CD-29JUN

HAEMOPHILIACS : AIDS LITIGATION

This note invites Ministers to review the government's position in the legal action involving HIV-infected haemophiliacs in the light of:

(i) a statement from the judge, Mr Justice Ognall, inviting the parties to consider an out-of-court settlement (Flag A)

(ii) advice from Counsel

(iii) a submission from Regional Directors of Public Health (RDPHs) critical of the Government's present stance (Flag B).

Leading Counsel, Mr Andrew Collins, stands ready to advise Ministers further on the next steps.

Current Policy

2. Ministers have so far based their policy on the recognition that we have a strong legal case, and that to settle out of court (thus implying we were unsure of the outcome) would set a disastrous precedent. In particular,

(i) Ministers have agreed that we should taken an early opportunity to argue that government has no duty of care to individual patients but only to the public in general. Establishing this principle is crucial to head off other potential litigation, GRO-D ;

(ii) similarly, we wish to establish the principle that the courts should not attempt to "second guess" ministers' decisions on matters of policy such as resource allocation;

(iii) even if these general arguments fail, we would still be able to argue that Government action at every stage was reasonable in the light of the state of medical knowledge at the time;

iv) if we settle (especially at this stage) it will raise expectations that Government will be prepared to give substantial compensation in any similar case in which NHS patients suffer as an unintended by-product of their treatment. In effect, we would be opening the gates to the principle of no-fault compensation for medical accidents without any rational debate of its merits;

(v) if a settlement for the haemophiliacs had the feared result of encouraging litigation in other comparable cases this would not only be hugely expensive: it might also encourage over-defensive licensing decisions, medical treatment and prescribing, undermine confidence in the licensing arrangements and make it more difficult to persuade experts to sit on the Committee on Safety of Medicines (CSM) and other advisory committees.

The Government has therefore made clear that it denies either legal or moral liability and will fight the case on its merits. This is consistent with the stance taken on similar instances (GRO-D GRO-D) involving the government as the Licensing Authority and the CSM.

The Judge's Statement

3. The statement from Mr Justice Ognall, the trial judge, starts with what appears to be a broad hint that the Plaintiffs will have great difficulty in winning their case. He then goes on to suggest that the government, irrespective of any question of negligence, could be said to have a moral duty to take into account the particular circumstances of the plaintiffs - in particular the fact that they have suffered for no fault of their own "under the aegis" of NHS treatment, and that many will die before the litigation is resolved (colleagues advise that this last point is exaggerated). He suggests that the law should not "be made a scapegoat" for what may be seen as a denial of plaintiffs' just rights. Finally, he invites all parties to consider a compromise and offers to help, for instance in determining the quantum of any compensation.

4. The judge's statement gives unexpected confirmation of our assessment of the chances of legal success. Of course, the legal action is still at a fairly early stage - for instance, the judge has not yet seen submissions from the expert witnesses on either side - and the crucial passage in the statement is carefully worded. But it is clearly intended as a warning to the plaintiffs not to overestimate their chance of success.

5. However, the judge's quite unprecedented statement also emphasises the high costs, political as well as financial, if the current policy goes wrong. Throughout the proceedings he has given the clear impression that his sympathies are with the plaintiffs and - if they manage to put a convincing case together - that must increase the likelihood that he will decide in their favour and that any award would be very expensive. Even at this stage, if the substance of the judge's comments are publicised that will increase the public pressure on the government to act. (Fortunately, as far as we are aware, circulation has so far been limited to the London solicitors and counsel for the various parties; the judge stressed that his statement was made in strict confidence.)

<u>Counsel's Advice</u>

6. Andrew Collins, our leading Counsel, has confirmed his earlier view that we have a very good chance of a successful outcome for the great majority of cases. In particular, he considers that the plaintiffs could not sustain a case against the Licensing Authority and the Committee on Safety of Medicines. (There are a small number of cases, - some involving plaintiffs who can prove that they were infected at a relatively late stage in the developing understanding of the method of transmission of AIDS, and an even smaller number in which the plaintiffs may be able to argue successfully that they were treated with unnecessarily large quantities of Factor VIII, - for which the legal arguments are more finely balanced.) Counsel agrees that if we successfully defend this case it should discourage future litigation.

7. Mr Collins also said that in his experience for a Judge to make comments of this nature was unique. On the face of it we could ask the Judge to disqualify himself from further involvement in the case on the

basis of bias but he did not consider that the Central Defendants should take the lead in such an application. He felt happy to support an application if other defendants or plaintiffs made one, but if he was to initiate such an application himself he considered he would need express instructions from the Attorney General to do so.

