15th July 1991

STATUS REPORT ON

MEDICAL NEGLIGENCE CASES

Part A - Cases Settled

Name of Case	Amount
LPN 69	£55,000
LPN 46	£20,000
LPN 122	£15,000
LPN 35	£60,000
LPN 25	£85,000
LPN 26	£50,000
LPN 71	£ 4,500
LPN 181	£40,000
TEVB 001	£15,000
WB 001	£ 5,000
AMCG 027	£53,000
MK 021	£68,000
AGP 001	£27,000
MK 001	£15,000
LC 022 (subject to infant approval)	£130,000
ME with HJJJ 030	£36,500
SI 025	£57,500
SI 015	£10,000
WB 002	£89,000
SPN 20	£65,000

TOTAL 20

Part B - Offers Rejected

Name of Case	Offer	Counter Proposal
LPN 73	£100,000	£120,000
LPN 84	£ 16,000	£ 25,000
M&M 008	£ 10,000	£ 20,000
M&M 009	£ 16,650	£ 20,000
HS 003	£ 30,000	£ 50,000
FF 004	£ 90,000	none

TOTAL 6

Part C - Offers Made and Outstanding

Name of Case	Offer
JKP 19	£20,000

TOTAL 1

Part D - Cases where instructions are awared to make offers

Name of Cases

FF 002 (from Central Defendants)
AMCG 021

TOTAL 2

Part E - Cases where Health Authority Defendants have indicated an intention to make proposals but are awaiting Special Damage calculations

Name of Cases

JKP 047
JKP 116
JKP 92
MPN 106
JKP 27
JKP 28

TOTAL 6

Part F - Cases where Health Authorities have concluded that there is no negligence or are otherwise pleading a defence to protect the position

Name of Cases

NV 004
SI 012
SI 021
JKP 03
JKP 033
JKP 037
JKP 107
DMS 99
JKP 109
JKP 43
JKP 35 (Doubtful)
JKP 19 (Doubtful)

JKP 86 (Doubtful)

TOTAL 13

Part G - Cases which have been withdrawn from the list of Medical Negligence Cases subsequent to 1st May

JKP 046
JKP 144
JKP 034
JKP 104
JKP 131
JKP 105
JKP 139

TOTAL 7

Summary of cases put forward on 1st May

Settled	20
Withdrawn	7
Outstanding	28
Total	**55**

Summary of 28 outstanding cases

In negotiation	9
Possible negotiations	6
Defending	13

JKP 3

The Plaintiff is an adult haemophilia B. It is alleged that he was treated with commercial product an a time when there was sufficient supplies of domestic Factor ~~VIII~~ IX available.

Professor Hardisty comments that the Plaintiff was on home prophylaxis with a very large amount of Factor IX concentrate from at least 1975. He apparently received a single dose of commercial concentrate in July 1980 but apart from this, treatment was exclusively with NHS concentrate until April 1985, heat-treated commercial Factor IX concentrate then became available and he was switched to this and remained on it until February 1986 and at this date heat-treated NHS concentrate was provided.

His first HIV positive sample was obtained in February 1984. A sample obtained in December 1982 was tested retrospectively and proved negative. The ISC refers to a further negative result 22.5.85, but there is no record of this and the clinical notes made on that date record him as being HIV positive and it therefore seems that seroconversion occurred between December 1982 and February 1984. This was too long after the dose of commercial concentrate given in July 1980 to be attributable to it. It was before the use of heat-treated commercial concentrate, and therefore infection must have been with unheat-treated NHS Factor IX.

Conclusion - No negligence.

JKP 8

The Plaintiff's notes really make no allegations of negligence but simply statements of fact. The Plaintiff was a mild haemophiliac born in 1926 first treated with cryoprecipitate in the 1960's and switched to concentrate because of allergic reactions. He received both NHS and commercial concentrates in the middle 1970's onwards but was reported as negative in March 1985 and positive in June 1985. The Plaintiff had received no treatment for some time before March 1985 and it seems almost certain that HIV infection was due to the administration of commercial concentrate he received in March 1985 to cover an operation for the repair of an inguinal hernia. This operation could not safely have been performed without Factor VIII cover and at this date heat-treated commercial concentrates were regarded as the safest available and used for the operation. It appears that he seroconverted as a result of Armour ~~Y~~ concentrate.

Conclusion - No negligence.

