PART I

Re: HIV HAEMOPHILIAC LITIGATION

ADVICE ON LIABILITY

1. We are now asked to advise on the potential liability of the Department of Health, The Licensing Authority and The Committee on Safety of Medicines in the light of the information currently available to us.

2. At this stage our advice must be qualified by the limited amount of material presently available. We have had access to the pleadings, the bundles of publications relied on by the Plaintiffs and have considered part of the Government Defendants' discovery documents and first draft expert reports. We have not seen any discovery from the Health Authorities or CBLA, nor have we seen their expert reports or any expert reports served on behalf of the Plaintiffs. When these are available they may affect our opinion as to the potential liability in particular of the Department of Health.

3. This Advice will be divided into the following Sections:-

(A) principal allegations made against the Government

Defendants;

(B) whether any of the Government Defendants owe individual Plaintiffs a duty of care;

(C) legal issues relating to breach of statutory duty and Wednesbury unreasonableness;

(D) the allegations as to Hepatitis and self-sufficiency blood products;

(E) allegations in respect of screening for HIV;

(F) allegations in respect of heat treatment for HIV and/or Hepatitis;

(G) allegations as to warnings;

(H) causation in respect of Hepatitis and self-sufficiency;

(I) causation in respect of HIV allegations;

(J) overall assessment of the risk.

4. Separate short Advices are in preparation on the following matters:-

(1) the likely quantum of damages recoverable by individuals if successful, together with a broad assessment of global damages for all affected haemophiliacs;

(2) ways in which some compromise of the litigation could be achieved without creating a precedent or affecting other pending and possible litigation.

A. Principal Allegations

5. The principal allegations made against the Department of Health are as follows;-

(1) the Department of Health failed to achieve self-sufficiency for England and Wales in blood products by 1977 or at all and failed to devote adequate capital expenditure or other resources to the Blood Products Laboratory;

(2) the Department of Health failed to take proper steps to reduce reliance on imported commercial Factor VIII concentrate;

(3) the Department of Health failed to pay sufficient regard to the risk of Hepatitis or other viral infections and to take steps to reduce or eliminate the risk of their transmission through blood products;

(4) the Department of Health should have encouraged the use of heat-treated concentrates;

(5) the Department of Health should have ensured that the size of pools used in the manufacture of Factor VIII were kept small;

(6) the Department of Health should have instituted earlier screening of donors and testing for HIV;

(7) the Department of Health should have insisted on the introduction of heat-treated Factor VIII at an earlier stage;

(8) the Department of Health should have given better

warnings about the risk of Aids at an earlier stage.

6. The principal allegations made against the Licensing Authority are as follows:-

(1) they failed to have sufficient regard to the risk of blood products transmitting Hepatitis and other viral infections;

(2) they should have restricted product licences to heat-treated products from 1980 or shortly thereafter;

(3) they failed to pay sufficient attention to the risk of blood products transmitting HIV.

7. The following allegations made against the Committee on Safety of Medicines are as follows:-

(1) that they failed to give sufficient warnings as to the risk of blood products transmitting Hepatitis or other viral infections;

(2) they failed to advise the Licensing Authority of the desirability of licensing only heat-treated blood products;

(3) they failed to give sufficient warning of the risk of blood products transmitting the HIV virus.

8. Similar allegations are made against the Health Authorities but there are, of course, additional allegations in relation to the clinical management of patients.

B. Duty of Care

9. The question whether or not any of the Government Defendants owes a duty of care to individual Plaintiffs has already been considered in the Advice of 18th October 1989. It was also, in respect of the Department of Health, at the centre of the recent hearings before Rougier, J. and the Court of Appeal on the question of public interest immunity. So far as the Department of Health is concerned, it is clear that the Plaintiffs will be arguing that all the matters of which they complain were in the "operational" sphere and as such are areas in which a duty of care is owed to individual Plaintiffs and the Plaintiffs' claims are "justiciable". We remain of the view that the majority of the allegations made are in substance allegations going to the exercise by the Department of a discretion, in particular in relation to the allocation of resources. That is particularly so in the case of the allegations relating to Hepatitis and self-sufficiency and to the redevelopment of the Blood Products Laboratory. However, if the Plaintiffs can show that the relevant officials in the Department did not consider or put forward to Ministers important issues such as the problems of Hepatitis, or if it can be shown that the information provided as to the advantages and disadvantages and costs and benefits of self-sufficiency was materially misstated, the Plaintiffs may be able to mount an argument that there has been negligence falling within the operational sphere. Further, the allegations relating to steps taken when the risk of HIV became apparent, such as screening, heat-treatment and warnings, are far closer to the

operational sphere.

10. Lord Justice Ralph Gibson said (p.36 of the Transcript of Judgment) that the Plaintiffs had made out "at least an arguable case". He pointed to the fact that it would be rare for a claim based on negligence to be established particularly in view of the difficulty of proving a negligent breach of duty when the party charged with negligence is required to exercise discretion and to form judgements on the allocation of public resources.

11. Although we consider that as a matter of strict law the proper course is for a Court to conclude that all or the vast majority of claims against the Department of Health are not justiciable, we recognise that this is the kind of case in which all Courts will strive (as the Court of Appeal did on the public interest immunity question) to find in favour of the Plaintiffs on the existence of a duty of care if they are able to devise a means of doing so. We do not therefore consider that it would be appropriate to proceed on the assumption that the Courts will hold that no duty of care exists.

12. So far as the Licensing Authority and Committee on Safety of Medicines is concerned, we see no reason to qualify our earlier advice that no duty of care should be found to exist in favour of individual Plaintiffs. There are, as it seems to us, very powerful public policy considerations which militate against such a duty of care and the Licensing Authority should not, in carrying out its very important function in protecting the health

of all, be required to consider the possibility of civil liability if an error is made. The position of the CSM seems to us to be a fortiori. We therefore expect the claims against the Licensing Authority and the CSM to fail as a matter of law. We also think that it is most important that it should not be conceded that there ever could be liability on the part of the Licensing Authority or the CSM.

C. Issues as to breach of statutory duty and Wednesbury unreasonableness

13. It is unfortunate that the Court of Appeal shrank from the logical step of holding that the claim for breach of statutory duty must fail. However, they did indicate their lack of enthusiasm for it and we remain of the view that the Plaintiffs' claim for breach of statutory duty is likely to fail.

14. So far as the claim for Wednesbury unreasonableness is concerned, it seems that the Plaintiffs will put their case on the basis that decisions involving policy questions such as the allocation of resources, were so illogical and unreasonable that no Minister properly advised could have taken them. It seems likely that they will not simply assert that the decision was inherently unsatisfactory but will seek to demonstrate that the Department failed to place the relevant information before Ministers. One suspects that the two principal matters upon which reliance will be placed are an alleged failure to warn Ministers of the seriousness of the risk of Hepatitis and an

alleged failure to provide sufficient and adequate information as to the practicability and economic value of achieving self-sufficiency and the funds required to do so.

15. Insofar as the Plaintiffs are able to show that the decisions taken were irrational or unreasonable, then there seems no reason why a cause of action should not be held to exist, given the approach taken by the Court of Appeal. However, as will appear below, we have seen little or no evidence that such an approach is sustainable on the facts.

D. The Risk of Hepatitis

16. In paragraphs 19 to 23 of the Re-Amended Statement of Claim the Plaintiffs make a number of assertions in relation to the association of the risk of Hepatitis with treatment of haemophiliacs. Those assertions can be summarised as follows:-

(a) that haemophiliacs were at particular risk of infection with Hepatitis B, Hepatitis NANB and other viral infections because of their dependence on blood products;

(b commercial concentrate was several times more likely to transmit Hepatitis and other viral infections than NHS concentrate;

(c) concentrate made from large pools of donors increased the risk of Hepatitis and other viral infections.

17. Those assertions are supported by a whole range of printed papers which are listed in Appendix 1 to the Re-Amended Statement of Claim. Many of these are short extracts and out-of-date. A majority relate to whole-blood transfusion rather than Factor VIII and IX. However, the following general propositions may be derived from the articles relied on by the Plaintiffs:-

(a) that paid donors, particularly in the United States, tend to come from the poorer social groups and to have a higher incidence of Hepatitis than more well off groups;

(b) that as a result, whole blood transfusions from voluntary unpaid donors tended to produce a lower risk of Hepatitis than transfusions from paid donors to commercial companies, by a factor ranging between 4:1 and 10:1;

(c) that the programme adopted in many parts of the United States of using voluntary rather than paid commercial donations has led to reduction in the incidence of Hepatitis;

(d) that there was some evidence that concentrate made from voluntary donations had a lower risk of transmitting Hepatitis but because of the large pool sizes used, the contrast was less clear as some risk of Hepatitis remained within voluntary donor groups;

(e) that advanced methods of screening for Hepatitis B had largely removed that threat as a cause of Hepatitis following transfusion with blood products by the end

of the 1970s but that the final elimination of Hepatitis B was likely to be more effectively achieved by selecting voluntary donors and other screening of donors than by more sensitive methods of screening donations;

(f) that NHS concentrate carried a lower risk of Hepatitis than imported commercial product;

(g) that until an effective means was found of identifying and screening against NANB Hepatitis, the best way of reducing this risk was by eliminating commercial donors;

(h) that severe haemophiliacs were likely to have built up a resistance to Hepatitis because of previous infection by elements of the virus in earlier transfusions;

(i) that the greatest risk of Hepatitis was to those who had not previously received blood products.

18. Arising from those assertions, the Plaintiffs allege that the Department failed to appreciate sufficiently the risk of infection with Hepatitis and to take any or any sufficient steps to remove or reduce that risk by eliminating imported commercial concentrate, encouraging heat treatment, reducing full sizes and advising alternative forms of treatment.

19. Before assessing the force of these allegations, it is necessary to consider the parallel assertions and allegations in respect of self-sufficiency.

20. The section of the Re-Amended Statement of Claim dealing with self-sufficiency is that between paragraphs 24 and 38. The principal assertions are as follows:-

(a) that at all material times it was more economically efficient to produce Factor VIII in the United Kingdom than to import it, alternatively that was the position shown by the best available estimates;

(b) that estimates of the relative cost and benefits of self-sufficiency did not give sufficient weight to the increased expense of treating haemophiliacs infected with Hepatitis as a result of treatment with imported commercial concentrate;

(c) that the best estimate of the requirement for Factor VIII in England and Wales was between 38 and 53 million units per annum the majority of which would be concentrate rather than cryoprecipitate and that those estimates grew steadily to an estimate of 100 million units per annum as the December 1981 estimate of a reasonable requirement for the mid-1980s;

(d) that from 1975 onwards the Department of Health committed itself publicly to ensuring that the United Kingdom was self-sufficient in blood products in view both of the economic efficiency of so doing and of the risks to haemophiliacs in any delay;

(e) that from 1970 to the mid-1980s the average size of donor pools used for NHS concentrate increased from 200 to approximately 15,000;

(f) that from about 1976 onwards the Protein Fractionation Centre in Scotland was capable of providing England with all or a sizeable proportion of its requirements for concentrate which could not be met by NHS concentrate made in England.

In this section the Plaintiffs also complain of lack of central administration or co-ordination within the National Blood Transfusion Centre.

21. Those assertions were backed up by a number of published articles. In relation to the capacity of the PFC at Liberton in Scotland, the Plaintiffs appear to rely only on one World in Action programme in 1975 and an article in September or October 1981. However, the published articles do not appear to provide objective evidence that as a matter of fact it was economically more efficient nor indeed that sufficient resources were or could have been made available to implement the capital programme spending which was needed. Rather, they rely on the amount that it would cost to import sufficient commercial product to satisfy anticipated demand, point to the difference in unit cost between NHS product and commercial imported product and argue that the difference in cost in each year would be sufficiently substantial to pay for capital spending relatively shortly.

