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24th August 2011/[redacted]

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Professor Longson
Director
Centre for Health Technology Evaluation
National Institute for Health and
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71 High Holborn
London WC1V 6NA

Dear Professor Longson

Please find attached a response to the NICE draft guidance on Fingolimod from investigators in trials across the UK. Given the timing of the deadline in August a number of colleagues had been unable to respond but are likely to add their support to this in due course.

Yours sincerely

[redacted]
Consultant Neurologist

Response to NICE decision on Fingolimod by UK trial centres

Dear Sirs

We are writing as multiple sclerosis (MS) centres with experience in the use of Fingolimod to express our disappointment at the NICE appraisal consultation document on the use of Fingolimod for MS (MS). We note the difficulties with the NICE decision on the first line disease modifying therapies which resulted in the "risk-sharing scheme" and the initial negative draft decision on Natalizumab that was later overturned. This suggests that there may be significant difficulties in how therapies in this complex area are appraised. This is reflected in the small numbers of patients who were part of the final economic model despite robust results from the appropriately powered phase 3 trials.

We are concerned to see that in the economic model one of the options offered to those patients who fail on a first line disease modifying therapy, as evident by ongoing relapses, to be best supportive care and believe that this does not reflect the standard of care provided in the UK and other developed countries.

We note that over 4000 patients have taken part in trials of this drug, totalling 14000 patient years of experience. This includes 265 patients in 24 study sites across the UK. The two pivotal phase 3 studies show a significant reduction in relapses not only compared to placebo but also a 52% reduction compared to a standard first line interferon therapy. We are particularly concerned that UK patients who have been on trials and continue to derive considerable benefit from this drug are allowed to continue to receive this therapy. We believe that this raises considerable ethical responsibilities.

There remains a limited number of therapeutic options available to people with MS. Therapeutic decisions require balancing risks and benefits and we believe that Fingolimod offers a strong therapeutic option to appropriately selected patients with aggressive disease including those who have failed first line therapies (the beta interferon group of drugs and glatiramer acetate) and where natalizumab may not be appropriate.

We would strongly urge NICE to reconsider this draft guidance and recommend its use in patients with active disease who fulfil the prescribing criteria.

Yours faithfully