Mr Davey PS to MS(H)

From: J C Dobson HS1

haemophilia.

1/35

Date: 26 October 1989

RW 30/10

Mr Rock
Ms Steil cmd

cc:		
	Mr A McKeon	PPS to SofS
	Mrs E Baldock	PS to MS(L)
	Miss Gwynn	PS/Perm Sec
	Mr Heppell	PG
	Mr Hart	Dir/Ops
	Mrs T Keswick	Pr/Off
	Mrs Cristopherson	ID
	Dr Metters	MED ISD
	Dr Pickles	MED ISD
	Dr Rejman	MED ISD
	Mr Barton	AIDS Unit
	Mrs Walden	AIDS Unit
	Dr Lader	AIDS Unit
	Mr Powell	Sol B3
	Mr Brand	Sol B3
	Mr Wilson	MCA
	Mr Gutowski	MCA
	Mrs Armstrong	Sol C5
	Mr Kendall	FA2
	Miss Pease	HS1
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HAEMOPHILIACS AND AIDS: SUNDAY TIMES CAMPAIGN

Your minute of 11 October to Mr Heppell asked for advice on various aspects of the current litigation and the related Sunday Times campaign.

2. I attach a paper which has been prepared in consultation with medical and legal colleagues, with Medicines Division, and with Finance. Part I reviews the current position both on the litigation and on the Macfarlane Trust. Part II considers a number of options for making more money available to the haemophiliacs. None of them are without difficulty; the cheaper ones are unlikely to buy much peace, and the more expensive ones run a severe risk of knock-on effects (eg on other litigation against the licensing authority, or of setting a precedent which would encourage other victims of medical accidents). And it is likely that Treasury would resist any additional expenditure so long as Counsel advises that we have a good chance of winning the case. Our advice therefore remains that ministers should continue with the litigation and should not signal any readiness to provide additional funding, beyond the steps already in hand to allow greater flexibility to the Trust (and a veiled promise to consider topping up when it is needed). Ministers are also invited to consider the possibility of responding to the more inaccurate newspaper comments, so far as this is possible or advisable now that the case is before the courts.

3. MS(H)'s specific questions on the Trust are covered at paragraphs 5 and 13 and Annex B of the paper.

[redacted]

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SMD/A:328

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Ref: Arth1910

HIV/HAEMOPHILIA LITIGATION

I. 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. MS(H) has seen Mr Wilson's submission of 18 10 89 on the question of whether the duty of care issue should be taken as a preliminary issue in the HIV (and Valium) litigation. He has commented that he does not think it would be to the Government's advantage to do so in the HIV cases. Counsel has advised that he sees difficulty in raising it in one case and not the other; he has suggested a possible approach and this is set out in a further submission coming forward separately on that issue. Minister may

also wish to note that Counsel for the Health Authorities has indicated he will wish to raise "duty of care" as a preliminary issue.

3. Our Counsel also wishes to take other preliminary points eg whether the Government's alleged failure to take action to protect haemophiliacs against hepatitis is relevant to HIV litigation. The upshot might be (especially if the duty of care issue <u>were</u>, after further consideration, to be run in the HIV case) 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 Plaintiff's chances of success were so slim that the case should not be funded. Counsel has advised that there are better prospects of success for those small number of Plaintiffs who were infected between heat treated factor Viii being introduced and it being readily available in the UK.

4. If the preliminary points did not succeed, the defence would contest allegations of negligence at the main hearing [probably early 1991]. 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).

Macfarlane Trust: Current Allocation Policy

5. From the outset Ministers have made it clear that the £10 million given to the Macfarlane Trust was not intended as a compensation payment to HIV infected haemophiliacs generally, but was to help in cases of genuine financial need. The Trust's allocation policy is set out in Annex A. Recently, they have extended help into the mortgage field in a limited way. Initially at least the total amount available will be relatively small (up to £1m) and help will be in the form of an interest-free loan towards part of the house purchase cost in return for an equity share. Outlays from the fund are now running at nearly £2m pa.

