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From: Peter Martin PH-BSEI

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BSE INQUIRY: LITIGATION/COMPENSATION

1. The Secretary of State asked for briefing on litigation and compensation in advance of his meeting with officials at 11.15 am tomorrow. I am attaching briefing on:

   - Human Growth Hormone and CJD litigation;
   - A general note on "no-fault" compensation; and
   - Hepatitis C and HIV in haemophiliacs.

2. I am expecting the following officials to be present at the meeting tomorrow: Pat Troop; Anita James and Greer Kerrigan from Sol; Margaret Jackman from MCA; Alan Harvey from PH6A; and Brian Bradley and me from the Liaison Unit.

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Background to Human Growth Hormone (hGH) and CJD Litigation

Pituitary derived hGH was used between 1959 and 1985 in treating children who suffered from growth hormone deficiency. The treatment allowed them to attain their full height potential. The hormone was obtained from pituitary glands taken from corpses at post mortem. Over the years the treatment gained an international reputation for success and was used worldwide.

In this country the process was originally performed within hospital and research laboratories. The manufacturing process was later transferred to the Centre for Applied Microbiological Research at Porton Down because of apparent defects in local practice - i.e. the hospital and research laboratories lacked the space and facilities to undertake the scale of production necessary to satisfy demand within the standards associated with good manufacturing practice.

Treatment with hGH ceased in May 1985 following the death of a hGH patient in America from CJD - a rare and incurable form of spongiform encephalopathy with a protracted incubation period and a transmissible agent that is highly resistant to sterilisation. A genetically engineered substitute has been in use since 1985.

Court Action

In November 1993 a Summons was received from solicitors seeking damages from the MRC and the Secretary of State on behalf of the dependants of one of the first hGH patients to die in the UK from CJD in 1990.

The action was heard in the High Court and judgement was given on 19 July 1996. The findings were that negligence was not found against the MRC at any time; and that the Department of Health had failed in its duty of care in the administration of the hGH programme. Following an appeal by the plaintiffs Mr Justice Morland reviewed his earlier decision and determined the following criteria of awarding damages when a hGH patient dies of CJD:

- they must have received hGH prepared according to the Wilhelmi or Hartree Wilhelmi protocol;

- at least 50% of their treatment with the Wilhelmi or Hartree Wilhelmi must have occurred after 1 July 1977; and they must have died of classic CJD.

The Department has paid compensation to those who were successful in the court action. Additionally compensation in damages, on the same terms as that decided by the court, will be paid to any hGH patient who contracts CJD in the future and meets the criteria set by the court. As CJD cannot be positively identified until after death, we will consider the payment of an interim award of damages to any patient who, in the opinion of clinicians expert in this area, appears beyond reasonable doubt to have classical CJD (i.e. not the variant of CJD associated with BSE).

Procedure for claiming compensation

This will commence when a person who has been treated with hGH starts to develop the symptoms associated with CJD. Their representative, usually next of kin, will contact a solicitor to take the case forward (normally Irwin Mitchell the lead solicitors in the court case). The solicitor will then lodge a claim with our legal branch seeking to establish that the claimant satisfies the criteria for compensation set by the court. We will then seek to confirm with the medical team caring for the patient, as far as can be confirmed before death, does have CJD. If the CJD diagnosis is confirmed, and the claimant satisfies the criteria set by the Court, compensation will be paid. If requested we will make an interim payment.

The amount of compensation is determined by negotiation between the two legal teams, in line with the tariffs set for compensation in similar cases. Compensation is based upon loss of amenity, pain and suffering, loss of future earnings, cost of care etc. In each case the level of compensation is based upon individual circumstances i.e. age, dependants, possible future earnings etc.

Examples of Compensation

Example 1 - a consultant orthopaedic surgeon in his early/mid forties with a wife and two dependent young children. Compensation was based upon the cost of care whilst he was ill, the loss of expected future income, together with that of his wife who will now be the sole parent, elements for loss of amenity, pain and suffering and other miscellaneous items. In this case the final settlement came to £1.4m.

Example 2 – an unmarried women in her mid/late thirties with no dependants and in a low paid job. Compensation was based upon cost of care while ill, loss of future income, elements for loss of amenity, pain and suffering and other miscellaneous items. In this case the final settlement came to £30,000.

