

? FINAL VERSION
SERVED

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
Re: HAEMOPHILIAC LITIGATION
THE MAIN DEFENCE OF THE FIRST CENTRAL DEFENDANTS
(The Department of Health and the Welsh Office)

SC/89/9000

Ref to Re- Amended Main
Statement of
Claim para.
nos.

DEFINITIONS

1. 1. The First Central Defendants will adopt the definitions and abbreviations set out in paragraph 1 of the Re-Amended Main Statement of Claim for the purpose of this Defence with the following exceptions:-

(a) ASTMS is now MSF;

(b) it is denied that the definition used for "intimate" provides a cogent or useful definition of a group with similar interests and at similar risk. The First Central Defendants will refer more specifically to "established sexual partners" and to "parents" being parents or guardians of minor or dependent haemophiliacs;

(c) it is denied (in so far as the same may be alleged) that the purported definition of "other viral infection" used in this paragraph or in paragraph 22A provides a positive

rather than negative definition.

DESCRIPTION OF PARTIES

2(1) The First Central Defendants will hereinafter be referred to as "the Departments".

2(2) All references to paragraph numbers are to the Re-Amended Main Statement of Claim except where otherwise stated.

+ Relevant references to the ^{Re-Amended} Main Statement of Claim are also included in the margin for easy reference.

2. 2(3) As to the categories of Plaintiffs set out at paragraph 2:-

(a) it is denied that the use of the words "who have ... been infected with HIV" provides a clearly defined or useful description of Plaintiffs otherwise falling into various categories. The Departments will plead to the categories of Plaintiffs as though such words were deleted. The Departments will contend that individuals should not be included in any of the present categories unless they have sero-converted;

(b) it is not admitted that those Plaintiffs falling within categories 2(a)(iii) and 2(b)(iii) properly fall within the scope

of this litigation or that their inclusion is consistent with the Re-Amended Main Statement of Claim as presently pleaded. The Departments will refer to such Plaintiffs, so far as may be necessary, as "heat-treated cases";

(c) as to the categories set out at paragraph 2(g), it is not admitted that HIV antibody- negative parents or established sexual partners of haemophiliacs who have sero-converted and/or developed AIDS have any cause of action against the Departments. It is denied that any other intimate of such a haemophiliac has a cause of action herein;

(d) save as aforesaid the Departments accept and adopt the definitions of the various categories of Plaintiff used in the Re-Amended Main Statement of Claim as set out in paragraph 2 thereof.

DUTIES

3. 3. (1) As to the first sentence of paragraph 3, the Departments admit that the various Acts there specified imposed some duties upon them but such duties as the Plaintiffs may prove were imposed for the benefit of the public at large, and are owed not to individual Plaintiffs but to the public at large.

(2) As to the particular responsibilities therein alleged:

(a) in respect of those at (a) to (d) inclusive the Departments do not admit that they had a duty (whether owed to the Plaintiffs or any of them or at all) to provide any of the said services, but admit that where the same were provided by them they were responsible therefor.

(b) It is admitted that the said statutory duties involved the responsibilities at (e) - (g) inclusive insofar as the acquisition and dissemination of such information, formation and dissolution of such advice and/or warnings were appropriate or necessary and insofar as the provision of health services is or was concerned.

(c) The alleged responsibility at (h) is admitted insofar as the provision of health services is concerned save that it is denied the Departments had any right or duty howsoever arising to impose any instructions which would interfere with the clinical freedom of doctors.

(d) The responsibility at (i) is admitted.

(3) Save as aforesaid paragraph 3 is denied.

4-8. 4. The Departments admit and aver that paragraphs 4, 5, 6, 7 and 8 summarise certain sections of the Medicines Act 1968 and Orders made thereunder. The Departments will refer to the said Act and Orders at the trial hereof for their full terms and effect.

9-12A

5. Save as set out above and save that it is admitted and averred that the Secretaries of State have from time to time made Orders under Sections 5 and 7 of the National Health Re-Organisation Act 1973 and/or Sections 8 and 13 of the National Health Services Act 1977, to which Acts and Orders the Departments will refer at the trial hereof for their full terms and effect, it is denied that the duties pleaded in paragraph 3 were owed by the Departments "along with" the RHAs, DHAs and/or SHAs as alleged in Paragraphs 10, 11 and/or 12 or at all. The Statutory Instrument pleaded in Paragraph 12A is admitted and the Departments will refer to the same for its full terms and effect at the trial hereof. Save as aforesaid, it is denied that the Secretary of State for Social Services owed the alleged or any duties "along with" the CBLA as alleged or at all. The Departments do not plead to the remainder of paragraphs 9 to 12A inclusive.

