ANNEX A

THE DEPARTMENTAL RESPONSE TO NON-NEGLIGENT HARM: A GENERIC APPROACH

Introduction

1 There are many examples of drug reaction and medical treatments given in good faith where non-negligent harm has occurred and those suffering as a result could press for Government compensation. We have resisted calls for payments to those who have contracted hepatitis C (or CJD) through NHS treatment along with calls for a no fault compensation scheme for medical accidents in the NHS. Each time a concession is made it becomes more difficult to re-establish a credible ring fence to prevent further movement towards a general no fault scheme for medical accidents.

2 The sources of such non-negligent harm might be divided for convenience between:

i) reaction to drugs (or problems with medical appliances). This usually involves the NHS administering a proprietary product. If there are injurious effects the commercial manufacturers are usually the primary target for compensation, although the regulatory authority (MCA or MDD) might also be a possible target.

ii) Vaccine damage. The special feature of this is that the intervention is given primarily for the benefit of the population as a whole rather than for the sake of the individual alone. As a result the Government set up a vaccine damage compensation scheme.

iii) Infection arising from the transfer of blood, blood products, tissue or whole organs (transplants) from one body to another. Such products or services have been provided exclusively, or to a major extent, by the NHS. Commercial companies would only be involved if they were responsible, eg. for a commercial blood product. (In the case of the HIV haemophilia scheme this was not separately addressed because of special circumstances.)

iv) Medical damage caused by exposure to medical hazard associated with war. This might cover circumstances such as the radiation damage experienced by veterans of the early atomic bomb tests or "Gulf War syndrome". These are strictly matters for the MoD but any action by the DH might create a precedent.

3 Category (iii) would include transmission of HIV (AIDS), HCV (hepatitis C) and the agent that is alleged to cause CJD. Whilst these conditions have very different characteristics they can be ring fenced in the way shown above. This paper will seek to develop a generic response to non-negligent harm caused in this way.

Litigation

4 Before going any farther it is essential to determine whether there is a case to answer so far as negligence is concerned. This will vary from case to case. Assuming causation is accepted (and this may itself be a major contention) then it will depend very much on the circumstances and in particular on the state of medical knowledge at the time. If it can be shown that everything was done that could reasonably have been done then the NHS may have a sound defence. If on the other hand there is evidence that an individual medical practitioner has made a mistake this will be a matter for settlement by the Health Authority with the possibility of the practitioner facing GMC investigation if appropriate. Where the Department, or a substantial proportion of the NHS did not act responsibly then it will be for the department's lawyers to decide the best way of settling any cases brought. The Department may elect to settle out of court rather than be found negligent.

5 Litigation can be exceedingly expensive to all parties concerned and take a very long time although such considerations should not be the sole determinant of whether to defend, particularly where a major principle is involved. Nevertheless such factors do make the prospect of no fault compensation very attractive. Where there is no proof of negligence then any financial help given to a litigant would be linked to a payments scheme for assistance rather than by way of compensation. It would be essential to ensure that such payment prevented the recipient subsequently suing on generic issues.

No fault compensation

6 The Government opposes no-fault compensation for five reasons;

i) the proof of causation is still needed, and it could be just as difficult to establish that medical treatment had caused injury - and that it was not a foreseeable and reasonable result of treatment - as it would be to prove that someone had been negligent;

ii) there would be unfairness to others, in that those disabled as a result of a medical accident would be compensated but those disabled as a result of disease would not:

iii) it is quite possible that the costs falling on the NHS could increase substantially and this would inevitably reduce the amount available for direct patient care;

iv) negligence in the health care field is not considered to be fundamentally any different from negligence in any other walk of life, where claims for compensation are resolved through the courts; the present system arguably has a deterrent effect on malpractice and no-fault compensation could conceivably make doctors less careful.

v) in those countries which have such a scheme, the amounts payable are very small in comparison to what a case would win in the courts. For example, some of the countries which had schemes had to top up the standard no fault compensation payments in the case of HIV transmission by blood products.

What the Government can do

7 The whole adversarial nature of litigation puts the Government into a position where its reaction to a tragedy appears at best to be limited to sympathy and at worst denial of both liability and any help. There are clear advantages in being able to offer a more positive line.

8 There are a number of ways in which those infected non-negligently can be helped, including the full range of health, social and security services provided by the government. These provide a "safety net" albeit at a somewhat lower level than might be offered under a no fault compensation scheme. But no distinction is made between those whose condition or injury was caused by heredity, by disease or as a result of NHS treatment. In particular:

i) the NHS provides health care needs;

ii) social needs may be met through the local authorities;

iii) a whole range of social security benefits are provided by DSS (some on a means tested basis and some obtainable by all).

9 These factors are particularly important when comparisons are made with other countries in many of which Government does not provide these services.

What the NHS can do

10 So far as the NHS is concerned there is need:

i) to undertake whatever research may be appropriate to determine the cause of the infection, the aetiology of the disease and its treatment / management.

ii) to draw up and publish good practice guidance on treatment and ensure that all affected have proper access to facilities.

iii) to determine whether there are ways of identifying those who may have been affected (eg. by using "look back" procedures) so that they may be notified, counselled and any prophylactic action taken or treatment given.

iv) to support any self-help initiatives (eg. through S64 funding).

v) in the case of blood borne infection to take whatever steps are needed to secure the safety of the blood supply.

Payments schemes

11 In some cases the Government may decide that the circumstances of the case, the weight of public opinion or political pressure may make the introduction of some form of payment without admission of negligence either appropriate or inevitable. Any scheme would need to:

i) limit payments to those who could prove (or there was a clear presumption) that they have been directly or indirectly affected;

ii) establish a proper scheme with clear rules and procedures approved by Ministers and Treasury;

iii) grade the payments according to the extent of the harm and/or the need of the individual (where this is practical);

iv) include an appeals mechanism to judge difficult cases where the evidence is not clear cut (eg. against Judicial Review).

12 Consideration might also be given to the need to establish a discretionary trust scheme to provide assistance to the social care needs of those affected (possibly including their dependants).

CA OPU
10 February 1995