Both these cases are the extreme, but demonstrate the possible variances in those who may claim compensation. The average claim for compensation in the hGH/CJD litigation (excluding psychiatric harm) is about £100,000.

Psychiatric Harm

A further legal action was brought by those hGH patients who are claiming psychiatric harm as a result of knowledge that they are at risk of contracting CJD. The judge heard representations on this at a hearing between 25 and 27 November 1997 and, gave his finding on 18 December 1997. In summary, the Department was found negligent and those who satisfy criteria set by the court were entitled to compensation.

BRIEFING NOTE ON 'NO FAULT' COMPENSATION

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

2. In the NHS, 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.

3. The Royal Commission on Civil Liability and Personal Injury (1978), under Lord Pearson, came down against compensation for non-negligent harm in clinical accidents. However, as Ministers are aware from recent approaches, there are periodic calls for a no-fault compensation scheme to be adopted, often in respect of specific groups, including research subjects. Such calls are generally based on recognising the harm that has actually arisen (and/or, as some groups claim, might become apparent) as a result of NHS treatment, rather than its cause. There is also, of course, understandable sympathy for people who have suffered serious damage at the hands of a service in which they had placed their trust.

4. The principal counter-arguments to a no fault scheme are:

i. that victims of medical accidents would be compensated differently from those harmed in other ways;

ii. that it would (presumably) not assist people with congenital disabilities or who had been disabled though the natural progression of an illness or disease;

iii. that it could be just as difficult to establish that medical treatment had caused injury as to prove that someone had been negligent. The amount of compensation would still have to be established. Legal action (and legal fees) would not necessarily be avoided and the process could still be lengthy;

iv. that a substantial increase in costs falling on the NHS is likely thereby reducing the money available for direct patient care. There might also be cost implications for other parts of the public sector and so Treasury opposition could be anticipated;

v. that the cost burden of meeting injury claims would be shifted relatively from those who were negligent to the community as a whole and, by extension, to injured people themselves

vi. (as some argue) that the resulting "no fault" culture could diminish clinical accountability and the reassurance sought by patients that what happened to them will not subsequently happen to somebody else.

Costs

5. No reliable estimates are available. An intensive study would be necessary to establish these. However, independent estimates suggest that a 'no fault' scheme would cost the NHS £360m a year.

Health Select Committee Inquiry Report: Procedures related to adverse clinical incidents and outcomes in medical care

6. The Committee recommended that the "Department of Health reviews the issues and publishes a consultation document on the possible introduction of no fault compensation in the NHS."

- In its response the Government stated that it is "reviewing a range of issues relating to the payment of compensation in the NHS. There is no question that those who are damaged as a result of negligence should be able to obtain appropriate and adequate compensation. The key issue is to find the best way to provide it. The introduction of a no fault compensation scheme would have far reaching policy and financial implications which would need to be explored very carefully. The Government will take account of the Committee's views in considering these issues".

Ex gratia payments and specific compensation schemes

7. Exceptionally NHS bodies may, within delegated limits, make *ex gratia* payments on the merits of individual cases. Where clinical negligence is involved and a settlement has been negotiated following legal advice, the upper limit is £1m. In other cases, including those involving non-negligent harm, £50K is the maximum. According to the nature and severity of injury, a range of social security benefits, as well as health and social services may also be provided.

8. Exceptions to the "no fault compensation" rule is a scheme for paying people suffering vaccine damage which was established on public health grounds (Vaccine Damage Payments Act 1979) and is administered by the Social Security Benefits Agency.

9. The other scheme is for haemophiliacs and others infected with HIV through blood transfusions which was introduced because of the very special circumstances - and climate of the time - and was not intended by the previous Government to be a precedent.

10. A separate note has been provided by HSD3 describing the human growth hormone (hGH) and CJD Litigation and associated compensation 'scheme'. The Department accepted a High Court ruling that it had failed in its duty of care -had been negligent - in the administration of the hGH programme and has paid compensation to those who were successful in the court action. Additionally, compensation in damages, on the same terms as that provided by the court, will be paid to any hGH patient who contracts CJD in the future and meets the criteria set by the court.