HISTORY

13-15

6. Save that haemophilia is best characterised as a disorder rather than a disease, it is admitted that paragraphs 13, 14 and 15 describe various of the characteristics and set out the general incidence of haemophilia.

7. The Departments will further say that Factor VIII is a protein which is necessary for the normal clotting of blood. The gene for Factor VIII is carried on the X-chromosome so that the disorder is generally manifest only in males although it is transmitted through females.

16 8. It is admitted that paragraph 16 contains broadly accurate descriptions of various methods of treatment and/or management of haemophilia used currently and in the past. Some concentrate is also made within the National Health Service in Scotland. Further, plasmapheresis is an important method of plasma collection from voluntary donors in England and Wales. Save as aforesaid, paragraph 16 is not admitted.

17. 9. Paragraph 17 is admitted.

18. 10. Save that no admissions are thereby made as to the risk of

transmission of any specific disease, other than hepatitis, or as to knowledge of the same, paragraph 18 is admitted.

HEPATITIS

19. 11. Save that no generally accepted type of hepatitis NANB which could be identified as a specific type and which can properly be described as hepatitis C was identified and categorised prior to early 1989, paragraph 19 is admitted to contain a broadly accurate description of hepatitis and the causes of hepatitis arising from contact with blood or blood products.

20. 12. As to paragraph 20:-

(1) it is admitted that by virtue of their need for blood products, haemophiliacs were relatively more exposed to risk of hepatitis than the average population;

(2) it is admitted that at all material times haemophiliacs were at risk of infection with hepatitis NANB viruses from blood products used by them;

(3) it is admitted that at all material times prior to the introduction of screening for hepatitis B, haemophiliacs were at risk of infection with hepatitis B. The Departments will

aver that the introduction of such screening very substantially reduced such risk and that it was further reduced by the introduction of vaccination against hepatitis B;

(4) it is admitted that hepatitis B could cause serious illness and sometimes lead to death;

(5) it is further admitted that hepatitis NANB could cause serious illness and sometimes lead to death, although the incidence of morbidity and mortality is significantly less with hepatitis NANB than with hepatitis B;

(6) save as aforesaid, paragraph 20 is not admitted.

21. 13. Save that it is admitted and averred that at all material times the Departments were aware of the aforesaid risk of hepatitis being transmitted to haemophiliacs through blood products, paragraph 21 is not admitted.

22. 14. As to paragraph 22 :-

(1) no admissions are made as to the allegations relating to "other viral infections" and the Plaintiffs are put to strict proof thereof. The remainder of this paragraph is pleaded without prejudice to the aforesaid;

(2) paragraph 22(a) is not admitted;

(3) save that it is admitted that one donation infected with hepatitis can infect the whole pool, paragraph 22(b) is not admitted. Without prejudice to the aforesaid, it is averred that large pools were necessary in order to provide the amount of concentrate that was required;

(4) paragraph 22(c) is not admitted;

(5) paragraph 22(d) is denied. The Departments will aver that the difference in pool sizes in later years was not significant and that plasmapheresis on its own does not increase the risk but is likely to diminish it since a larger volume of plasma can be made available from a smaller number of donors;

(6) save as aforesaid paragraph 22 is denied.

22A. 15. As to paragraph 22A:-

(1) The Departments repeat paragraph 1(c) hereof;

(2) the relevance of the entity purportedly so defined is

denied;

(3) save that it is admitted that needle-sharing and promiscuous sexual activity can increase the risk and speed of viral infection, the last 5 lines of Paragraph 22A are not admitted and the Departments put the Plaintiffs to strict proof of each and every allegation therein contained.