22. The allegations which the Plaintiffs make in respect of self-sufficiency against the Department of Health are broadly as follows:-

(a) that the Department failed to achieve self-sufficiency by 1977 to 1978 or thereafter;

(b) that the Department allowed the Blood Products Laboratory to deteriorate so that it was declared unfit in 1980;

(c) that the BPL was badly administered;

(d) that there was no significant capital expenditure between 1975 and 1983;

(e) that there was a lack of proper assessment for future needs for Factor VIII and no proper effort to achieve sensible targets;

(f) that there was a failure to make use of the spare capacity in Scotland;

(g) that the programme of redevelopment of the Blood Products Laboratory was not set in place and pursued sufficiently swiftly from November 1981 onwards;

(h) that either the Health Authority should have been advised or instructed to use plasmapheresis from 1975 or thereabouts onwards, alternatively that the Health Authority should have been instructed or advised to approach commercial blood products manufacturers to fractionate plasma from volunteer donors in England and Wales;

(i) that there was a failure to create an effective and integrated national blood transfusion service.

23. It seems to us on the material available to us that the Plaintiffs are likely to fail as a matter of fact to show that

the allocation of resources towards achieving self-sufficiency was either negligent or so unreasonable as to be irrational. These events occurred at a time of financial cuts when budgetary pressures were extreme. It is beyond doubt that the pressure for capital spending on other forms of medicine and indeed other forms of Government expenditure was very considerable. Unless it can be shown that the Department under-estimated the risk of Hepatitis, it seems to us that there is little prospect of the Plaintiffs persuading a Court that no Secretary of State reasonably advised could have done other than devote substantial capital expenditure to achieving production targets in the National Health Service which would be sufficient to avoid the need to import commercial blood products. We should, perhaps, add that the condition to which the BPL was allowed to deteriorate is unhelpful, although not of itself directly relevant to the matters the Plaintiffs have to prove. Apart from producing embarrassment for the Department, it may assist a sympathetic judge to support a finding of unreasonableness.

24. Rather more difficult is the question relating to the seriousness of Hepatitis. The material before us suggests that the risk of Hepatitis B was diminishing significantly with the introduction of advanced methods of screening. Equally, although during the decade it became clear that much post-transfusion Hepatitis was due to another NANB Hepatitis virus, during that period the seriousness of NANB Hepatitis was considered to be relatively minor. It is only in the last few years that the seriousness of this condition has been more fully

appreciated.

25. On the information presently available to us we consider that it would have been perfectly proper to conclude that although there was a significant risk of Hepatitis infection from blood products, such risk did not outweigh the benefits and did not justify the expenditure necessary to achieve self-sufficiency faster than in fact occurred.

26. The difficulty is that the information suggesting that the link between risk of Hepatitis and self-sufficiency was fully considered or referred to Ministers is slight. It is also worrying that the estimates given to Doctor Owen which caused him to embark on a programme designed to lead to self-sufficiency were not revised with new estimates placed before Ministers for consideration during subsequent years.

27. It may be that these matters were in fact considered and the records have disappeared, but there is a risk that a Court might infer that insufficient information was in fact given to Ministers on these matters.

28. Of course, there was considerable evidence that even NHS product would transmit Hepatitis unless very small pool sizes were used as it may be that even a move to fully NHS voluntary blood products would only have reduced the risk of Hepatitis to a small degree.

29. In summary therefore we consider that there is some limited risk in this area but that the Plaintiffs are likely to fail to prove their allegations.

E. Allegations in respect of screening for HIV

30. This whole Section begins with the premise set out in paragraph 62 of the Re-Amended Statement of Claim that the Central Defendants should from July 1982 or soon thereafter have suspected that haemophiliacs would or might be subject to a grave threat of infection by AIDS through the use of blood products.