6. In allocating funds the Trustees do interpret 'need' in a broad way and officials have encouraged them in this view. As MS(H) already knows, there have been recent discussions on this issue which we propose should result in an exchange of letters between officials and the Trust. Our letter would confirm our understanding that the Trustees would not make more limited offers of help than they would otherwise consider reasonable simply to conserve funds. The letter will also advise the Trust 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 and the formal exchange will take place shortly. MS(H) may wish to note these developments and consider whether to publicise this via a Press Release.

II. OTHER OPTIONS FOR THE FUTURE

7. If Ministers are minded to review our current stance, possible 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 awards would be £50,000 for a Plaintiff with no dependants and £150,000 for those with a wife and family. We do not know how many haemophiliacs with HIV will pursue action but if all 1200 do, the total cost could be in the range of £60m to £180m shared among the defendants. An out-of-Court settlement (to forclose any future legal action) might cost at least two thirds of the total damages the Court might award, ie £40m-£120m. If the Department took its own initiative to settle out of Court, it would have to meet the whole bill itself. Ministers may find it difficult to persuade Treasury to find money for an out-of-Court settlement at this stage when Counsel feels the Plaintiffs will lose. It would of course spare the Government what is likely to be a considerable sum in costs of the litigation, both directly on behalf of the

the RHA's and indirectly through the Legal Aid Fund. The trial is likely to take 3-5 months and will involve at least 3 QC's about 6 juniors and all the necessary Departmental legal medical and administrative support.

10. Since the early 1980s, (with the Opren case still continuing) the Government, in its role as the Licensing Authority for medicines, has been involved in a number of court actions. So has the Committee on Safety of Medicines (CSM). It has always denied liability and resisted any overtures to be involved in out of court settlements because of the implied admission of liability and the risk that it would encourage further litigation and public pressure for similar settlements out of court. There is already, in addition to HIV, potential major litigation involving benzodiazepines, and the IUD Copper 7.

11. Whilst there may be unique features in the case of HIV, officials do not think that any out of court settlement in that issue could be effectively ring fenced so as not to create a precedent. Any such settlement would need to involve the Licensing Authority and the CSM - it could not just include the Secretary of State in respect of his NHS responsibilities. It would accordingly be a precedent for similar out of court settlement of other claims against the Licensing Authority and CSM. It would also be likely to encourage further litigation against the Authority, which would be damaging to the integrity of the licensing system. It could lead on to over-defensive licensing decisions and reluctance of academics to serve on CSM

and other S4 advisory committees, on which the Licensing Authority is reliant.

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. For instance, should the award be restricted to Plaintiff's in the action or offered to <u>all</u> HIV infected haemophiliacs? Should there be a standard amount or an award tailored to individual circumstances (eg whether legal costs had already been incurred, whether full-blown AIDS had developed, number of dependants etc)? In the latter case, would DH itself determine the schedule of awards to be offered, or would they make a total sum available and invite the Haemophilia Society - or the Plaintiff's solicitors - to allocate it?

<u>Option B: Explicitly increase funding to the Macfarlane Trust</u>

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 additional amount would be a matter of judgement. At one extreme an addition £5-£10m would at least indicate that the Government were sympathetic to the plight of haemophiliacs. But it would still leave compensation in the UK behind some other European countries (See Annex B). It would be unlikely to buy off the litigation (and might even be counter productive if it were

regarded as too mean). At the other extreme, an injection sufficient to satisfy the Plaintiff's financial aspirations would involve a substantial amount 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 that they have become infected with HIV as a result of contaminated 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 effected. Channelling more money through the Macfarlane Trust might not therefore dissuade many Plaintiff's from the Court action, even though it might reduce the (now very extensive) public sympathy for their cause. It is also possible that if haemophiliacs had received reasonable compensation the Legal Aid Fund would be unlikely to continue support,and thus effectively reduce the likelihood of litigation continuing.