23. 16. As to paragraph 23 :-

(1) save as aforesaid, it is not admitted that the facts alleged in paragraph 22 were or should have been known by the Departments;

(2) it is not admitted that the facts pleaded in paragraph 22A(a) were known by or should have been known by the Departments;

(3) it is denied that the facts alleged in paragraphs 22A(b) and 22A(c) were or should have been known by the Departments at any material time. Without prejudice to the generality of the foregoing the Departments will rely on the definitions of such viruses as evidence that these were facts which were not, should not and could not have been known to them.

17. The Departments will refer to the particulars set out in Appendix 1 and the documents there referred to at the trial hereof for their full terms and effect. It is admitted that the articles there referred to were published at or about the dates there shown. No admissions are made as to the accuracy of the summaries set out in Appendix 1. It is not admitted that all or any such articles support the allegations of knowledge pleaded. Without prejudice to the generality of the foregoing, the Departments will further comment on certain of the said articles and the purported summaries thereof by way of a separate schedule in due course.

THE ECONOMICS OF SELF-SUFFICIENCY

18. The Departments will plead more fully to the allegations relating to self-sufficiency when the Plaintiffs' definition of the said term has been properly particularised.

24-25 19. Paragraphs 24 and 25 are not admitted. Further and in any event, it is not admitted that the increased expenses of treating haemophiliacs infected with hepatitis were significant in terms of the overall analysis of the cost benefit ratio.

26. 20. Save that it is admitted and averred that the Departments took reasonable steps to consider inter alia the economics of

*Before
Schedule
to Counsel*

*return to Counsel
within 2 weeks.*

importing Factor VIII rather than producing it in the United Kingdom, paragraph 26 is not admitted. As to the various particulars pleaded in paragraph 26 and listed in Appendix 2, the Departments will refer to the same and to the documents there referred to at the trial hereof for their full terms and effect. It is not admitted that the summaries are representative and accurate or that the said particulars support the allegations of knowledge pleaded. Without prejudice to the generality of the foregoing, the Departments will comment on certain of the said particulars and the purported summaries thereof by way of a separate schedule to be served in due course.

27. 21. As to paragraph 27, it is admitted that estimates of consumption requirements for clotting products in the United Kingdom at various times were made in the various documents and debates referred to in the sub-paragraphs to paragraph 27. The Departments will contend that demand and estimates of demand grew rapidly and that all reasonable steps were taken to assess future requirements on the best information then available. Without prejudice to the generality of the foregoing, the Departments will rely on the variations in the prediction of need to show the difficulty of predicting such future requirements.

28. 22. As to paragraph 28, it is admitted that Parliamentary answers were given on the dates shown. It is not admitted that the

sub-paragraphs to paragraph 28 accurately or adequately summarise the purport of those statements and the Departments will refer to those written answers at the trial hereof for their full terms and effect and will in so far as necessary further comment on the same by way of separate schedule to be served in due course. It is denied that those Parliamentary answers taken together or separately in themselves constituted or involved or could constitute the commitment or recognition alleged in the preamble to paragraph 28.

29. 23. The first sentence of paragraph 29(a) is admitted. As to the second sentence, the Departments will refer to the said written answer for its full terms and effect. Paragraph 29(b) is denied. The Departments reserve the right to plead further to this allegation when the same has been properly particularised.

30. 24. Paragraph 30(a) is admitted. The capital expenditure relating to the Blood Products Laboratory in each year from 1975 onwards is set out in Schedule 1 hereto. Save as aforesaid, paragraph 30(b) is denied.

31-32. 25. Save that the 1983 figure for commercial concentrate should be 36,217 rather than 26,217, it is admitted that the figures set out in paragraphs 31 and 32 are broadly accurate.

33. 26. Paragraph 33 is denied. The Departments will refer to all relevant reports of the Medicines Division at the trial hereof for their full terms and effect.
34. 27. The Departments do not plead to paragraph 34(a). Paragraph 34(b) is denied.
35. 28. Save that it is admitted that the average size of pools increased substantially during the said period, paragraph 35 is not admitted.
36. 29. As to paragraph 36, it is denied, insofar as it be alleged, that the option there set out was reasonably practicable or that its benefits would have outweighed its cost and other considerations, including the time necessary to set up the same. Save as aforesaid, the said paragraph is admitted.
37. 30. As to paragraph 37, the publication of the broadcasts and articles there referred to is admitted. The conclusions referred to are not admitted. Save that it is admitted that the Departments were aware of the said broadcasts and articles and knew the capacity of the Protein Fractionation Centre in Scotland, the remainder of paragraph 37 is not admitted.
38. 31. The first two lines of paragraph 38 are admitted. It is

admitted and averred that there was no central administration and that such central administration was neither desirable nor necessary. Further, there was all necessary and appropriate coordination. Without prejudice to the generality of the foregoing, the Departments will contend, inter alia, that before the National Directorate was established, national meetings of Regional Transfusion Directors and of the Departments' Advisory Committee on NBTS took place to co-ordinate activities. Save as aforesaid, paragraph 38 is denied.