HEPATITIS C LITIGATION: BRIEF

Background

The litigation

The Hepatitis C litigation against the National Blood Authority is being brought to-day (10 October) on behalf of 111 claimants, who were infected with Hepatitis C through blood transfusions between **March 1988 and September 1991**. The case is being heard at the Royal Courts of Justice. The case is expected to run until after Christmas and is being brought under the Consumer Protection Act 1987. The legal arguments all revolve around the testing of blood for Hepatitis C. The Department of Health is **not** a party to the litigation. However the Department is roundly criticised in the claimants opening submissions for slow implementation of HCV screening of the blood supply.

Hepatitis

Hepatitis is inflammation of the liver. There are many different causes of hepatitis including alcohol, drugs, chemicals and infections especially viruses. Hepatitis due to infection is a major public health problem world-wide. The most common viruses that cause hepatitis are hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Both HBV and HCV can be transmitted by blood. HAV is usually transmitted by poor hygiene and only rarely through blood. There are around 300,000 people in the UK with HCV. An estimated **3,000 people are thought to have been infected through blood transfusions before a reliable screening test for HCV was introduced in September 1991.** The prevalence of hepatitis C in blood donors is now about 1/250,000. It is now very rare to have HCV infection following blood transfusion but it does occur when the blood donor is in a very early stage of the infection at which time tests can be all negative.

Hepatitis C and HIV in Haemophiliacs:

In England, around 4,000 haemophiliacs were infected with HCV before blood products began to be heat treated to inactivate viruses in 1985. About 1200 of these were also infected with HIV before a test became available to screen the blood from which the blood products they needed were made. People receiving blood and blood products were recognised at risk of hepatitis C and in the 1970s and 80s research was actively looking at ways of reducing this. For blood itself the focus was on screening it for infectious agents and excluding infected blood from the supply. For blood products there was the additional possibility of treating the blood plasma from which they were made with heat and chemicals to inactivate the infection. In the early 1980s transmission of HIV through blood and blood products was also recognised. HIV screening of the blood began in 1984 and effectively eliminated the infection from the blood supply and from blood products made after this time. The technology for inactivating viruses in the blood plasma from which blood products are made only became widely available from 1985.

At the time of the introduction of virally inactivated blood products in 1985, 98% of haemophiliacs were already HCV positive. Since then transmission of either Hepatitis C or HIV has been minimal usually due to some failure in good manufacturing practice.

What blood tests are now carried out on blood

All blood for transfusion is tested for Hepatitis B, Hepatitis C, HIV and Syphilis. Every donation of blood has been tested for Hepatitis C since 1 September 1991. Since the mid

1980s the plasma used to manufacture blood products (such as clotting factors for haemophiliacs) has been treated to remove viruses such as Hepatitis B & C and HIV.

HCV and compensation for Haemophiliacs

We have resisted compensation or special payments for haemophiliacs infected by hepatitis C through blood products on grounds that the NHS was not at fault and that state of the art treatment was used at all times in their treatment. The fact is that the technology to make blood products free from hepatitis C, in sufficient quantities to treat all haemophiliacs in the UK, was simply not possible prior to 1985. Once it was, the NHS introduced it. Government policy remains that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. The Haemophilia Society have a continuing active campaign underway seeking compensation.

There have been several representations to the Prime Minister and senior Ministers about the issue and Lord Morris is President of the Haemophilia Society. In addition there have been numerous PQs and debates over the past three years with support for the case for compensation from MPs of all parties. We support the Haemophilia Society with considerable S64 grants to support people with HCV and NICE have recently approved combination anti HCV treatments.

Haemophiliacs infected with HIV through blood products in the 1980s?

1200 haemophiliacs were found to have developed HIV through the blood products treatment they received in the late 1970s and early 1980s. HIV litigation was underway in 1988 but a settlement was reached in 1988 and a system of special payments introduced and extended in 1992. The financial arrangements and ongoing support for **the remaining 450 haemophiliacs infected with HIV** continues to be administered by the MacFarlane Trust set up by Government at the time.

In general, compensation is only given for those who suffer negligent damage from NHS treatment. The payments to haemophiliacs with HIV were made in exceptional circumstances – life expectancy at the time for haemophiliacs with HIV was dramatically reduced and there was no treatment. In addition, there was huge stigma attached to those infected no matter how the infection was acquired.