JKP 014

Born GRO-A 39, died of AIDS GRO-A 89. Haemophilia of moderate severity diagnosed in infancy, Factor VIII recorded variously as less than 1%, 1.6% and 4%. The Plaintiff evidently suffered fairly frequent joint bleeds, resulting in quite serious disorganisation of the right knee and left ankle, both of which required surgical intervention.

He was evidently treated with cryoprecipitate until June 1982, when he had an operation for the removal of a haemophilic cyst behind his right knee which was covered with NHS Factor VIII concentrate. He started home treatment in April 1983, presumably with concentrate, though the notes contain no indication of source or batch numbers. An operation for fusion of the left ankle was performed in October 1985 under cover of concentrate, again no indication of the type or batch numbers is given in the available notes.

The Statement of Claim gives the date of the first positive HIV test as 12.12.85, but the notes include a letter dated 15.10.85 which states that the Plaintiff was then HIV positive. I can find no actual laboratory report of HIV testing in 1985 or before, but it would appear that seroconversion took place before the operation on the left ankle in October 1985, and probably resulted from infection by concentrate used for home treatment from April 1983 onwards. It is not clear from the records why the decision to start home treatment was made at this time, when the Plaintiff was evidently suffering only rather infrequent bleeds, but it is doubtful whether the use of concentrate could be held to have been negligent at this time, when no AIDS had yet been reported in UK haemophiliacs and the relative risks of Factor VIII containing products were still very imperfectly understood. On the 24th June 1983 the Haemophilia Reference Centre Directors recommended the use of DDAVP or cryoprecipitate in appropriate cases, though they accepted there was insufficient evidence as yet to restrict the use of imported concentrates. It might well have been appropriate at

this time to test the Plaintiff for his response to DDAVP (because of the relative clinical severity of his disease, I think it rather unlikely that this would have proved adequate treatment for him), or to switch him back to cryoprecipitate, though this would probably have meant abandoning home treatment. I have no criticism of the use of NHS concentrate to cover the operation in June 1982, or of concentrate to cover the operation in October 1985, by which time it appears that he had already seroconverted. I think however that the continuing use of commercial concentrate throughout the second half of 1983 and 1984 in a patient who had previously been adequately treated with cryoprecipitate could reasonably be regarded as having been negligent. I can find no record in the notes of how frequently treatment was administered during this period or with what type of concentrate.

Conclusion : Doubtful

JKP 19

JKP 19 is the wife of JKP 20 a severe haemophiliac.

The allegation is that she received no counselling and no test until over 12 months after the date of her husband's positive test. No allegations of clinical negligence is made in relation to JKP 20.

Professor Hardisty states that JKP 20 was treated with Factor VIII concentrate from about 1981. There is no record of the actual date of his first positive test but it was known that he was HIV positive at the time that JKP 19 had her first blood sample test in January 1986. His seropositive status was confirmed on a sample taken in February 1986. He could have been infected at any time since 1981.

JKP 19 should have been informed of her husband's seropositivity and properly counselled as soon as it had been known, but in the circumstances it is far from certain that this would have protected her from infection in view of the long probable interval between her husband's own date of infection and the availability of testing. Whilst Professor Hardisty therefore accepts that it was negligent not to counsel the wife of a haemophiliac as soon as it was discovered that he is HIV positive, he has two reservations concerning the present case, first there is no evidence at the actual interval between the positive test obtained on JKP 20 and that on JKP 19, and secondly JKP 19 was in all probability already herself infected before her husband was found to be HIV positive, so that the avoidable delay in counselling her may have made no difference to her infection.

Conclusion - Doubtful.

JKP 027

Severe haemophilia born GRO-A 4, (younger brother of JKP 028), diagnosed at the age of 2 months and treated from that time onwards exclusively with Factor VIII concentrate. There is no record of the type of concentrate given in August 1984, but he received commercial (Armour) concentrate from February 1985 to September 1986 (apart from a single dose of heat-treated NHS concentrate (8Y) on 22.1.86). He was switched to 8Y concentrate in November 1986 and continued to receive this throughout 1987. Heat-treated commercial concentrate became available at the beginning of 1985, but I cannot tell from the batch numbers whether the material administered to the Plaintiff in 1985 was exclusively heated treated; in any event, the type of heat-treatment used by Armour subsequently proved to be incompletely effective in destroying HIV.