31. From paragraph 72 of the Re-Amended Statement of Claim onwards the Plaintiffs assert that the exclusion of high risk donors including homosexuals, bisexuals and intravenous drug abusers reduces or eliminates the risk of blood being infected with HIV as does the use of screening of blood donations. In paragraph 80 it is asserted that reliable blood screening tests were available in or about 1984 or alternatively in early 1985 but that routine blood screening did not begin in the United Kingdom until October 1985.

32. The articles referred to in support of that merely identify hopes expressed in 1984 that screening tests would be introduced but accept the fact that the first application for marketing of a screen test was approved by the FTA in the United States on 2nd March 1985.

33. The allegations made in Part 4 of paragraph 83 against the Department of Health are based on a failure from 1982 onwards to consider surrogate testing and the failure to impose screening tests as a matter of routine from mid-1984 or later.

34. There are further allegations that warnings of high risk groups and their exclusion by confidential instructions and advice should have been adopted earlier.

35. From the information presently available to us and draft expert advice that we have received, it seems clear that there were good reasons why warnings from 1982 onwards were not stronger and why screening tests were not introduced as soon as they were approved in America. Essentially, the emerging knowledge of AIDS and the public reaction to it was such that there were significant dangers associated with exaggerating the risk to high risk groups, thus creating a crisis of confidence, when it was by no means certain that all homosexuals were in such a group or that AIDS would become such a serious problem or reach such crisis proportions. Because of the long time span between infection with the virus and the development of AIDS, the evidence available suggested that relatively few haemophiliacs had been infected with AIDS in those early years.

36. The justification for not introducing the American screening tests appears to have been partly economic, but principally the desire to have a test which was appropriately sensitive. That is to say, it should detect the virus but should not produce too

many false positive results, thus undermining confidence in the Blood Transfusion Service and losing donations and causing fear and concern amongst those wrongly diagnosed as HIV positive.

37. It is our view that the steps taken by the Central Government Defendants will be held reasonable by a Court in the circumstances. The wisdom of hindsight should not be allowed to affect decisions which were taken carefully and with due consideration. However, the undoubted fact is that the AIDS epidemic and its affect on haemophiliacs was so severe that in retrospect it would have been preferable to have put out stricter warnings and to have introduced a screening test at the first available moment. Thus it is likely that the Court will hold that as a matter of fact the steps taken were inadequate and could have been improved. That falls far short of negligence but nonetheless does create a situation in which Courts may be tempted to seek to impose liability. Questions of causation arise which are considered later in this Advice.

F. Allegations in respect of heat-treatment for HIV and/or Hepatitis

38. In paragraphs 39 to 43 of the Re-Amended Statement of Claim the Plaintiffs allege that heat-treatment was widely known to be effective against Hepatitis, that it was available from 1980 in West Germany and the Central Defendants should have been aware of that. In paragraphs 65 to 69, it is asserted that heat-treated Factor VIII was available from April 1985 in the United Kingdom but that the Central Defendants should have known from

February 1983 at least that it could offer total or substantial protection against infection with HIV.

39. Those assertions are backed up by a series of articles, most of which refer to heat-treatment of other blood products. It appears to us that the Plaintiffs have essentially misunderstood the nature of some of these articles which do not support the contention that effective heat-treatment against Hepatitis was available except in very small quantities by one method used in Germany from about 1980 onwards which produced very little Factor VIII per donation of blood by comparison to normal manufacturing methods.

40. The allegations in Section 3 of paragraph 83 against the Department of Health suggest that heat-treatment should have been considered from 1970 onwards and introduced by at least 1980 against Hepatitis and other viral infections. They also allege that from mid-1982 onwards heat-treatment should have been used against HIV contamination. The allegation is that heat-treatment had been used for all blood products from 1980, then effective heat-treatment against AIDS could have been introduced long before April 1985.