HEAT TREATMENT

39. 32. Paragraph 39 is admitted.

40. 33. As to paragraph 40, it is admitted that heat treatment of blood products used to treat haemophiliacs might have offered some protection against infection with hepatitis B and/or NANB. Save as aforesaid, paragraph 40 is denied.

41. 34. Paragraph 41 is not admitted. It is denied that commercial heat-treated clotting concentrate of proven quality, safety and efficacy was reasonably available in reasonable quantities prior to the middle of 1985. Although some heat-treated concentrate was available in West Germany earlier, this was produced only in very small quantities and the method of production involved the use of

very large quantities of plasma to produce a very small quantity of concentrate.

42. 35. Save that it is admitted and averred that work to reduce by heat treatment the transmission of certain viruses through Factor VIII and Factor IX was commenced at the BPL in November 1981, paragraph 42 is not admitted.

43. 36. Save in so far as relates to matters admitted in the two preceding paragraphs, paragraph 43 is denied. It is admitted that the articles referred to in Appendix 3 were published at about the dates there indicated. The summaries thereof are not admitted to be full and/or accurate. It is not admitted that all or any of such publications support the allegations of awareness made. The Departments will refer to the said particulars and documents at the trial hereof for their full terms and effect, but without prejudice to the generality of the foregoing will further comment as necessary by separate schedule to be served in due course.

OTHER SOLUTIONS

44. 37. As to paragraph 44:-

(1) it is admitted that cryoprecipitate carried a lower relative risk of transmitting hepatitis than treatment by concentrate;

(2) it is not admitted (in so far as the same may be alleged) that cryoprecipitate was as suitable for home use as concentrate;

(3) it is averred that because its potency is variable accurate management of haemophilia was and is made more difficult by the use of cryoprecipitate;

(4) it is denied (if and in so far the same may be alleged) that sufficient cryoprecipitate was available for the treatment of all or most of the haemophiliacs who were at any material time being treated with concentrate;

(5) save as aforesaid, paragraph 44 is denied.

45. 38. Save insofar as expressly admitted in the preceding paragraph hereof, it is denied that the Departments could or should have known or did know the matters set out in paragraph 44. As to the particulars of knowledge alleged in paragraph 45 and Appendix 4 and the documents there referred to, the Departments will refer to the same at the trial hereof for their full terms and

effect, but without prejudice to the generality of the foregoing will comment further by way of separate schedule in due course;

46. 39. Save that it is averred that desmopressin was only suitable as a treatment in certain circumstances, paragraph 46 is admitted.

47. 40. Save in so far as admitted in the preceding paragraph it is denied that the Departments knew or should have known of the matters pleaded in paragraph 46. As to the particulars referred to in paragraph 47 and Appendix 5 and the documents there referred to, the publication and dates of such documents are admitted. It is not admitted that the summaries are full or accurate or that the said particulars support the allegations of knowledge. The Departments will refer to the same at the trial thereof for their full terms and effect but without prejudice to the generality of the foregoing will further comment by way of separate schedule in due course.

48. 41. Save that it is admitted and averred that bovine concentrate was introduced in the 1950s but was found to be quite unsuitable, the first sentence of paragraph 48 is denied. The second sentence is admitted. The Departments will aver that no animal concentrates of proven safety, quality and efficacy were available for use prior to December 1984 when porcine concentrate was first licensed. Animal concentrate was and is indicated only for Factor

VIII patients with inhibitors and is suitable only for a small proportion of such patients. No admissions are made as to the Animal Factor IX or as to the transmissibility of "other viral infections". Save as aforesaid, paragraph 48 is denied.