The Statement of Claim gives the date of the first HIV positive test as 21.2.87, but the notes contain no record of HIV test results before 1988. The note for 30.8.85 states "blood for HTLV taken again" and a letter from Dr. John Martin in the notes of the Plaintiff's brother (JKP 028), dated 31.12.85, states that both brothers were then HTLV3 (HIV) positive, although the first mention of HIV positivity in the Plaintiff's own notes is in a letter dated 21.7.87, it therefore appears that seroconversion took place in 1985 or earlier.

The risk of AIDS to haemophiliacs, and the possibility of removing these risks by heat-treatment of concentrate, were already beginning to be appreciated at the end of 1984, when the Plaintiff was first treated, and I think it must be accepted that it was negligent to treat him with concentrate at this time rather than with cryoprecipitate. There appears to have been no good clinical reason (e.g. major haemorrhage, home treatment) for preferring concentrate to cryoprecipitate, and it would certainly be indefensible if any of the commercial concentrate given in 1985 was unheat-treated. If cryoprecipitate was unavailable at this time, then either

heat-treated commercial concentrate or unheated NHS concentrate should have been used until such time as NHS heat-treated concentrate became available.

Conclusion - Negligence.

JKP 028

Severe haemophilia, born GRO-A (elder brother of JKP 027), diagnosed November 1982 aged 6 months and treated exclusively with Factor VIII concentrate from that time onwards. He received two doses in 1982, 16 in 1983, 19 in 1984 and about 30 in 1985. Commercial material was given in March 1983, but apart from this there is no record of source or batch numbers until December 1984 when he receive a dose of NHS concentrate. From the 2nd to 19th January 1985, he was treated with a total of 26 ampoules of commercial concentrate batch Y88908: this was probably unheat-treated, since heat-treated commercial concentrate only became available sometime during that month. A single dose of NHS concentrate was given on 29.3.85, and subsequently more commercial concentrate (presumably heat-treated) during 1985 and 1986.

The first mention in the notes that the Plaintiff was HIV positive occurs in a letter from Dr. Martin dated 31.12.85, but a note dated 8.8.85 states "blood taken for HTLV3 screening". There are no actual laboratory results of HIV testing earlier than 1988.

I do not believe that it can be held to have been negligent to treat a baby boy with commercial Factor VIII concentrate at the end of 1982, when the risks of AIDS were not well appreciated. During the following year however, and particularly after June 1983, when the Haemophilia Reference Centre Directors issued their first recommendations on treatment, the risk should have been recognised: a switch to cryoprecipitate at that time might still have protected the Plaintiff against HIV infection. In the light of the further recommendations of December 1984, it must be held to have been negligent to treat the Plaintiff with unheat-treated commercial concentrate in January 1985 (if this was indeed the case). I do not think this case is defensible.

Conclusion - Negligence.

JKP 33

It is alleged that the Plaintiff was a mild adult who received cryo. between 1975 to 1980 but was then switched to concentrate. When he heard of the risks of Factor VIII concentrate in 1984, he refused further treatment with concentrate and has not to this date taken any since.

Professor Hardisty comments that the Plaintiff was a mild to moderate haemophiliac who had fairly frequent bleeds following minor injuries. He was HIV positive in August 1985 with no previous negative results.

To have switched the Plaintiff's treatment from cryo. to concentrate in 1979/80 cannot be regarded as having been negligent. The notes do not provide details of concentrates given, but at least some of it was NHS and it is well known that supplied of NHS concentrate at this time were insufficient to provide for the needs of all haemophiliacs. HIV infection may have resulted from concentrate given at any time from 1979 onwards and may well have antidated knowledge of the risks of such infection.

Conclusion - No negligence.

JKP 035

Mild haemophilia, born GRO-A 81, diagnosed May 1982, treated exclusively with Factor VIII concentrate and never with cryoprecipitate or DDAVP. So far as I can ascertain from the notes he received three doses of concentrate in November and December 1982, four more between March and July 1983, and then no more until after the date of his first HIV positive test which was obtained on 15.8.85 and tested 13.9.85. The concentrate given in November 1982 was evidently NHS and that in April 1983 was commercial, but the sources and batch numbers of the remaining doses are not stated in the notes.