41. We do not consider on the material currently available to us that the Plaintiffs will establish that effective heat-treatment against Hepatitis was available, except through the West German method which was not readily available and which would have required huge supplies of blood donations to make the

necessary Factor VIII, before February 1985. Even at that stage the amounts available were limited and we consider that the date on which heat-treated Factor VIII was made available in England & Wales, namely April 1985, was the earliest that could have reasonably been achieved.

42. We therefore would expect these allegations to fail. However, there are certain areas of vulnerability, in that home produced heat-treated product was made available slightly earlier in Scotland. That heat-treatment was carried on as an experimental method with no certainty that it would be successful, but in the event it was. It should be noted that other methods of heat-treatment which had been considered effective against Hepatitis were not so and indeed were not effective against HIV either.

43. There must also inevitably be the possibility that a Court would hold that the introduction of heat-treated product could have been brought forward by a few months (perhaps three or four) and there is some evidence that non-heat-treated product continued to be used at least for a matter of weeks after heat-treated product became readily available. The Central Government Defendants could have prohibited or advised strongly against such action.

44. It is therefore apparent that there may be a small window of opportunity from the middle or end of 1984 to early 1985 in respect of which the Plaintiffs may have a chance of proving

liability, but they will have to overcome the hurdles of showing that it would have been reasonable to carry out a process which may have inactivated or reduced the effectiveness of the Factor VIII with no certainty that it would eliminate the virus.

G. Allegations as to warnings

45. This part of the Re-Amended Statement of Claim relies upon the earlier parts and effectively is based on the assertion that both donors and recipients of blood and blood products should have been warned much earlier of the risk of Hepatitis and subsequently of AIDS; that doctors should have been advised against using blood products from 1982 onwards except where essential, because of the risk of AIDS and that generally the Plaintiffs and their doctors should have been given more direction as to the risk of the AIDS epidemic.

46. Whilst in hindsight these allegations are clearly right and it would have been better to have given more warnings, we do not consider that there is at present sufficient evidence that there was neglect in this matter. However, it will be necessary to look closely at the advice given by the Department and the Licensing Authority in respect of the use of blood products after the risk to haemophiliacs became apparent.

H. Causation in respect of Hepatitis and self-sufficiency

47. Even if the Plaintiffs were to be successful in showing that the Central Government Defendants were negligent in failing to pay proper heed to the risk of Hepatitis and in failing to take sufficient steps to achieve self-sufficiency in blood products, they still need to overcome two substantial hurdles in order to establish their right to damages. The first obstacle relates to the legal question as to whether or not negligence in respect of the risk of Hepatitis and other viral infections is causative of the damage suffered by Plaintiffs becoming infected with HIV virus through blood products. The argument will no doubt be mounted by the Plaintiffs, following the case of Hughes v. Lord Advocate, that it was foreseeable that haemophiliacs would suffer infection by viruses through blood products and it matters not that the particular virus from which haemophiliacs did suffer was wholly different in character from Hepatitis, much more severe in its consequences and wholly unknown at the time of the operative alleged negligence. The defence open to the Government is to argue that the Hepatitis risk and any negligence in relation to it is so wholly different from the utterly unforeseeable advent of the AIDS virus that any negligence in relation to Hepatitis and self-sufficiency was not causative of the damage actually suffered by the Plaintiffs.

48. We consider that such a defence is eminently arguable and would normally stand a reasonable prospect of success. However,

it is open to the Court to hold that HIV is a virus as is Hepatitis and that the Government cannot shelter behind the increased severity of the AIDS virus. Overall, we consider that there is a reasonable prospect of our argument succeeding but this is one of the more difficult areas so far as Government Defendants are concerned.

