Ref: Arth1910

HIV/HAEMOPHILIA LITIGATION

CURRENT POLICY

Litigation

1. Following previous discussions with Ministers, the Department and the other 'central defendants' in this action (Committee on Safety of Medicines; Licensing Authority; Welsh Office) are presently acting on the policy that the Plaintiff's claims should be put to the Courts, and that all allegations of negligence should be contested. Officials know from a meeting with representatives of the other defendants (Health Authorities) that they are assuming the same stance. Facts are still being collected for Counsel, but officials believe all the Plaintiff's allegations can be successfully countered. It is also known that the Haemophilia Society sought legal advice some time ago on whether actions for negligence might succeed; they were advised against pursuing such actions.

2. Our Counsel has advised that the "no duty of care" argument should be deployed as a preliminary point to seek to remove the central defendants (alternatively CSM and LA) from the action altogether. [Mr C Wilson's submission of 18 10 89 refers].

3. Counsel also wishes to take other preliminary points eg whether action to protect against hepatitis is relevant to HIV litigation. The upshot might be that so much of the Plaintiff's case would be removed as to undermine the whole case. The Legal Aid Board might reach the view that the Plaintiffs chances of

success were so slim that the case should not be funded.

4. If the preliminary points did not succeed, the defence would contest allegations of negligence at the main hearing [probably November 1990]. We believe that we could present a robust defence, given;-

i. the uncertainties in scientific knowledge of the AIDS virus and its routes of transmission in the early 1980s,

ii. the very considerable efforts made, once the nature of the threat became clear, to protect against it (eg screening of blood donors).

Current situation on Macfarlane Trust

5. From the outset Ministers have intended that the £10 million given to the Macfarlane Trust should be used to meet need and that it was not intended as a compensation payment. The Trust's allocation policy is set out in Annex B. Recently, they have extended help into the mortgage field and their policy is to share costs with the haemophiliac to the extent necessary to support the mortgage in return for an equity share. Outlays for the fund are now running at some £2m pa.

6. In allocating funds the Trustees do interpret 'need' in a broad way and officials have supported them in this view. MS(H) knows of the proposed exchange of letters between Mr Heppell and the Trust. Ours would confirm that "the Trustees would not make more limited offers of help than they would otherwise consider

reasonable simply to conserve funds". They ~~are~~ were also advised that the right time to approach Ministers for additional funding would be when funds were sufficient to meet commitments for only another two or three years. The proposed reply from the Trust warmly welcomes these reassurances. [The letters can now be "officially" exchanged and published so that the current situation is on the record.]

Future Options

7. If Ministers are minded to review our current stance, the main options for dealing with this litigation and/or for increasing the financial help presently on offer to haemophiliacs are as follows.

Option "A": Out of Court Settlement

8. The Haemophilia Society, MPS, the Press and a substantial body of opinion within the NHS favours an "out-of-Court" settlement, so that those suffering the effects of HIV infection can quickly be assured of financial security.

9. "If the case is lost in Court, our Counsel suggests award would be in the range £40,000 - £100,000 depending on each Plaintiff's circumstances. We do not know how many haemophiliacs with HIV will pursue action but if all 1200 do, the total cost would be £40m to £120m shared among the defendants. An

out-of-Court settlement would cost around two thirds of the Court cost ie £36m to £80m but if the Department took this option initiative on its own, it would have to meet the full cost. Ministers may find it difficult to persuade Treasury to find money for an out-of-Court settlement at this stage when Counsel has not advised that the case can be won".

10. Moreover, a settlement out-of-Court on the HIV litigation is likely to provoke claims by other groups seeking compensation from the MCA by this route. [An immediate example might be the benzodiazepines (valium) litigation where the Department is not presently co-joined (with the manufacturers and doctors) as defendants. Circa 40,000 Plaintiffs are involved].

11. Another consideration would be the effect upon the licensing system itself. Experts would be hesistant/reluctant to endorse a product as worthy of licensing if they may be sued and face costs without proof of negligence.

12. Even if in principle Ministers were inclined towards an out-of-Court settlement there are some difficult questions of detail to be resolved, some of which might prove contentious. An award to all HIV Plaintiff's or to all haemophiliacs? A standard amount or a tailored award? Would the Haemophilia Society (or the Macfarlane Trust) be involved in assessments, etc.

Option B: Explicitly increase funding to the Macfarlane Trust

13. The Macfarlane Trust could be given additional funds, again

on an ex-gratia basis. Realistically the Trust Deed would need to be amended to place minimal emphasis on "means testing" and perhaps to allow substantial help with loans for housing etc. The settlement amount could be substantial, perhaps moving towards the likely range of costs for an out-of-Court settlement. It is difficult to assess whether increasing the Trust Fund financially will meet the Plaintiff's other motivation(s) for the Court action, viz to establish official recognition of their HIV positive status via blood products. Some might proceed with litigation in any event. Moreover, there are signs that the haemophiliacs are looking for a lump sum without having to submit to any 'needs' test however generously it is applied. Channelling more money through the Macfarlane Trust might not therefore dissuade many Plaintiff's from the Court action.

