

To: Anita James, SOL

From: R M Gutowski

Date: November 2003

Copies: Mary Trefgarne  
Davina Hampson  
Vicki King  
Jill Taylor  
Denise O'Shaunessy

**GRO-A v NEWCASTLE PCT**

1. I have now had the opportunity to consider the Judgement of Mr Justice Owen and the Witness Statement of Dr Claire Bradford in some detail.
2. It is clear that Newcastle PCT in reaching their decision as to treatment for **GRO-A** were heavily influenced by Health Service Circular HSC 1998/033 and the cost of the recombinant treatment that **GRO-A** was insisting upon. HSC 1998/033 sets out the background to the decision by the Secretary of State relating to the provision of recombinant Factor VIII for specific patients with Haemophilia A. In essence Health Authorities and trust were expected to ensure that new patients with Haemophilia A and patients with Haemophilia A under the age of 16 had access to recombinant Factor VIII. **GRO-A** did not fall into either of those two categories. The circular also stressed that the clinical care for recommending the general use of recombinant Factor VIII had not been made and that plasma derived Factor VIII had a very good safety record. It was therefore on this basis that the Newcastle PCT's Management Team decided that **GRO-A** should continue to receive clinically effective treatment, namely plasma derived Factor VIII.
3. I would just mention that HSC 1998/033 acknowledges the need that additional funding will be made available to provide the recombinant Factor VIII to implement the decision and the means for claiming the money is covered in HSC 1998/147 dated August 1998. HSC 1998/033 was then followed up by HSC 1999/999 which extended the Department's policy to provide recombinant Factor IX for new patients and children under the age of 16.
4. In her Witness Statement Dr Bradford makes reference to the Government announcement in February 2003 that extra funding over three years to provide synthetic clotting factors for all haemophilia patients, not just those under the age of 16, where these are recommended by clinicians. The level of funding available in the first two years means that not all patients can be move to recombinant initially and that a phasing process was required. A Recombinant Working Group was established to oversee the process and concluded that phasing in should be by age band rather than starting with

those seen to present a special case. I can provide relevant papers on the Working Group if you feel that Counsel would find them useful.

5. I am conscious that Counsel may want a Conference prior to the Hearing but you should be aware that I am on annual leave 17-19 November although I am coming into the office on the morning of 17 for a recombinant meeting. A Conference this week would be best otherwise could any written questions next week be directed to Jill Taylor.

R M GUTOWSKI  
PH6.6  
Room 633B SKH  
Ext GRO-C