49. 42. Save as specifically admitted in the preceding paragraph, it is denied that the Departments knew or should have known the matters pleaded in paragraph 48. As to the particulars of knowledge alleged in paragraph 49 and the documents there referred to, the Departments will refer to the same as necessary for their full terms and effect. Without prejudice to the generality of the foregoing, the Departments will further comment by way of a separate schedule to be served in due course.

AIDS

- 50-60. 43. Save that the last sentence of paragraph 53 and paragraphs 56 and 58 are not admitted and that the implications alleged in paragraph 60 are not admitted, it is admitted that paragraphs 50 to 60 inclusive provide a broadly accurate summary by way of background of AIDS and its history. It is not admitted that such paragraphs contain a full or comprehensive analysis and the Departments will respond to the same fully by way of expert evidence and will comment on the matters referred to in paragraph 60 by way of separate schedule, in due course. Save as aforesaid,

the said paragraphs are not admitted.

61. 44. Save that it is admitted and averred that the Departments were aware of the development of knowledge of AIDS and of the spread of AIDS, paragraph 61 is not admitted. The Departments will refer to the particulars and documents referred to in paragraph 61 and listed in Appendix 6 at the trial hereof. Without prejudice to the generality of the foregoing, the Departments will further comment on the said documents by way of separate schedule in due course.

62. 45. Paragraph 62 is too general to plead to and is not admitted. The Departments will plead further thereto when the same has been properly particularised.

63-64 46. The articles referred to in paragraph 63 are admitted. The summaries of them are not admitted to be full or accurate. The purported synopsis in the preamble to paragraph 63 is not admitted to be an accurate or fair summary. The Departments will refer to the said articles so far as may be necessary at the trial hereof for their full terms and effect but without prejudice to the generality of the foregoing further comment by way of separate schedule to be served in due course. Paragraph 64 is denied.

HEAT TREATMENT

65. 47. As to paragraph 65, it is admitted and averred that heat treatment as now developed offers very substantial protection against the transmission of HIV. Save as aforesaid, the said paragraph is not admitted.

66. 48. Save that the alleged implication is denied, the first sentence of paragraph 66 is admitted. Save that it is admitted that small quantities of heat treated concentrate were available during the second half of 1984, it is not admitted that concentrate of proven quality, safety and efficacy that had been heat-treated in order to reduce the risk of the AIDS virus was obtainable in reasonable quantities from abroad as alleged in the second part of paragraph 66 or at all.

67. 49. The first sentence of paragraph 67 is admitted. The second sentence is not admitted.

68. 50. Paragraph 68 is not admitted.

69. 51. In so far as the Plaintiffs rely on a date of February 1983 or any date prior to the latter part of 1984 and save in so far as expressly admitted in relation to paragraph 65, paragraph 69 is denied. As to the particulars of knowledge alleged and the particulars and documents set out in Appendix 7, the Departments will refer to the same at the trial for their full terms and effect. It

is not admitted that the said documents provide evidence of the alleged knowledge. Without prejudice to the generality of the foregoing the Departments will further comment on the said particulars by way of a separate schedule to be served in due course.

70. 52. Paragraph 70(a) is denied; paragraph 70(b) is admitted.

71. 53. Save as is set out in the preceding paragraph, paragraph 71 is denied. The Departments will refer to the particulars and to the documents set out in Appendix 8 at the trial hereof for their full terms and effect. Without prejudice to the generality of the foregoing, the Departments will further comment in due course by way of separate schedule.

SELECTION AND SCREENING OF BLOOD DONORS

72. 54. It is admitted that the measures set out in paragraph 72 reduce the risk of blood being infected with HIV. It is not admitted that it eliminates such risk.

73. 55. Paragraph 73 is admitted.

74. 56. No admissions are made as to the date by which the Departments should have realised the matters set out in paragraph

74. The particulars of knowledge are not admitted, save that the various events are admitted. The Departments will refer to the same at the trial hereof for their full terms and effect. Without prejudice to the generality of the foregoing the Departments will further comment on the matters set out in the said Appendix by way of separate schedule to be served in due course.

75. 57. Paragraph 75 is not admitted. Further and in any event, surrogate testing for AIDS was not and is not feasible for routine large scale screening. So far as hepatitis is concerned, there would be severe difficulties in distinguishing between those who had been infected previously and those who had been vaccinated. The elimination of donors who were hepatitis B antibody-positive (but antigen-negative) would exclude large quantities of blood which did not carry the AIDS virus.