Option C: Ex-gratia Payment

14. An amount could be allocated on a "no-fault compensation" basis that would provide an ex-gratia payment to haemophiliacs without either admitting liability or involving the Macfarlane Trust. Costs would be similar to those for Option A. Ministers have opposed "no-fault compensation" schemes since the Pearson Commission reported in [ ]; also the option might suffer the same objections from Plaintiffs as Option B.

Option D: Panel of Inquiry

15. An option mooted by an NHS Haemophilia Centre Director

(attached to the Haemophilia Society) was that a Commission of Enquiry might be established. This could <u>either</u> assess the government's record over the relevant period, <u>or</u> consider the case for an ex-gratia payment or both. Officials believe this would need to be linked to an immediate ex-gratia award (perhaps to the Macfarlane Trust) to overcome the recurrent argument by the Plaintiffs that however the issue is resolved it should be with all speed.

Option E

16. As a matter of general policy the Department has maintained a low profile in the face of critical Press and public "rehearsals" of the HIV litigation.

17. The allegations and misinformation contained in the Sunday Times campaign and elsewhere could be responded to forthrightly. The most blatant examples (eg that NHS heat-treated Factor Viii appeared one year after [USA] product) could be the subject of an approach to Lord Justice Ognall on contempt. If a response would not itself be held in contempt, a parallel history of the facts could form the basis of a Departmental Press Release. Annex A to this submission addresses the main points mentioned in the Sunday Times campaign.

18. The Plaintiffs are following normal procedure in litigation of this kind in singling-out only one of the defendants for attack. In this case it is the Department of Health, since we are seen as being the direct or indirect debtor in the event of a

successful action by the Plaintiffs.

Summary

19. Our advice remains that the Department should continue to defend the Court action, but put a little more money into the Macfarlane Trust and make this known publicly. Attempts could also be made on the publicity front to consider the critical reporting so far.

Ministers may however wish to consider:-

i. whether they would wish any of the alternative options to be worked up in more detail;

ii. whether they would wish us to begin soundings with Treasury on the possibility of increasing by whatever means the funding available to HIV - infected haemophiliacs.

Arth2010

ANNEX A

The points addressed below are those made with hindsight in the Plaintiffs main statement of claim; and those singled out in the current Sunday Times campaign viz:-

a. <u>If heat-treatment techniques had been deployed against hepatitis it would have inactivated HIV when it appeared in the 1980s.</u>

There was no imperative to do so. Since the early 1970s effective tests have been used to screen blood donations at source for the most dangerous form of hepatitis (Hepatitis 'B'). Hepatitis A is not life-threatening. Nevertheless some heat-treatment methods were tried. These early methods were either ineffective, or so reduced the yield of Factor VIII from plasma as to make self-sufficiency unattainable. [Some strains of Hepatitis (known as Non A Non B) are resistant even to some <u>current</u> heat-treatment techniques].

b. <u>England and Wales should have been self-sufficient in blood products earlier.</u>

Ministers took the decision to build a new Blood Products Laboratory at Elstree in 1981; before the cause of AIDS was established. It has been fully funded. If built in 1976 [David Owen was Health Minister] it would have been against a demand of 16 million international units (miu's) of Factor VIII. Totally inadequate against todays demand for over 90 miu's. Over 70% of this demand is now met by the new factory built by the Government.

c. <u>American heat-treated Factor VIII was available in October 1984, but NHS not until October 1985.</u>

Not true. Some heat-treated F8 was made at BPL Elstree in [January] 1985 and from April 1985 <u>all</u> F8 manufactured there was heat-treated. Factor IX is much more difficult to heat-treat. This became available from BPL in October 1985. Commercial product was immediately available on a "named-patient" basis; doctors had clinical freedom when prescribing and some did prescribe heat-treated Factor VIII in 1984.

d. <u>Factor VIII "was first introduced in 1970"</u>

Incorrect. The first Factor Viii was produced in 1957.

e. <u>The Blood Products Laboratory reduced production of Factor VIII in the mid 1980's "because the building was declared unfit for production".</u>

Incorrect. Production had to be suspended while ovens were installed to heat-treat Factor VIII and Factor IX. Otherwise there was expansion of production in the original and th n in the new facility.

f. <u>"Britain has always been self-sufficient in Factor IX".</u>

Incorrect. We became self-sufficient via the new BPL at Elstree.

g. <u>The Macfarlane Trust has proved ineffective.</u>

The Macfarlane Trust provides financial help to haemophiliacs and their dependants, including juvenile dependants. It must therefore operate over many years and plan accordingly. They make single payments, regular payments and payments for a holiday to relieve stress etc. It does not provide compensation, but complaints that it is ineffective <u>in its task</u> are totally unjustified.

h. <u>Other countries have been more generous/settled out-of-Court.</u>

There have been no Court settlements yet and other circumstances vary greatly. In <u>West Germany</u> companies are liable by law and settlements of £15-£165,000 (average £27,000) have been reached between pharmaceutical companies, insurers and claimants. One or two cases are pending against the Federal Government which does not accept liability. In <u>France</u> a "solidarity fund" provides an average of £10,000 (income related) and spread over several years. Only those with AIDS benefit; no agreement reached for those who are HIV positive. In <u>Denmark</u> ex-gratia payments of £8-10,000 were recently increased to £20-25,000. <u>Norway</u> have provided ex-gratia payments of about £2000. A Court case against the Government is nearing completion in <u>Canada</u> but no actual details are yet known.