Reetan Patel
National Institute for Health and Clinical Excellence
MidCity Place
London WC1V 6NA

Dear Sir,

Re: Single Technology Appraisal for Natalizumab for the treatment of Multiple Sclerosis - ACD

As a person with HARRMS I would like to make a number of points which I feel have not been adequately covered or addressed in the above document.

Do I consider that all of the relevant evidence has been taken into account?

No, I do not.

The entire document makes no reference to the actual experience of MS sufferers who have received Natalizumab and I believe that this aspect of discussion has been largely ignored. We have simply been treated as statistics. Although I was invited to attend the recent NICE first appraisal (March 6th 2007) and made a considerable effort to appraise myself of the background and discussion areas, when I attended the meeting I was barely spoken to at all. In fact I felt that the entire exercise was a waste of my time. I do hope that the sentiments and experiences of MS patients will be taken into account and that NICE will not simply focus on cost above all other factors. If the latter is your only concern, perhaps you would refrain from 'going through the motions' of involving patient experts in your discussions. On that day you seemed to have forgotten that patient experts are simply that - experts in their particular disease, their treatment and their results and experiences. We are not statistical machines and we are not data driven.

I believe that it is ESSENTIAL to evaluate the experiences of patients with MS and to factor this into your deliberations. This will reinforce in your minds the stark contrast in terms of quality of life and cost to the NHS, to life with and without Natalizumab. You cannot put a price nor place greater emphasis on a sustained relapse free period - which is what Natalizumab so effectively gives us. Over a 2 year period a person with HARRMS can expect 2-3 relapses, each relapse

lasting weeks or months with no guarantee of a recovery – even slight or partial. THIS is the stark reality for us - there is no guaranteed recovery, the damage has been done and there is no going back. You will appreciate that a decision made to participate in any drugs trial requires considerable courage and now, taking Natalizumab on the current trial is a little like being a member of 'The Last Chance Saloon' - Natalizumab IS our last chance, currently it is our ONLY chance. There is nothing else out there for us.

Do I consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence?

No, I do not.

Whilst I appreciate that the discussion about the cost effectiveness of Natalizumab is very important, I believe - as the document explores and concludes - that it is difficult to make a realistic and accurate comparison of the cost/benefit of Natalizumab versus currently used therapies and that this relies on a great deal of subjective extrapolation. In essence, you are comparing apples with pears - different treatments which have different outcomes and different track records in terms of duration of experience. I believe it is wrong to reject the treatment on the basis that you don't have enough health economic data of the right kind at this point. By doing so you deny patients the opportunity to experience a considerably better quality of life - a treatment that is twice as effective in the reduction of relapses and in delaying the progression of disability than any currently used therapies.

I know we are not living in an ideal world where every therapy can be paid for. However, I believe that the benefits of Natalizumab are considerable and that it makes sense both in a health economics and patient wellbeing context to approve the drug. I believe that if you do so - we will be able to conclude - in the fullness of time - that this does indeed make cost effective as well as humanitarian sense.

There is also the issue of emotional wellbeing and the emotional cost. The financial cost of Natalizumab is freely talked of but you also have to factor in the emotional costs placed upon our husbands, wives, children and parents - plus THEIR financial costs of taking care of us. That’s not just the odd day here or there, it is a consistent, relentless and unpredictable cost to them.

During the first appraisal a great deal of time and discussion was spent discussing the EDSS module but the results and relevance of this do not capture the essence of actually living with a progressive disease It is wrong to place emphasis and make a decision based on a result that is taken once a month during an infusion visit, under pressurised conditions and when the patient is acutely aware of 'being up against it'. Surely the results are more significant when

taken on a day in day out basis of patients living their lives - day to day life just as easily provides us with cognitive, physical and mental tests as a planned testing module.

The central focus for NICE should now surely be – 'How can we query value for money when Natalizumab represents the best evidence based treatment for MS in almost 30 years'?

This is fact and not assumption.

Do I consider that the provisional recommendations of the ACD are sound?

No, I do not.

To offer 'best supportive care' is not the right comparator, therefore it is not an option. We do not have the luxury of being able to accept a 'hold off' treatment package. We cannot accept just 'holding off' until (in your opinion) a more cost effective drug is found. This will take time and that is one thing you don't have when living with a progressive disease. MS is for life. Why should we be given this life sentence of a progressive disease to endure, when there is a remedy to ease that sentence? I, and many others, stand to benefit so much from Natalizumab and we should not be let down. It is self evident that we DO benefit from Natalizumab therefore we should be allowed access to it. There is no such thing as a risk free drug and all medication nowadays comes with a health warning - but with these health warnings there has to be a sense of proportion, and no more so than with the risk of PML. But I am an educated and well-informed woman, more than capable of making an informed decision for myself and I confidently say that, if allowed Natalizumab, I have so much to gain and nothing to lose from taking it for the rest of my life. MS is a treacherous disease with a host of debilitating symptoms - but one of the worst aspects is not the disease itself but its uncertainty and unpredictability. Therefore the knowledge that Natalizumab may not be available to me is unfathomable based on the clinical and patient evidence seen.

Caroline Haynes

April 18th 2007