76. 58. The reliability of the tests referred to in paragraph 76 is not admitted. In any event, evidence as to the reliability of such tests was not available immediately and the tests themselves were not readily available in reasonable quantities immediately thereafter.

77. 59. Paragraph 77 is admitted. It is averred that such was a policy decision but was also and in any event a reasonable and proper decision and precaution.

78. 60. Paragraph 78(a) is admitted. Paragraph 78(b) is not admitted.

79. 61. Paragraph 79 is admitted.

80. 62. Paragraph 80 is denied. The Departments will refer to the particulars of knowledge and the various reports statements and editorials there set out at the trial hereof for their full terms and effect. Without prejudice to the generality of the foregoing, the Departments will further comment on the said particulars by way of a separate schedule to be served in due course.

81. 63. Paragraph 81 is ^{not} admitted.

82. 64. As to paragraph 82, no admissions are made as to the nature and extent of any duties owed by the Departments. The Departments specifically deny that the alleged or any duties of care were owed to individual Plaintiffs or to any of them. If and insofar as necessary the Departments will say that, as a matter of public policy, it would be neither just nor reasonable that such a duty of care should exist and/or be imposed. Save as aforesaid, paragraph 82 is denied.

BREACH

83. 65. It is denied that the Departments, their servants or agents,

were negligent and/or in breach of statutory duty as alleged in paragraph 83 or at all. The Departments repeat paragraph 3(1) hereof.

83. 66. As to the particulars of breach alleged under paragraph 83 the Departments will say:

(1) in respect of each and every allegation made and each and every admission which follows hereafter it is denied that they or any of them constituted or involved any actionable negligence or breach of statutory duty on the part of the Departments;

(2) if and insofar as any of the allegations and/or admissions thereto relate to policy and not operational decisions, including and in particular issues of resource allocation, the Departments expressly deny that any breach or breaches which the Plaintiffs may prove is or are actionable by the Plaintiffs or any of them.

(3) Without prejudice to the generality of the aforesaid:

1. SELF SUFFICIENCY AND THE BLOOD TRANSFUSION SERVICE

83. (a) as to sub-paragraph (a), it is admitted that up to and including a date 2 to 3 years after 1975 or thereafter blood products made from blood not donated in England and Wales were used in England and Wales. It is denied if the same be alleged that sole reliance upon home donated and processed products was either practicable or necessary. The Defendants will plead fully to sub-paragraph (a) when the Plaintiffs have defined "self-sufficiency";

83. (b) as to sub-paragraph (b) it is denied that the BPL deteriorated as therein alleged. It is further not admitted if the same be alleged that the Departments were at the said time liable in respect thereof;

83. (c) sub-paragraph (c) is denied. The Departments devoted such capital expenditure to the BPL as was reasonably estimated to be necessary for the discharge of their statutory duties in all the circumstances;

83. (d) sub-paragraph (d) is denied. The BPL was at all times properly administered by those responsible therefor;

83.

(e) as to sub-paragraph (e), it is admitted and averred that the initial estimate in 1981 was £21.3m.

Save as aforesaid, sub-paragraph (e) is denied. It is averred that all due diligence was employed in adopting and implementing appropriate policies for the development of the BPL. In particular and without prejudice to the generality of the aforesaid a total sum of £57m was allocated for capital expenditure and exceptionally the Departments authorised the use of a "design and build" contract to ensure speedy development;

83.

(f) as to sub-paragraph (f) it is admitted that the redevelopment of the BPL commenced in or about 1982 and that England and Wales continued and continue to import blood products made from blood not donated in England and Wales. Save as aforesaid, the said sub-paragraph is denied. The Departments repeat sub-paragraph (a) above;

83.