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. The advantage of this option is that:-

a. by removing the stigma of means testing it may make it easier for Plaintiffs to accept it as an adequate recompense for their injury - some might wish to pursue the claim in order to pin the blame on the Government, but if only a few persisted in this way the action would collapse.

ii. it would be evidently a direct payment from Government rather than from some anonymous 'special fund'.

Costs (for a scheme likely to prove acceptable) would be similar to those for Option A. Ministers have opposed "no-fault compensation" schemes since the Pearson Commission reported in 1978, largely because of the knock on effects; we would find it difficult to find convincing arguments for why haemophiliacs were thought a uniquely deserving group.

Option D: Commission of Enquiry

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 either assess the government's record over the relevant period, or consider the case for an ex-gratia payment along the lines of Option C, or both. Officials believe this would need to be linked to an interim 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. The eventual cost of this option might be similar to that of Option A (or C); the advantage is that it might be slightly easier to avoid knock-on-effects, since we could always refer back to the Commission of Enquiry (C of E) judgement that haemophiliacs were a particularly deserving

group. (But such a C of E would itself be a precedent).

Option E: Publicise the Government's position

16. As a matter of general policy the Department has so far maintained a low profile in the face of critical Press and public "rehearsals" of the HIV litigation. This could be taken to imply inertia or lack of concern. As a final option, on its own or in combination with one or other of Options A & D, the Government could take steps (within the constraints imposed now that the matter is before the Courts) to set the record straight.

17. The allegations and misinformation contained in the Sunday Times campaign have already attracted Mr Justice Ognall's attention. He is being provided by our Counsel with material relating to the Opren case, and Mr Justice Hirst's response, to help in deciding whether a Court Order might be appropriate. 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. Distorted comparisons with compensation available in other countries (often more limited than the UK's) could be challenged. Annex B to this submission rehearses the possible response to the main points mentioned in the Sunday Times campaign.

Financing

18. It is highly unlikely that Treasury would agree to providing any substantial additional funding, particularly as the advice from Counsel is that we would win the case in Court. The Department's own resources are very tight: there is virtually no

flexibility this year and already strong pressure on next year's resources. These mean that an out of Court settlement is not likely to be a runner, and that it will be hard to fund any lesser concession.

Summary

19. In the light of difficulties with Options A, C and D, our advice remains that the Department should publicise the extra flexibility we have offered to the Macfarlane Trust but continue to strongly defend the Court action. Attempts could also be made on the publicity front to counter 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.

HS1

October 1989

CONFIDENTIAL

THE MACFARLANE TRUST

GRANT ALLOCATIONS POLICY

FOR PROFESSIONAL USE

Payments from the Trust will be of two kinds:

1 Single payments

2 Regular payments – towards the cost of heating, diet or laundry, etc.

Single Payments

Single payments will cover a wide range of items within the terms of the Trust Deed. Payments must be related to need, but this does not mean only financial need. Help is often needed to relieve the stress of living with HIV infection and payments will be made where there is such a need. Holidays or family outings are two examples, but there are many other things which could be considered. There will be payments to assist with costs related to managing illness and maintaining good health; examples of these would be clothing, bedding, washing machines or driers.

Single payments will be made on the basis of need in a broad sense, not based on income. Many families which seem "better off" find that their standard of living has fallen, giving rise to difficulty. It is hoped that these families will make application to the Trust, when there is a need.

Single payments will be available to:

a People with haemophilia who are HIV positive, and to the families and dependants of these people.

b Wives and children of those people who had haemophilia, were HIV positive and who have died. Children will be eligible for single payments until they complete full-time education, or reach 18 years, whichever is later.

c Parents caring for a son with haemophilia who is HIV positive, provided the son lives with them. If the son has died, payments may be made where the need is related to HIV.

All grants are authorised by the Allocations Sub-Committee of the Trustees, which normally meets once each month. However, this Committee has delegated authority to the Administrator and Social Worker to make immediate payments of up to £500 which fall within certain guidelines.