49. Rather more importantly, the Plaintiffs will have to show that the achievement of self-sufficiency and the supply of blood products obtained wholly from volunteer donors in the United Kingdom would as a matter of fact have eliminated or significantly reduced the risk of infection by HIV. The problem is, of course, that some volunteer donors in the United Kingdom also suffered from HIV and some NHS batches were, it appears, contaminated with HIV virus. One infected donation in a batch would have been able to infect the whole batch of Factor VIII with HIV. It is for that reason that the Plaintiffs have also argued that pool sizes should have been kept very low. The weakness of that argument is that economic and effective mass production of blood products can apparently only sensibly be achieved by reasonably large pool sizes. It appears to us at present that it would not have been practicable for this country to have achieved self-sufficiency whilst maintaining small pool sizes in the region of 150 to 200 donations per pool as appears to be suggested. Experience in, for example, Australia seems to lead to the conclusion that self-sufficiency would not necessarily have resulted in a lesser incidence of infection.

50. The Plaintiffs, of course, also allege that the shortfall in production could have been made up by using the capacity at the Scottish plant at Liberton. Apart from the question of the costs of gearing up Liberton and of overcoming Trade Union resistance, as to which we have at present no concluded view, we will need in due course to consider whether donations from volunteers in Scotland were also likely to contain an element of HIV.

51. Overall, we consider that this is going to be a difficult area for the Plaintiffs. The very fact that they make allegations about non-heat-treated National Health Service blood products indicates their difficulty. There may have been less risk of AIDS infection with an all volunteer population, but it will be difficult for any individual Plaintiff to show that if he had been treated with NHS product he would not have become infected with the HIV virus.

I. Causation in respect of HIV allegations

52. There will undoubtedly be a small number of Plaintiffs who can overcome difficulties of causation in respect of HIV allegations by showing that stored samples indicate that they were HIV negative until perhaps 1983 or 1984, or that they had not received any concentrated blood products prior to that date. In such circumstances, if they can show that there was negligence on the part of the Government Defendants in not introducing heat-treatment, screening or clear warnings earlier, they are likely

to succeed in their claim. One has in mind particularly Plaintiffs who may have been mild haemophiliacs treated for the first time with imported commercial Factor VIII at a time well after the discovery of the AIDS problem. If no heat-treated or screened product was available, then alternative forms of treatment may have been more appropriate (which is a matter for clinical management and for claims against the Health Authorities rather than the Government Defendants) or they may be able to show that heat-treated product or screened product could have been made available if the Government had acted more swiftly.

53. However, for the vast majority of the Plaintiffs, the reality appears to be that certainly severe haemophiliacs were infected with the HIV virus before the virus itself was identified. By the time something could have been done about it, it was too late to prevent the tragedy. The position may be slightly different with mild haemophiliacs who had not received much Factor VIII before say 1982 but we consider there is a real difficulty for the majority of Plaintiffs in this action in showing that any negligence by way of delay in introducing measures against HIV were in fact causative of their infection with the virus.

54. However, the lack of early samples for many Plaintiffs may mean that the Court has no clear evidence as to when they first sero-converted and there may be a risk that the Court will assume late sero-conversion against the Government rather than early sero-conversion against the Plaintiffs.

J. Overall assessment of the risk

55. It will be clear from the earlier parts of this Advice that much further work needs to be done before a final assessment of the risk of Plaintiffs succeeding at trial can be established. However, at present it is our view that the Government Defendants will succeed in defeating the Plaintiffs' claim on each of three grounds:-

(1) the existence of a duty of care;

(2) negligence or breach of duty;

(3) causation.

56. However, it will equally be clear that there are a number of areas in which risks exist and it would therefore not be appropriate to proceed on the assumption that the Plaintiffs' claim will fail.

57. What is perhaps worth some consideration is that it is possible that the Plaintiffs will succeed in showing negligence but will fail either to prove a duty of care or to prove causation or in appropriate places to prove Wednesbury unreasonableness. Even if the Courts do not succumb to the temptation to find the Government Defendants liable if they can be shown to be negligent, the outcome of such a trial in which the Government was found to have been negligent but to have escaped liability because of what many would regard as technicalities in the law, would no doubt bring adverse public

comment.

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ADVICE ON LIABILITY

TREASURY SOLICITOR