(g) as to sub-paragraph (g) it is denied if the same be alleged that there was a need for a nationally managed service. The service provided was integrated efficient and effective;

83. (h) sub-paragraph (h) is denied. The Departments repeat sub-paragraph (g) above. At all material times local management by RHAs was effective, efficient and accountable;
83. (i) sub-paragraph (i) is denied. The Departments took reasonable steps to assess future needs, inter alia, by setting up in or about February 1981 a Working Group to consider the same and/or by consideration of returns and advice/information submitted by Haemophilia Centre Directors and other published studies;
83. (j) sub-paragraph (j) is denied. The Departments repeat sub-paragraph (i) above. Proper and reasonable targets were set;
83. (k) sub-paragraph (k) is denied. Targets should not and can not be "imposed". Proper and reasonable targets were set and notified to RHAs;
83. (l) as to sub-paragraph (l), it is admitted that the Departments did not use any spare production capacity in Scotland to eliminate or reduce the Welsh and English need to import commercial factor VIII

concentrate. It is denied if the same be alleged that such use was necessary, practicable or viable; or that it could be quickly implemented;

83. (m) as to sub-paragraph (m) the Departments repeat sub-paragraph (l) above;

83. (mA) save that the Health Authorities were advised by means of the Working Group Report it is admitted that the Departments did not instruct or advise the Health Authorities as alleged in sub-paragraph (mA). It is denied, if the same be alleged, that such further instruction or advice was appropriate, necessary or practicable;

83. (mB) it is admitted that the Departments did not instruct or advise the Health Authorities as alleged in sub-paragraph (mB). It is denied, if the same be alleged, that such instruction or advice was appropriate, necessary or practicable.

2. MANUFACTURE OF NON-HEAT-TREATED CONCENTRATES

83. (n) As to sub-paragraph (n) the Departments will say that an increase in donor pools for Factors VIII and IX was the only practicable means of processing sufficient material so as to maximise home production;

83. (o) as to sub-paragraph (o) the Departments repeat sub-paragraph (n) above;

83. (p) sub-paragraph (p) is denied. The Departments will rely inter alia on the fact that production increased at the rate indicated at paragraph 25 above or a similar rate;

83. (q) sub-paragraph (q) is admitted. The said fall in production was the inevitable consequence of a suspension of production while recently developed heat treatment processes were introduced to increase the safety of the product.

3. HEAT TREATMENT

83. (r) Sub-paragraph (r) is denied. The Departments at all material times paid sufficient regard to the considerations set out thereunder. Without prejudice

to the generality of the aforesaid, it was essential that any method of heat-treatment adopted should maintain quality and efficacy of blood products as well as achieving viral inactivation;

83. (s) sub-paragraph (s) is denied. The research undertaken by and at BPL was reasonable and sufficient;

83. (t) it is admitted that the Departments did not impose in 1980 the use in England and Wales of heat-treated Factor VIII and IX concentrates in place of non-heat-treated products. It is denied that any known risk of hepatitis and/or other viral infection was sufficient to necessitate the said imposition. Further or alternatively, such imposition was impossible and/or impracticable because no or no sufficient quantities of safe and efficacious heat-treated products of satisfactory quality were available at that time. In August 1985 (in the case of Factor VIII) the Departments informed clinicians that there was no further need to use untreated Factor VIII for reasons of lack of supply. Further or in the further alternative the Departments deny that they had a right or duty unreasonably to interfere with clinical

freedom by imposing any such requirement of use;

83. (u) as to sub-paragraph (u) the Departments repeat sub-paragraph (t) above mutatis mutandis;

83. (v) as to sub-paragraph (v), it is admitted that home donated and produced heat treated Factors VIII and IX concentrates were not produced before 1985. It is denied that production alternatively production in sufficient quantity by 1980 was reasonably practicable;

83. (w) as to sub-paragraph (w) the Departments will say that they had no right or duty so to interfere with clinical freedom. The Departments informed clinicians that there was no further need to use untreated Factor VIII for reasons of lack of supply;

83. (x) it is admitted that the Departments did not instruct or advise Health Authorities or clinics as alleged in sub-paragraph (x). It is denied, if the same be alleged, that any such advice or instruction by the Departments was necessary. Without prejudice to the generality of the aforesaid, proper and sufficient advice was being given by the Haemophilia Reference

Centres to other Centres as the Departments well knew. Such advice was a matter of clinical experience and the Haemophilia Reference Centres were the appropriate source for such advice.

