Dr Terry Mitchell MA MD FRC-Path

23 June 2008

Mr Jamie Beagent Leigh day & Co Solicitors Priory House 25 St John's Lane London EC1M 4LB



Dear Mr Beagent,

Re: Douglas Fraser & Kevin Short v NICE - Case Number: CO/10408/2007.

Until recently I was for many years the Consultant clinical lead (CNCC) of the Norfolk, Suffolk & Cambridgeshire NHS ME/CFS Service. Further to the query regarding the composition of the Guideline Development Group (GDG) for the NICE guidelines relating to ME/CFS. I confirm that I was hugely disappointed to find that the membership of the GDG did not include any of my clinical colleagues who over the years have seen large numbers of patients with ME/CFS. In my view this resulted in an unbalanced analysis as many who were on the GDG seemed to have strong leanings to the psychological / psychiatric approach to this devastating illness.

The experience of those conducting clinical trials is likely to be more selective and does not represent the daily burden of having to manage and treat 100% of those diagnosed (using strict criteria) in a 'real' Norfolk/Suffolk/Cambridgeshire/Greater-Peterborough population of approximately 2.5 million people at a rate of 500-550 new ME/CFS patients/year. The remit of the GDG/Nice Guideline was to aid diagnosis as well as patient management. I fail to see how this can be properly done when the GDG has, on its own admission, failed to fully consider the substantial existing clinical and peerreviewed knowledge base. Conversely, the GDG has placed undue reliance upon a small number of RCTs that were methodologically flawed because they did not adequately define the patient population for whom the guideline was intended.

I also have to say that I was astonished to discover that the systematic evidence review (authored by Bagnall et al – York/CRD 2005), specifically commissioned to support the NICE ME/CFS guideline, omitted the serious concerns highlighted in their previous review of the same literature (JAMA 2001) that such evidence was seriously flawed.

I would be very happy to provide further testimony on these and related matters either in writing or to the court in person – health permitting.

Yours sincerely,

Terry Mitchell MA MD FRC-Path

Cc: Mr Kevin Short.