Re

TBC 1

Important
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Subject: CJD - human growth hormone judgement
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please find attached a very brief note about today's judgement. My apologies this has been prepared in haste.

David Roberts
HCD SCS(B)1

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mobile GRO-C

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CONTAMINATED PITUITARY GLAND DERIVED HUMAN GROWTH HORMONE OR GONADOTROPHIN: THE JUDGEMENT : A BRIEF SUMMARY

1. We have now received the judgement of the High Court of Justice on this case. In brief, the judge has decided that the Department was negligent not to have suspended the human growth hormone (HGH) programme for new patients commencing treatment after 1 July 1977. This means that the Department has been found to have been negligent.

2. The judgement does not find that there was negligence in respect of patients who received the treatment before 1 July 1977 or who were already receiving treatment before this date and continued to be treated afterwards.

3. We believe that this excludes most of the plaintiffs (who were taking the HGH before 1 July 1977), probably leaving only 5 to 7 deaths, although there are likely to be further cases which have not yet developed into the disease.

Negligence

4. The judgement falls against the Department rather than the MRC because it was the Department who were responsible for the programme at this time. However, Departmental and MRC officials were heavily criticised. In particular the judge found that:

- there was no negligence prior to 1977 - basically because of the lack of evidence of the risk of contamination;
- although the initial reaction of the MRC staff to the first available evidence (October 1976) was good they then, showed a negligent lack of urgency delaying obtaining research and further expert advice for 2 years;
- the relevant (DHSS) committees (HSHGHC and the Committee for Safety of Medicines) were deliberately not informed of the risks by the medical and scientific staff of the Department (in the hope that the risk would never materialise);
- negligence is established in the failure to carry out a frank and informed reappraisal of the programme in the early months of 1977.

Line to take

5. The full judgement is complicated and we will not be in a position to comment until next week. In the meantime, the line to take is:

> **" We will study last Friday's judgement in detail and consider what response is appropriate. We remain committed to providing, through the NHS, suitable support and counselling to all patients treated with human growth hormone, or gonadotrophin, and their families."**

What happens next?

6. Lawyers will consider the judgement, it is likely that we will go back to Court in October.

(A background note is attached below.)

HCD SCS(B)1: 19 July 1996

BACKGROUND

FINANCIAL COMPENSATION FOR PATIENTS WHO HAVE RECEIVED TREATMENT WITH ALLEGEDLY CONTAMINATED PITUITARY GLAND DERIVED HUMAN GROWTH HORMONE OR GONADOTROPHIN

1. During the period 1959-1985 human growth hormone and gonadotrophin was extracted from pituitary glands taken from human cadavers. Growth hormone was used to promote growth in children who suffered a deficiency in this hormone. Gonadotrophin was used to stimulate fertility in women. In 1985 growth hormone was associated with the transmission of Creutzfeldt Jakob Disease (CJD), and these treatments were withdrawn.

2. Since then there have been 16 deaths from CJD among some 2,000 patients who received growth hormone treatment in the UK. There have been no cases of CJD amongst women (about 300) who received gonadotrophin treatment in this country, but 5 women who received this treatment in Australia have since died from CJD.

3. Litigation, against the Department and the Medical Research Council, has been undertaken by families seeking compensation for those who have died. Many former patients still alive, both growth and gonadotrophin recipients, await the outcome of the action. We expect that they will seek compensation for psychological damage caused by the anticipation that they too will contract CJD.

4. Judgement was issued on Friday 19 July. In brief, the judge found that the Department was negligent in allowing new patients to commence treatment from June 1977. He did not find that the MRC (or the Department) were negligent in respect of patients receiving human growth hormone (HGH) before that time or in respect of patients who were already receiving HGH before June 1977 who continued to receive it. The judgement criticised Departmental and MRC officials for their lack of negligent lack of action and urgency when the risk of contamination became known.

5. The Department is considering the implications of the full judgement (which is 85 pages long) before deciding on a response to the judgement.

FINAL VERSION OF BRIEFING AGREED WITH NBA 8/7/96

The safety of blood is kept under regular review by the expert Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation. There is no hard evidence of a link between BSE in cows and CJD in humans, and no evidence of any risk of transmission of CJD through blood or blood products. However, as a precautionary measure, individuals with central nervous system diseases or risk factors for CJD, including relatives of those who have died from CJD, are excluded from giving blood.