Witness Name: Andrew Michael March

Statement No: WITN1369014

Exhibits: WITN1369015-63

Dated: March 2020

INFECTED BLOOD INQUIRY

EXHIBIT WITN1369035

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME ONE

(April 1989)

CONTAINS:

1. Terms of reference. Note: It's not expressly stated, but we believe the real reason the ACVSB was formed was to give risk analysis and cost-benefit analysis, general accountancy and identification of where savings could be made.
2. Awareness of possibilities of plasma pool contamination.
3. Several references to "Spiking studies" in relation to HTLV-I and also to 'fractionations" and virus inactivation processes – clearly spiking is a standard technique.
4. EEC Directive on Blood Products – Takes effect on new products from January 1992 and existing products December 1993.
5. CJD (classic / sporadic) is mentioned as an area where the FDA have pronounced and that the UK could be lagging behind.
6. CMV testing is considered to be brought before the committee.
7. Ethics? Dr Pickles questioned whether it was more ethical for recipients of hGH (Human Growth Hormone) to learn of the risks from the media rather than from their doctor. **Note**: We would suggest that this is not the first time this concept has been used on patients and that ethics aside, suits both physicians and the Department quite nicely.
8. Awareness is evidenced that (in relation to hGH) the contamination of the plasma pool could also spread infection to considerable number of recipients of blood products.
9. Crown Immunity or Crown Privilege is mentioned in relation to licensing. **Note: Attention should be paid to the date here – April 1989 – the commencement date of the HIV Haemophilia Civil Litigation.**
10. Product Liability – Not doing donor testing, which is currently being done in the US might have implications for product liability.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME TWO

(May 1989)

CONTAINS:

11. EEC Directives on Blood Products: A Suggested Amendment to have blood classified as a medicinal product. This is important because this issue has come up before (in 1981) and Government have procrastinated over it previously and it comes up from time to time as and when it suits them. **Note:** It appears here that the ACVSB committee are attempting to 'dilute' the scope of the EC Directives on Blood Products and the ACVSB committee anticipate the their amendment will be rejected by the Commission. (In fact it does get rejected, see ACVSB Volume 3 for July 1989.)
12. **Knowledge of Chiron HCV test in May 1989 and desire expressed to test without recourse to Chiron. Note:** The phrase "*without recourse to Chiron*" could only mean that they were attempting to copy the isolates for the new HCV test so that a UK firm, could bring out their own test and avoid paying royalties to the US company.
13. Non-A Non-B Trial: NANB Testing should not be introduced into the NBTS prior to the results of the UKBTS Non-A Non-B Hepatitis trial.
14. On a handwritten page within the minutes, Prof. Zuckerman estimates that the results of the Chiron test kits were only 50% reliable – yet his comments should be viewed in the context of his desire to "have no reliance on Chiron".

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME THREE

(July 1989)

CONTAINS:

15. Non-A Non-B Hepatitis: Need for a prospective study of post transfusion NANB (in blood recipients or **stored sera** from **haemophiliacs** – July 1989.) (Please note this data-gathering on UK haemophiliacs and also evidence of the possession of stored sera on persons with haemophilia.)
16. Data on Haemophiliacs to go to Dr A Rejman (DHSS Med SEB/B). **NOTE:** This is important because of the date as it represents a specific request from the DOH to garner information on UK Haemophiliac at a time when they are litigating against the DOH (i.e. April 1989-1991). It is also important because Dr A Rejman
17. There is evidence that the new Chiron HCV test had been used in first time recipients of Factor 8Y. Further study of haemophiliac sera was advocated – July 1989.
18. Dr Mortimer (PHLS) considers the results of the new Chiron test as reliable and is asked to forward all contribution on Non-A Non-B to Dr Rejman of the DHSS.
19. EC Directive on Blood Products: **Commission rejects amendment** – found incompatible with the terms of Article 1 (2).
20. SNBTS writes to Dr Canavan of DHSS regarding the definition of Operational Policy and practice in response to reports of product (blood or blood product) infectivity.

Transcript of Handwritten Notes (2 pages) from ACVSB Volume 3

Dr J. S. Metters – Taking over from Harris in Aug.
(Note: current Chairman is Dr E L Harris)

1. **EEC**
   - Modification rejected.
   - Appendix 2 of Directive now being developed.
   - Pass on comment Medicines Control Agency.
   - Important for PFC - G. Schild is Chairman. *(Note: Dr Geoffory Schild, CBE: Director of the UK NIBSC from 1985 to 2001)*

2. **H.G.H** *(hGH - Human Growth Hormone)*

Preece Study (*Note: Preece is a Professor*)

Started research project

- establish state of health of recipients.
- establish whether or not blood donor or has been donor
- no look back action.

AZ [*Note: AZ is Prof A. Zuckerman*] - