latter which requires appraisal of the cost. In the former case NICE must have regard to the broad balance of clinical benefit and cost, and the degree of clinical need (see paragraph 2(4)(a) and (b)); but it is not required to appraise the costs against the clinical benefits. The difference is crucial. In the case of health care interventions, a cost benefit analysis will be both crucial and practicable. In the case developing guidelines, costs will have to be taken into account; but as part of a broad balancing exercise.
120. Furthermore, even if Mr Hallin overcomes this hurdle, he faces difficulty on facts.

### **CBT**

121. The GDG was fully aware of the risk of statistical bias in the Dutch Survey of the cost effectiveness of CBT. Paragraph 6.3.2 of the Full Guideline noted:

There does not appear to have been any attempt to correct for this difference between comparison groups, and this may have led to bias in the analysis. Sensitivity analysis was carried out to test the robustness of the result when the incremental health gain is reduced.

122. In their witness statements Professor Littlejohns and Professor Baker explain both the nature of the concerns and the steps taken to address those concerns. It seems to me that in the light of this evidence the contention that the GDG made no attempt to correct for bias is untenable. The Guideline recognised that reducing the utility gain led to a measured reduced cost effectiveness. The issue was referred to the Guideline Review Panel (under the chairmanship of Professor Drummond, one of the county's leading health-economists). The panel concluded that the evidence was sufficiently robust to support a conclusion that CBT was cost effective.
123. It was for the GDG to address the concerns which it had identified and that the way in which it did so was for the GDG. Assessment of evidence was for the fact-finding body; and the contention that the GDG's view of the matter was unreasonable, irrational and flawed is without merit.

### **GET**

124. There was no specific report dealing with the cost-effectiveness of GET. Professor Baker dealt with the matter at §137 of his 1st witness statement.

The GDG considered that the modest cost of GET programmes were at a low enough level that when weighed against the likely benefits of treatment the use of GET programmes was

sufficiently cost-effective to be recommended for use in the NHS.

In his view this approach was consistent with what was said in the Guidelines Manual:

... Economic analysis may also not be a priority when it is obvious that the resource implications are modest in relation to the expected health gains.

125. Mr Hallin's complaint that all this should have been set out in the Guidelines is in my view also without substance.

#### **Conclusion on the IP claim**

126. I have concluded that the argument advanced on behalf of the Interested Party is wrong; and in all the circumstances the claim fails for insufficiency of interest.

#### **Summary of decision**

127. For the above reasons I have concluded that:

- i) The Claimants' claim must be dismissed; and
- ii) The Interested Party's claim must also be dismissed.

#### **Afterword**

128. I have already expressed my concern at the nature of the allegations that were made against members of the GDG. There are two points that arise from the Claimants' approach to this litigation.
129. First, unfounded as they were, the allegations were damaging to those against whom they were made; and were such as may cause health professionals to hesitate before they involve themselves in this area of medicine. A perception that this is an area of medicine where contrary views are not to be voiced, and where scientific enquiry is to be limited, is damaging to science and harmful to patients.
130. Secondly, these types of allegation may also have the effect of putting people off from serving on GDGs. Professor Baker expressed this concern at §26 of his 2nd witness statement.

... I would also like to note that the fact that such allegations have been made in legal proceedings, and the fact that the individuals involved have had to submit their own version of events to the court in witness statements in order to defend themselves means that it is likely that they will think twice before being GDG members again. There is a real danger that health professionals will become reluctant to serve in GDGs again.

The comment is fair; and explains the robust approach taken by NICE in defending these proceedings.