Requests for larger sums or which fall outside the routine guidelines will be dealt with at the next monthly meeting, except in extreme urgency when special arrangements can be made for early payment.

Payments will not be made for items normally provided by the local authority or Department of Social Security. In the case of funeral costs, single payments will be considered for reasonable costs not covered by Social Fund Payments, and also towards the cost of providing a simple headstone.

Payments from the Trust will not affect entitlement to Social Security benefits and need not be declared to the Department of Social Security. Claimants applying to the Social Fund shall not be asked about payments from the Trust, nor should they be told to apply to the Trust instead of the Social Fund.

Frequency of payment – each application will be considered on its merits, therefore there will be no restriction as to how often a person may apply.

Applicants may ask that a decision be reviewed. Review will be by the full board of Trustees.

Regular payment

This system of payments is intended to top-up the income of people on low income, whether from low wages or from benefits. It is aimed at assisting those people who are finding it difficult to meet the cost of heating, diet etc, particularly those on benefit who were unable to obtain an additional allowance for these costs.

The regular payment is meant to relieve the constant worry over basic day to day living costs that some families are experiencing. It will be assessed on the basis of weekly income and expenditure, but will probably be paid on a monthly basis.

Regular payments will be available to people with haemophilia who are HIV positive and meet the conditions explained below. They may also be available to dependants of people with haemophilia who have died as a result of HIV/AIDS.

People who qualify for the regular payment will still be eligible for single payments.

The amount of the payment is based on trying to ensure that the net (disposable) income of a household will not fall below a level which allows adequate heating and diet and some balance to maintain the quality of life.

ANNEX A

This required net income will be calculated initially on the following basis.

Householders – couple £65.00

Householder – single £45.00

Additional members of the household/family

Single adult £35.00

Children under 18 years £20.00

A figure of £35.00 will be added for each member of the family who is HIV positive.

The actual net income is the sum of money which the person, or family has to live on after deduction of housing costs, and fares to and from work. It is the "Take home" pay after deduction of Income Tax and National Insurance which is used in this calculation. Family Credit and Child Benefit will be taken into account together with income from any other source. Attendance Allowance and Mobility Allowance are not included.

If the actual net weekly income is less than the required figure, the difference (up * to a maximum of £20) will be paid by the Trust. The following example should illustrate what is meant:

Mr and Mrs Smith have three children aged 9 years, 13 years and 15 years. Two children are HIV positive.

Qualifying figure for this family.

Parents – couple (householder)	£65.00	
Children – £20 x 3	60.00	
2 family members HIV positive	70.00	
		£195.00

Actual Income (weekly)

Take home pay	£220.00	
Child Benefit	21.75	
Total		£241.75

Deduct (weekly rates)

Rent/Mortgage	£35.00		
Rates	15.00		
Fares to work	10.00		
Deduct		£60.00	
Actual Net Income			£181.75

Deduct Actual Net Income	£181.75	
from qualifying figure	£195.00	
		£13.25

* now £25

In the example shown, a regular weekly payment would be made of £14.00 (ie £13.25 rounded up).

In the case of a single person living with his family, the calculation could be based either on the finances of the family as a whole, or on the financial circumstances of the person with haemophilia, taking into account his contribution towards the costs and rent or mortgage and rates. Whichever method seems most appropriate for each applicant will be used.

Initially the maximum regular payment will be £20.00 per week, the minimum will be £5.00 per week. Should a family qualify by as little as £1.00, the minimum £5.00 will apply.

General Notes

The qualifying figures and maximum sum of the regular payment will be kept under review to monitor the effectiveness of the system and to take account of inflation.

Decisions will be made by the Administrator and Social Worker on the basis of the guidelines set down. These decisions will be reviewed by the Trustees if requested by an applicant.