4. SCREENING OF DONORS AND TESTING FOR HIV

83. (y) Sub-paragraph (y) is denied. The Departments fully appreciated the categories of high risk donors and acted accordingly. In particular, from 1983 advice as to known risk categories was given to blood donors by leaflet;
83. (z) as to sub-paragraph (z) the Departments repeat paragraph 57 above;
83. (aa) as to sub-paragraph (aa) the Departments deny that they should have so directed RHAs and/or the National Blood Transfusion Service. They comment as follows:
- (i) identification of homosexuals, bisexuals and/or intravenous drug abusers (a) would have been impracticable or impossible and/or (b) would have involved an unreasonable

intrusion of privacy and/or (c) would have involved so great a deterrent to donation that the supply of donated blood would have been so reduced that the effectiveness of the service would have been at risk;

(ii) as to sub-paragraph (ii) the Departments repeat sub-paragraph (z) above;

83. (ab) it is admitted that routine testing as alleged in sub-paragraph (ab) was not undertaken until October 1985. It is denied if the same be alleged that testing was reasonably practicable before that date. The Defendants repeat paragraph 58 above;

83. (ac) as to sub-paragraph (ac) it is admitted that such testing was not introduced inter alia because the test methods available were not sufficiently reliable. It is denied that the adoption of such policy was wrong and/or negligent;

83. (ad) sub-paragraph (ad) is admitted. It is denied if the same be alleged that such testing could or should have been imposed.

5. HEPATITIS AND/OR RISK OF OTHER VIRAL INFECTIONS

83. (ae) Sub-paragraph (ae) is denied. All relevant risks, including those set out at (i), (ii) and (iii) insofar as they relate to hepatitis were considered and taken into account;

83. (af) it is admitted that the Departments did not take any of the steps set out under sub-paragraph (af). As to that at (i) thereunder it was not practicable or reasonable^{or} necessary. As to those at (ii) - (vi) the same would have involved the unreasonable limitation of effective treatment of haemophiliacs and/or an unreasonable and/or unnecessary interference with clinical judgment.

(6) AIDS Risk

83. (ag) Sub-paragraph (ag) is admitted. The Departments were so aware and did so act;

83. (ah) sub-paragraph (ah) is admitted. The Departments did keep themselves so informed and

did so act;

83. (ai) sub-paragraph (ai) is admitted. The Departments did know of the said suspicion and did act in the light of it;

83. (aj) sub-paragraph (aj) is denied. The Departments at all material times considered and took into account the said risk;

83. (ak) as to sub-paragraph (ak) the Departments repeat sub-paragraph (af) above mutatis mutandis;

83. (al) sub-paragraph (al) is denied;

83. (am) sub-paragraph (am) is denied;

83. (an) sub-paragraph (an) is denied. The Departments repeat sub-paragraphs (ag) - (aj) above mutatis mutandis;

83. (ao) it is denied that the Departments should have directed or advised RHAs, DHAs, SHAs and/or prescribing doctors as alleged in sub-paragraph (ao). Any such advice or direction would have involved an

unnecessary and unreasonable interference with matters of clinical judgment. It is denied if the same be alleged that such continued use could or should have been prevented by the Departments. The permitting of such use was necessary for the continued effective treatment of all haemophiliacs.

(ap) sub-paragraph (ap) is admitted.

83A 67. It is denied that the Departments or either of them have at any material time acted outside the discretion conferred upon them by Parliament whether in the respects alleged in paragraph 83A or at all and/or that they have at any material time acted unreasonably and/or so as to frustrate the objects of the statute conferring the discretions. Further or alternatively, it is denied if the same be alleged, that any action outside the limits of the said discretion and/or unreasonable action and/or any action which frustrated the objects of the statute, would give rise to any cause of action on the part of the Plaintiffs or any of them.

84- 68. The Departments do not plead to paragraphs 84-95A.
95A

96. 69. It is not admitted that the Plaintiffs or any of them have suffered loss or damage and the alleged causation thereof is denied.

X

70. Each and every allegation contained in the Re-Amended Main Statement of Claim and not expressly pleaded to herein is denied.

JUSTIN FENWICK
HELEN ROGERS

Served this 31st day of MARCH 1990

Treasury Solicitor
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Solicitor for the First Central Defendants

IN THE HIGH COURT OF JUSTICE

QUEEN'S BENCH DIVISION

RE: HAEMOPHILIAC LITIGATION

THE MAIN DEFENCE OF THE FIRST
CENTRAL DEFENDANTS (DEPARTMENTS)

D E F E N C E
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AND THE WELSH OFFICE

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