With hindsight, one can state that the Plaintiff might well have been treated successfully with DDAVP and/or cryoprecipitate, in which case he would probably not have been infected with HIV. All of the concentrate which he received before his HIV seroconversion, however, was given at a time when knowledge of the risks involved was very imperfect, and only a single dose was given after the recommendation of the Haemophilia Reference Centre Directors to use DDAVP and cryoprecipitate in preference to concentrate. I therefore regard this as a doubtful case.

Conclusion - Doubtful

JKP 36

The allegation is that the Plaintiff was a severe child haemophiliac born in GRO-A 1977 and treated with nothing other than concentrate. Professor Hardisty comments that he was treated with Factor VIII concentrate from 1980 or earlier. This was almost entirely commercial until July 1983 and then apparently exclusively NHS until 1984 when heat-treated material became available. The notes record that blood was taken for HIV testing in August 1985 but there is no laboratory report on this sample and the first mention of his HIV positive status occurs in a letter dated 19th September 1985.

The Plaintiff's treatment with Factor VIII concentrate started at least two or three years before AIDS was described in haemophiliacs and was standard treatment at the time. The change from commercial to NHS concentrate in the middle of 1983 and subsequently to heat-treated commercial and then heated NHS concentrate was perfectly appropriate responses to the development in knowledge at the time and in line with the recommendations of the Haemophilia Centre Directors.

Conclusion - No negligence.

JKP 46

The Plaintiff was born in GRO-A 1977 and alleges all treatment was in hospital as he did not go on home treatment until 1988. Retrospective testing shows that he was HIV positive in 1984. They accept that there are no special features about this case and it is somewhat surprising that it was put forward.

Professor Hardisty comments that the Plaintiff was a severe haemophiliac with frequent bleeds, treated with both NHS and commercial Factor VIII concentrate from July 1978. HIV positive sometime in 1984 but the exact date of the sample is not recorded. No previous negative sample obtained.

Concentrate was certainly the treatment of choice for this severely affected boy, and was begun long before the risk of HIV infection had been recognised. Infection certainly occurred before heat-treated material was available and probably before there was any evidence of the greater risk from commercial than from NHS concentrate.

Conclusion No negligence.

JKP 047

The allegation is that the Plaintiff was a mild child born in 1976 who was treated with nothing other than concentrate.

Professor Hardisty states that the Plaintiff required treatment three or four times per annum on average for tooth extractions and bleeds following minor injuries. He was treated with concentrate exclusively from 1982 onwards. The record of sources of concentrate and batch numbers are incomplete but it appears that commercial concentrate was given in 1982, NHS in 1983/1984 and treated material thereafter. He was stated to have been HIV positive since July 1985 although the notes do not contain the actual laboratory report.

Although with hindsight it can be argued that many of this boy's bleeds could have been satisfactorily treated with cryoprecipitate or even DDAVP, it cannot be said to be negligent to have treated him with concentrate in the period 1980 through 1982 before the risks of AIDS was appreciated. Although it appears that treatment was changed in 1983 or 1984 from commercial to NHS material, records are insufficiently complete to be sure that this policy was adhered to. If the Plaintiff had been continued to be treated with commercial concentrate after about June 1983, this would have been contrary to the Reference Centre Directors recommendations to use cryoprecipitate or DDAVP for mild cases. A switch to NHS concentrate from that date would have been acceptable, provided it was adhered to. In the absence of evidence on this point, this must be regarded as a doubtful case.

Conclusion - Doubtful.

JKP 57

Severe haemophilia, (Factor VIII less than 2%), not moderate as stated in the ISC, born 2 GRO-A 7, diagnosed at 16 months of age. Treated on numerous occasions from 1980 onwards with Factor VIII concentrate, predominantly commercial but also NHS. So far as I can ascertain from the batch numbers both unheated NHS and heated commercial concentrates were given during the first 6 months of 1985, and thereafter only heat-treated material. HIV positive 1.8.85, no previous negative result.

It cannot be regarded as negligent to have used Factor VIII concentrate, whether commercial or NHS, for the treatment of severely affected haemophilic children in the early 1980's, before AIDS was discovered, nor is it likely that the Plaintiff would have been protected from HIV infection had treatment been changed to cryoprecipitate in 1983, when the relative risks began to be apparent, since he had then already been receiving commercial concentrate for some three years. It would have been a counsel of perfection to use only home produced concentrate from the middle of 1983 until heat-treated commercial material was available, but supplies were probably inadequate to permit this. A very doubtful case.