8. Counsel nevertheless suggests that we should consider seriously the judge's proposal. His personal view is that the government would do well to make a further 'political' gesture to avoid the embarrassment of a legal wrangle likely to continue through the whole of 1991. He believes that this could be contrived in a way which would avoid setting any legal precedent for other groups (see below). He accepts that any kind of deal might arouse expectations that other groups could look for similar treatment if they mounted an effective public campaign linked to legal action, and that the final judgement is a political not a legal one.

The Submission From RDPHs

9. Following a meeting earlier this year CMO invited RDPHs to put their concerns in writing and the result is at Flag B. RDPHs argue that the HIV-infected haemophiliacs are indeed a special case, because their condition is incurable and fatal, has an insidious effect on family relationships, and carries with it an unmerited stigma. They believe that the public would welcome further special treatment for this unique group and that such a settlement could be 'ring-fenced'. In contrast, fighting on uses up scarce legal and management resources and puts a strain on the relation between haemophiliacs and their doctors, many of whom are implicated in the litigation.

Discussion

10. On one possible view, neither Mr Justice Ognall's statement nor RDPHs' submission significantly changes the balance of the arguments between the current policy of fighting on and the alternative of seeking an out-of-court settlement. (Ministers will recall that when it was agreed last December to make the ex gratia payment of £20K per family, the alternative option of an out-of-court settlement was explicitly rejected.) If the statement is publicised and there is renewed pressure

on the Government to take a more compassionate stance, we would stand by the argument that the Government has already shown its compassion by the £20,000 lump sum and by promising that the original Macfarlane Trust will receive the additional funds it requires to meet genuine cases of financial need. In addition, we could point out that some of Mr Justice Ognall's reasons for urging compassion are in fact very general and would, if taken to their logical conclusion, justify introducing the principle of no-fault compensation for a wide variety of medical accidents. It would be wrong - so we might argue - for Government to overturn the conclusions of the Pearson Commission simply on the basis of a single case. Moreover, even though the original £20K payment did not (as hoped) deter any plaintiffs, it is possible that as the case comes closer to trial, and the expenses mount, more and more plaintiffs may drop out. The judge's remarks may ultimately help to bring this about if it becomes plain that the government will not back down.

11. In short, there are some valid arguments for maintaining the current position in its essentials. This would be perfectly compatible with some modest additional help for the haemophiliacs through the Macfarlane Trust, as already agreed in principle, subject to negotiation with Treasury - see para 16 below.

12. However, Ministers may wish to take the opportunity of the Judge's intervention to review again whether the present approach towards the litigation is the correct one. After all, the government has already recognised the special plight of the haemophiliacs in setting up the original Macfarlane Trust and in the subsequent ex-gratia payments. If any change were to be considered, we would need to consider how far it would be possible:

(i) to limit the immediate costs;

(ii) to reduce the risk of knock-on effects.

A number of possible options could be considered. All would require additional funding, which would not be easy to secure. If ministers wish to consider any of these further, Counsel has offered to give further advice on the choice of options and the methods which could be used to put them into effect.

13. The simplest option (A1) would be for the government to announce that it had reassessed the position of the HIV-infected haemophiliacs - for instance, in the light of new evidence on the number of infected spouses - and had decided to increase the lump-sum ex-gratia payment (or the funding of the Macfarlane Trust). No out-of-court settlement would be offered. But a substantial increase in the ex-gratia payment would put the government in a stronger moral position and it might be possible to start using more aggressive tactics to put pressure on plaintiffs to drop out before the trial proper starts in early 1991 (see para 15 below). Against this is the "Danegeld" argument - each further concession increases the expectation that the government will eventually capitulate completely. It is relevant to note that very few plaintiffs dropped out after the announcement of the £20K ex-gratia payment, indeed quite the opposite. An alternative (A2) which avoids this trap is to try to force the legal case to collapse and only then - having won the legal argument - to offer a further ex-gratia payment.

14. A second approach (B1) would be to invite Counsel to negotiate behind the scenes for a settlement which would then be presented as an ex-gratia payment, on the unspoken understanding that the great majority of plaintiffs would drop out. The danger of this approach is that even if the behind-the-scenes negotiations were kept secret, it would be widely assumed that the government had, in effect, admitted liability and had settled to avoid the risk of losing in court. The same difficulty applies to the variant (Option B2) of an explicit out-of-court settlement, whatever form of words is agreed as part of the terms of the settlement.