At the outset, a lump sum will be paid to those receiving a regular payment. It will be equivalent to backdating the regular payment to 16th November 1987, provided the applicant would have been eligible from the time. If the person was not eligible for all of that time, the lump sum will be adjusted and related to the point at which the applicant would have become eligible.

In the case of a person who has died, but who would have met the criteria for this payment, a lump sum will be paid to his widow/dependants, whether or not they qualify for weekly payments in their own right.

Regular payments from the Trust will not affect Social Security benefits and need not be declared to the Department of Social Security.

The Macfarlane Trust, PO Box 627, London SW1 0QG. **October 1988**

ANNEX B

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 rarely blood borne; and mortality is very low in developed countries. 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>

This needs to be seen against the background of enormous expansion in demand for Factor VIII in the 1970's. 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 it had been built in 1976 [when David Owen was Health Minister] it would have been against a demand of 16 million international units (miu's) of Factor VIII. This would be totally inadequate against todays demand for over 90 miu's. Over 70% of this greatly increased 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.

d. The Blood Products Laboratory reduced production of Factor Viii in the mid 1980's "because the building was declared unfit for production".

Production had to be suspended while ovens were installed to heat-treat Factor Viii and Factor IX. Otherwise there was expansion of production first in the original and then in the new facility.

e. "Britain has always been self-sufficient in Factor IX".

We have generally been self-sufficient in Factor IX, but while heat-treatment ovens etc were installed at Elstree, 2 million units (of 9 million total) were imported in 1985/86.

f. The Macfarlane Trust has proved ineffective.

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 in its task are totally unjustified.

g. Other countries have been more generous/settled out-of-Court.

There have been no Court settlements yet and other circumstances vary greatly. In West Germany 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 France 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 Denmark ex-gratia payments of £8-10,000 were recently increased to £20-25,000. Norway have provided ex-gratia payments of about £2000. A Court case against the Government is nearing completion in Canada but no actual details are yet known.

For comparison, the UK ex-gratia payment (through the Macfarlane Trust) is currently equivalent to about £8,000 per head, and is available to all HIV infected haemophiliacs (not just those with AIDS).

File

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THE TIMES

HOME NEWS 5

Woman to sue over fear of catching Aids

By Frances Gibb, Legal Affairs Correspondent

A young wife is making legal history by suing the Government for damages to compensate for the misery of watching her HIV-positive husband suffer and for her own fear of becoming infected.

Solicitors have issued a High Court writ claiming damages from Mr Kenneth Clarke, the Secretary of State for Health, from Sir Patrick Mayhew, the Attorney General, and several regional health authorities.

The woman alleges that negligence on the part of the health service resulted in her haemophiliac husband contracting the HIV virus, which can lead to Aids, from an injection of blood-clotting agent.

A detailed statement of her financial claim will be submitted later, though it is not known when the case will be heard in court.

The couple, who live in the Midlands, are keeping their identity secret but they have authorized Mr Steve Bennett, their solicitor, to speak for them. Mr Bennett, whose Birmingham firm, McGrath and Co, is handling claims for 100 haemophiliacs, said: "This woman is seeking compensation from government departments not because she has contracted Aids but because she is "at risk" of doing so through her husband."

The writ was issued after advice from leading counsel that the "intimates" of haemophiliacs had a case for seeking compensation. When the woman, who is in her twenties, submits her statement of claim, it could set a precedent.

"Wives suffer the psychological damage of worrying whether they will become infected, remembering the incubation period can be three years. They also have the distress of having to watch their loved ones suffer and die," Mr Bennett said.

The High Court has appointed Mr Justice Ognall to oversee the hundreds of civil cases pending from patients who are infected from unscreened blood.

The Prime Minister this week in the Commons rejected a Tory backbench call for immediate compensation for haemophiliacs who caught Aids through contaminated blood.

THE TIMES

● Urgent steps are needed to protect women undergoing artificial insemination treatment against the risks of Aids infection from inadequately screened donor semen, according to the *British Medical Journal* today.