Conclusion - No negligence.

JKP 60

This child haemophiliac severe, born in GRO-A 1976 died in GRO-A 1986. It is alleged that from 1979 onwards treated with concentrate but his mother says that he was on cryo. up to the age of 3 with no adverse reaction.

Professor Hardisty comments that the Plaintiff was treated at Alder Hey Hospital Liverpool until May 1984 and then at Glynned Hospital North Wales on home treatment. Treatment was evidently with concentrate from an early age but the Liverpool notes are currently not available. Treatment in Wales was almost exclusively with NHS concentrate with the occasional doses of commercial concentrate presumably because of insufficient NHS material being available. HIV positive in July 1985 with no previous negative results although a sample was taken on the 30th January 1985 but evidently not reported on.

Currently Professor Hardisty can only make the general point here that treatment of a severely affected infant or young child with concentrate is not of itself negligent, cryoprecipitate is unsuitable for home treatment in many instances and has many disadvantages. NHS concentrate should have been preferred to commercial from about mid-1983 but supplies were inadequate to adhere entirely to this counsel of perfection, only heat-treated concentrate should have been used from early 1985 as was indeed the case here.

Needs reconsideration once Liverpool notes are available, in the meantime no evidence of negligence.

Conclusion - No negligence.

JKP 72

The Plaintiff is a severe child born in March 1980 but not treated until 1984 and then only with concentrate.

GRO-A

Professor Hardisty comments that he was in fact treated at Hull with cryoprecipitate until July 1983 and then transferred to Norwich where he was first seen in January 1984. The only records of replacement therapy after this date are in June 1984 when he received NHS concentrate and from February to May 1985 when he received commercial heat-treated concentrate and from July 1985 onwards when treatment was with heat-treated NHS concentrate.

The available notes contain no actual records of the date of HIV testing. The ISC gives 25th January 1985 as the date of first positive result with no previous negative results but the Defence states that he was negative in January 1985 and positive in January 1986. If the latter dates are correct, then he may have been infected by heat-treated concentrate. It was not negligent to treat this severely affected haemophiliac child with concentrate and heat-treated material was used as soon as it became available, first commercial and subsequently NHS.

Conclusion - No negligence.

JKP 086

A pharmacist born GRO-A 41, died GRO-A .91 Haemophilia B (Christmas Disease, Factor IX deficiency), diagnosed aged 12. Apparently fairly severe with frequent joint bleeds, particularly into the knees and elbows, but the notes contain no actually Factor IX assay results. Treated with fresh frozen plasma until April 1975, and thereafter with Factor IX concentrate. On home treatment from 1979 or earlier. First HIV test on sample taken on 14.8.85 and reported on 18.9.85 was positive. This result was discussed with the Plaintiff on 4.10.85 when his wife was tested and found to be negative.

According to the Statement of Claim the Plaintiff was told by Dr. McVerry in January 1985 that the NHS Factor IX which he was receiving was not heat-treated (in contrast to Factor VIII) because it was "perfectly safe". If so (there is of course no record in the notes of this conversation), it must be accepted that this was an unjustified prediction in the then state of knowledge. In fact, the first seroconversion of a Haemophilia B patient receiving NHS Factor IX concentrate was recorded in the following month (February 1985). Although the risks of HIV infection from Factor IX concentrate appeared to be lower than those from Factor VIII, and although this Country was self-sufficient in home produced Factor IX concentrate, which could reasonably be expected to be safer than unheated imported material, it was certainly not justifiable to state that no risk attached to the use of unheated NHS Factor IX concentrate. Heat-treated NHS material did not become available until October 1985, when the Plaintiff was immediately switched onto it. Had he been warned of even a slight risk from the use of unheated material in January 1985, he might well have opted to revert to the use of fresh frozen plasma (although this could not have been used for home treatment), or of heat-treated imported concentrate (though it could be argued that the safety of this material was no more certain than that of unheat-treated NHS concentrate. It was in fact the general practice throughout 1984 and 1985 to treat Haemophilia B patients with home

produced concentrate, except for a period of a few months between the introduction of imported and home produced heat-treated material, during which some patients were switched to the former. I regard this as a somewhat doubtful case: in the state of knowledge at the time, I do not believe that it can be held to have been negligent to continue to treat the Plaintiff with home produced unheated concentrate until heat-treated material was available, but the alleged statement that the unheated material was perfectly safe could be held to have been negligent in that it failed to give the Plaintiff the opportunity of considering the relative risks of this and other possible forms of treatment.