15. A further approach would be to take up the suggestion of a commission of enquiry. This could be used in one of two ways:

(i) the commission could be asked to consider whether the haemophiliacs constituted a sufficiental special case to justify a further ex-gratia award; and if so, on what basis (Option C1). This option could well prove more costly in the short-term than any form of out-of-court settlement but it does have the advantage that a form of 'ring-fence' is built in from the start. (There is, of course, some risk that the commission would

conclude that both the haemophiliacs and other categories of medical accident should receive compensation.) One disadvantage is that if the commission were to do their job thoroughly there is no certainty that they would be much quicker than allowing the litigation to take its course;

(ii) alternatively, an out-of-court settlement could be linked to a commitment to review the general case for a no-fault compensation scheme for medical accidents (C2). This would signal the government's wish to respond to public sympathy for this particular group of patients, without making unwise changes to policy (or setting the precedent for such changes) on the basis of a single case. The likelihood is that the review would confirm the findings of the Pearson Commission against any form of general no-fault compensation. However, there is a risk that the review itself would be coloured by the favourable treatment given to haemophiliacs - it is unlikely that it would conclude that this treatment was unnecessary - and so that the outcome would be exactly the opposite to that intended. It would also in practice be impossible to limit the review to medical accidents, since other types of accident (eg major transport accidents) raise similar problems of the moral responsibility of government to help innocent individuals who are harmed by some public sector agency. For these reasons, any proposal for such a review would have to be cleared with a wide range of interests including the Home Office, DTI and Treasury, all of whom would be likely to be very resistant.

Costs

16. Whichever of the options was selected, it would almost certainly be necessary for political reasons to extend any further payment to all the 1200-1400 or so HIV-infected haemophiliacs and their families, not just the 800 who have joined in the action. RDPHs have estimated that a settlement could be bought at a cost of perhaps £50K per family on average or £60-70m altogether (some £36-46m over and above what has already been paid). This seems a reasonable estimate, though we would seek Counsel's confirmation if Ministers seriously wish to consider any of the options. Any sum of this magnitude would need to be agreed by

the Treasury and it is extremely unlikely that they would readily agree - particularly because of the possible knock-on effects to other cases, however well we try to ring fence any offer.

17. Ministers may wish to note that Council estimates the cost of a trial at up to £10m. He further estimates very roughly, as the plaintiffs circumstances are not known, that if we lost compensation would be in the order of £100-150m.

Conclusion

18. Officials have found it difficult to reach a consensus view on what is a fairly unpalatable set of options. There is clearly no certainty that any of the options outlined in paras 12-15 would be effective in "ring-fencing" any further special treatment for the haemophiliacs. However, the haemophiliacs have caught the public sympathy and there are grounds for arguing that their precise circumstances - a high degree of harm which cannot be clearly linked to the negligence of any agency - are unlikely to be repeated in any other group. Ministers will need to judge whether the political costs of maintaining the present line outweigh the risks of setting an expensive precedent if some further easement is offered.

Handling

19. If Ministers agree to fighting on, we will need to discuss with Counsel the best way in which this decision should be communicated to the Judge and to the plaintiffs' solicitors. The aim should be to maximise the effect on the plaintiffs - to persuade as many as possible to drop out at this stage - while minimising any adverse publicity. Counsel has suggested some additional ways of putting pressure on the plaintiffs (eg pointing out that Government will be looking to recover full costs from any plaintiffs who continue and eventually lose) although the immediate political cost of this ploy would have to be carefully weighed against the possible benefit of an early end to the litigation. In parallel, we could prepare defensive briefing or speaking notes for Ministers to emphasise, if necessary, how much the government is already doing on behalf of haemophiliacs.

20. If Ministers prefer to explore the other options, we will prepare alternative handling advice. We would also need to consider an early approach to Treasury. We will need to make some response to the judge by the end of September.

21. Either way, Secretary of State may wish to minute the Prime Minister with his proposals in the light of her earlier interest. He may also wish to consult the Law Officers, perhaps by way of an official approach to their secretariat.

Decision Required

22. Ministers are invited to consider whether to fight on, or to invite officials to explore with Counsel ways in which further special treatment could be ring-fenced. Ministers are also invited to agree that officials should:

(i) work up with Counsel detailed proposals for communicating their decision to the trial judge, plaintiffs' solicitors, and the public;

(ii) prepare a minute for Secretary of State to send to the Prime Minister;

(iii) take advice of the Law Officers' secretariat.

23. Ministers may wish to hear Counsel's advice at first hand before deciding.

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