HM 15

Lord Hunt

From:Jill Taylor
HSD2

Date: 15 December 2000

Cc: Emma de Zoete PS/PS(L)
Alison Pitts-Bland COMMS
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MEETING WITH THE MANOR HOUSE GROUP – 18 DECEMBER 2000

Purpose of meeting

1. The Manor House Group wrote to you on 12 September asking to meet with you to discuss their case for compensation for haemophiliacs infected with hepatitis C through NHS treatment. You met with the Group last year and the same issue was raised. The Group is aware of the Government's position on compensation but their letter states that they have a "solution " to this issue that they wish to discuss with you. I have spoken to the acting Secretary Mrs Bullen, who declined to give me any details of their proposal preferring to speak with you first. Other issues that may be raised include compensation for people with variant CJD and provision of Recombinant Factor 8.

2. I have been advised the following are attending from the Manor House Group:

Mr David Tompkins - Chair
Mrs Monica Powell – Secretary – may not attend due to her husband's illness
Mrs Diane Bullen – Acting Secretary
Mr Peter Mossman – Member –

Background

3. Background notes are attached on:

A. Manor House Group and application for section 64 funding

B. Haemophilia and hepatitis C - compensation

C. Variant CJD – compensation

D. Haemophilia - condition

E. Provision of Recombinant Factor 8

F. Treatment for hepatitis C – NICE recommendations

Conclusion

4. The Manor House Group (and The Haemophilia Society) continue to press for compensation for those haemophiliacs infected hepatitis C through NHS products. The Government's decision remains that compensation or financial help is only given when the NHS, or individuals working in it are at fault.

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A

THE MANOR HOUSE GROUP

The Manor House Group was formed about 7 years ago as a campaigning and self help group for haemophiliacs with hepatitis C. The membership is UK-wide but mainly in the Midlands and North West. The Group broke away from the Haemophilia Society because they did not think the Society was pursuing vigorously enough the matter of compensation for haemophiliacs infected with hepatitis C.

Section 64 project funding

1. Following your meeting last meeting with the Manor House Group it was agreed that DH should try to ensure that the Group receive some funding from the Department's Section 64 fund for voluntary organisations.

2. An application for core funding for £10,000 for 3 years from 2000/03 was received on 10 November 2000. This was a very late application for a grant that should commence in April 2000. The objectives for using the core grant, outlined in the application, are to establish a small office run by employed staff and volunteers which will expand the existing support service to a nation-wide scheme offering emotional and practical support to those who require it. There are plans to have a 24-hour telephone helpline, an up to date library and free internet use to users. The group intends to offer advice on stress management and make available the support of a trained counsellor. The budget for this provided by the Group is £139,177 over the 3 years. There is no indication that other funding is actively being sought, which, if a £10,000 section 64 grant were awarded, would leave a shortfall of around £36,000 per year.

3. On speaking to the current Treasurer it was clear that although he had signed the application form for grant funding he was unaware of the contents, he had signed the completed form but had not read it.

Finances

4. The Group has submitted financial accounts for the period April 1999 to October 1999. These accounts show a gross income of £8,190. The application for section 64 funding provides an updated statement of accounts to October 2000 showing income as £10,939 (over 19 months) but this includes £1,500 from DH for purchase of a computer. **It is not clear from the accounts whether they have been properly audited.**

5. We know that there has been a discrepancy in the accounts that the Group has been unable to rectify with the previous treasurer - the Charity Commission has been informed. We understand there is also a problem with missing receipts for travelling expenses. It is clear there is very little money behind the organisation.

6. Section 64 grants are awarded on terms and conditions agreed by the Treasury. The Manor House Group has asked for a grant that exceeds their total income. In order to award more than 50% of voluntary organisations' income there are strict criteria

financial monitoring which the Group does not meet. If we awarded a section 64 grant for 50% of their income this would not achieve their objectives for core funding.

Conclusion

7. It is clear that the Group need much tighter financial control with proper accounts and auditing. The current application for a 3year £10,000 Section 64 grant will not meet the objectives set out in their application - costed at £46,000 each year and there is no indication that other funding is being sought. The Group has already been advised that they are unlikely to be successful. We have suggested that they meet with officials to discuss a more realistic application in 2001.

B

HAEMOPHILIA AND HEPATITIS C

1. A number of people with haemophilia were infected with hepatitis C through blood products up to 1996 before these products could be virally inactivated. As you know the Haemophilia Society has campaigned for many years for the Government to give financial assistance to these people, just as haemophiliacs who contracted HIV through blood were compensated in 1987. However, Ministers decided in 1998 that no financial assistance would be given. The previous Government came to the same conclusion in 1996.

3. The Haemophilia Society continues to press the case for financial assistance for haemophiliacs with hepatitis C and a number of PQs have been asked on this by Lord Morris, President of the Society.

Safety Measures

4. Since the mid 1980s blood products for haemophiliacs have been treated to destroy hepatitis C, hepatitis B and HIV as well as a range of other viruses. Fresh blood cannot be virally inactivated because the chemical treatment would destroy the blood.