Conclusion: Doubtful

JKP 92

Severe Haemophilia (Factor VIII < 1%)

D.O.B.: GRO-A /81
Diagnosed: June, 1982

Treated exclusively with Factor VIII concentrate, and never with cryoprecipitate. The first treatment was given on 1/11/82 for a gum bleed following injury, and the next on 16/6/83 for a bitten tongue. The notes contain records of treatment on 7 occasions in 1983, 10 in 1984 and many subsequently. He is stated to have received a single ampule of Factorate (i.e. Armour concentrate) in July 83, and batch A26005 (also Armour) in September 1985, but these are the only two records in the notes of the type of concentrate given until February, 1987 when he was receiving heat-treated NHS concentrate (8Y). Blood was evidently first taken for HIV antibody testing on 5/8/85, but no result of this test is recorded in the notes, and the first record that he was HIV positive occurs in a letter dated 27/7/87.

Although AIDS had been described in American haemophiliacs by November 1982, when the plaintiff was first treated with factor VIII concentrate, the risks of such treatment were not yet generally appreciated. By mid 1983, however, the risks of imported concentrates were becoming clearer, and the Haemophilia Reference Centre Directors had recommended the use of cryoprecipitate in small children. It could be held that a failure to switch the plaintiff's treatment to cryoprecipitate from this date, and to continue to treat him regularly with concentrate (at least some of which was imported) was negligent, and I think such a claim would be difficult to defend. All of the patient's bleeding episodes appear to have been of a relatively minor nature, such as could have been controlled with cryoprecipitate, and he was not started on home treatment until 1990.

Conclusion: Negligence.

JKP 105

The Plaintiff's allegations are that the Plaintiff was a severe haemophiliac child born in GRO-A 1976 and was given no treatment other than concentrate save for one isolated treatment in 1982 with cryoprecipitate.

Professor Hardisty states that in accordance with the policy at Liverpool Children's Hospital he was treated with concentrate from 1978 onwards. There are no records of the type or batch number until January 1983 when he received commercial concentrate, March 1983 NHS, and December 1983 commercial. In June and August 1984 he received NHS concentrate, and thereafter heat-treated concentrate first commercial and then NHS. There is a record that blood was taken for HIV testing in August 1985 but the earliest positive laboratory result is dated December 1987, and there is no mention in the notes of his being HIV positive before this date.

The Plaintiff was treated with Factor VIII concentrate from 1978 onwards i.e. about four years before AIDS was described in an American haemophiliac. This was probably mainly commercial material since NHS concentrate was in very short supply in the early 1980's. An attempt was made in 1983 to switch to NHS concentrate, although the extent to which this was achieved cannot be judged in the absence of complete records.

HIV infection was probably derived from concentrate before the risks were appreciated. A switch to cryoprecipitate in 1983 would have deprived the Plaintiff of the great advantage of home treatment and would probably have been too late in any event.

Conclusion - No negligence.

JKP 109

Severe haemophilia, (Factor VIII less than 1%), born GRO-A 80, diagnosed aged 6 weeks. First treated with cryoprecipitate in February 1981 and received a total of 11 packs of cryoprecipitate and 6 ampules of commercial Factor VIII concentrate during that year. During 1982, he received 24 packs of cryoprecipitate and 21 ampules of commercial concentrate and in 1983, all his treatment was with commercial concentrate. In 1984, he was treated with commercial concentrate until May when he was switched to NHS concentrate, apparently on account of a presumed reaction to the commercial material resulting in a coughing fit. He was started on home treatment at this time, and thereafter received NHS concentrate exclusively, heat-treated NHS concentrate being introduced in April 1985 when it first became available. The first HIV antibody test was carried out in 1986 on a sample obtained some time in 1983 (probably April) and proved positive.

The Plaintiff's HIV infection was most probably due to commercial concentrate which he received during 1982 or 1983, well before the risks of this form of treatment were generally recognised, before the viral cause of AIDS had been established and before the Haemophilia Reference Centre Directors had issued any recommendations on treatment in the light of the impending epidemic. The switch from commercial to NHS concentrate was made in May 1984, six months before the Reference Centre Directors recommended this change, and heat-treated NHS concentrate was introduced as soon as it became available. It think it would be very difficult to establish a claim on negligence in this case.

Conclusion: No Negligence.

JKP 116

The Plaintiff alleges that he is a mild adult who had only ever had two or three treatments in his life in 1984 for a relatively minor physical problem which involved elective surgery.

Professor Hardisty comments that the Plaintiff was a mild haemophiliac born in GRO-A 1967 and first diagnosed at the age of 17 following emergency surgery for an injury. Factor VIII was found to be 28%. Further surgery was required and was covered with Factor VIII concentrate, fresh frozen plasma and cryoprecipitate as well as whole blood. There is no record in the notes as to the type of Factor VIII concentrate given. It appears that he received no further Factor VIII concentrate after November 1984 although he was evidently given cryo. in July 1985 to cover an operation for the removal of an in-growing toe nail.

He was found to be HIV negative at this time, July 1985, and positive in April 1986. It is difficult to reconcile the apparent date of seroconversion with the dates of the Plaintiff's treatment.

If he was infected by a blood product, then Factor VIII concentrate received at the end of 1984 would appear to have been much the most likely source despite the negative result in July 1985. Despite the mildness of the Plaintiff's haemophilia, skin grafting was adequate justification for the use of concentrate rather than cryoprecipitate. It could be argued that NHS rather than commercial concentrate should have been used at this date, and also that the diagnosis of haemophilia as the cause of the bleed into the leg should have been made before surgical intervention, in which case the latter might possibly have been avoided. It would appear however that the possibility of haemophilia was not considered until the initial emergency surgery was followed by continued bleeding.

Conclusion - A somewhat doubtful case.

JKP 122

The Plaintiff was a severe child born in GRO-A 1977. All that is said by way of "allegation" is that he was on cryoprecipitate until 1979 and then put on Factor VIII no record of tranexamic acid being used until 1985.

Professor Hardisty states that in June 1979 he was found to have developed an antibody to Factor VIII which made the use of cryoprecipitate inappropriate and he was switched almost completely onto concentrate, chiefly commercial. Home treatment started in 1981. Very frequent bleeds into joints and muscles, for which tranexamic acid would have been quite inappropriate. HIV positive in 1983 (tested retrospectively in 1985).

This is an example of an early seroconversion due to infection by commercial concentrate before the risk of AIDS to haemophiliacs had become apparent. The use of commercial Factor VIII concentrate for the treatment of severely effected children was standard practice in 1979 through 1983.

Conclusion: no negligence.

JKP 139

The allegation is that the Plaintiff was a mild adult born in 1968. Although allergic to cryoprecipitate it is alleged that no alternatives seemed to have been considered and all the records from 1989 onwards show that he was treated with NHS and commercial concentrate. The allegation is that there seemed to be no consideration of any other treatment.

Professor Hardisty states that the Plaintiff was treated with cryoprecipitate until May 1979 when he developed an allergic reaction to it and was switched to Factor VIII concentrate. Although a mild haemophiliac, his unruly behaviour made him unduly injury prone, so that he required more replacement therapy then might otherwise have been the case. Almost all of it for post traumatic bleeding. He received both NHS and commercial concentrate on several occasions during 1981 and 1982, and from 1983 onwards until heat treated material became available he received only NHS concentrate. DDAVP would not have been suitable for the treatment of Post-traumatic haemorrhages, particularly as in this case, there was evidently some doubt about the patient's actual Factor VIII concentration, which varied from occasion to occasion. First positive test (on retrospective testing) July 1984. The most likely source of infection would have been commercial concentrate administered in 1981 or 1982 before the risk of AIDS was known.

Conclusion: No negligence.

JKP 149

Plaintiff is a mild haemophilia born in 1976. Treated on numerous occasions from 1979 onwards with Factor VIII concentrate both NHS and commercial as was then standard practice. NHS concentrate was used exclusively from November 1983 until the end of 1984 after which treatment was switched to heat-treated commercial and subsequently heat-treated NHS. HIV positive October 1984 with no previous negative results.

The use of concentrate rather than cryo. was standard practice and it was not negligent in the case of this child. The use of commercial concentrate was avoided in 1983 as soon as it began to be probable that it carried a greater risk than NHS concentrate and heat-treated material was introduced when available.

Conclusion - No negligence.