5. Screening of blood donors for hepatitis C was introduced in September 1991. Early screening tests for hepatitis C were available from 1989 but had too many false positives and false negatives. Expert advice was not to introduce these early tests because they were not accurate enough to allow proper screening of the blood supply.

COMPENSATION

6. At present, compensation is, in general, paid only where legal liability can be established. The underlying principles are clear-cut and independently established under the common law. They apply to personal injury cases in general - not only those arising from health care. Compensation is payable where it can be shown that:

- a duty of care is owed by the NHS body; and
- there has been negligence (act or omission); and
- there has been harm; and
- the harm was caused by the negligence.

C

COMPENSATION FOR THOSE PEOPLE WITH VARIANT CJD

1. The decision not to compensate people with hepatitis C stems from the well-established policy that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. Screening of blood donors for hepatitis C was introduced in September 1991. Early screening tests for hepatitis C were available from 1989 but had too many false positives and false negatives. Expert advice was not to introduce these early tests because they were not accurate enough to allow proper screening of the blood supply.

2. The plight of individuals and families affected by variant CJD is, by contrast, the result of a unique set of circumstances for which society as a whole must bear a moral responsibility.

3. The Government is making £1 million available to fund care packages centrally and is strengthening the support that the national CJD Surveillance Unit is able to provide by recruiting additional staff and establishing a Managed Care Network to provide clinical and practical advice to those taking on responsibility for the care of patients with vCJD for the first time. We are *not* talking about no-fault compensation but ex-gratia payments for a group of people who because of exceptional circumstances, have endured and are enduring a particularly harrowing ordeal.

D

HAEMOPHILIACS

1. People with haemophilia are mostly male, with the women being carriers. Some female carriers also present mild symptoms of the disease and require treatment especially for surgery and at childbirth. Some rarer forms of haemophilia affect both sexes equally.

2. The number of people with haemophilia is likely to be increasing slightly. With the development of blood products to treat the disorder in the 1960s/70s, people with haemophilia increasingly had families. While genetic counselling and termination is a possibility, this is often difficult in a family with a history of haemophilia especially where there are good treatments and the family want male children.

3. In about one third of cases there is no family history of haemophilia, and the condition has arisen as a result of spontaneous genetic mutation.

4. Though the numbers with haemophilia and hepatitis C are relatively small, the underlying disease is said to make the hepatitis C more difficult to manage -liver biopsies cause bleeding even in non haemophiliacs and severe disease causes further bleeding disorder problems.

E

WHY ISN'T RECOMBINANT (SYNTHETIC) FACTOR 8 AND FACTOR 9 AVAILABLE TO ALL HAEMOPHILIACS AND NOT JUST NEW PATIENTS AND CHILDREN UNDER 16?

There is no evidence that recombinant Factors are more effective or safe than plasma-based products. However, we recognised the fears of parents of children and indeed all those receiving blood products about infectious agents, which may as yet be unrecognised and transmissible through blood. We therefore instructed health authorities to provided recombinant products to new patients and children under 16 with haemophilia. Patients outside these categories can receive them if they are prescribed for them. I will be meeting with the Haemophilia Society on 20 December to discuss this issue further.

Background

Recombinant Factor 8 is a synthetic clotting product used in the treatment of haemophilia. Understandably, when action was being considered to protect the public against the theoretical risk of vCJD, people with haemophilia and their families were particularly worried in case vCJD could be transmitted through blood.

We asked NHS Trusts and Health Authorities to make recombinant Factor 8 available to new patients and children under 16 from 1 April 1998 and Factor 9 from April 1999. Patients who receive the recombinant product will continue to receive it after age 16.

The requirement to provide these products for young people and new patients does not mean that others outside these categories cannot receive the treatments, if they are prescribed for them. However many clinicians will be deterred by the additional costs of using recombinant products.

Scotland, Wales and Northern Ireland have adopted a policy of providing recombinant clotting factors for all patients. Haemophilia Society and the UK Haemophilia Doctors Centre Organisation will be meeting PS(L) on 24 January to discuss this issue further.

F

TREATMENT FOR HEPATITIS C

1. The outlook for the treatment of hepatitis C is improving. In 1995 the first treatment, an antiviral therapy, became available. Interferon with ribavirin was licensed last summer. The National Institute for Clinical Excellence (NICE) were asked to review all the evidence on the effectiveness of ribavarin and alpha interferon therapy and having assessed the evidence to give recommendations on its clinical effectiveness. On 31 October NICE published its recommendations that patients suffering from moderate or severe hepatitis C should be given a combination of the drugs.

2. The indications are that the newly licensed combination therapy (alpha interferon with ribavirin) is considerably more effective than interferon monotherapy (40% against 20% or less). On 31 October 2000 guidance was issued to all NHS bodies and clinicians following NICE recommendations and the NHS allocations announced earlier this year included provision for funding these.

3. In a speech to the NICE conference on Thursday 30 Nov 2000 SofS said:

"I can also announce today that we will introduce explicit monitoring so that we know that every health authority and NHS trust is taking full and proper account of each NICE appraisal. Monitoring will take place shortly after the publication of each NICE appraisal and then six months later to track progress on implementation. The Commission for Health Improvement will then incorporate successive NICE appraisals into its routine clinical governance monitoring".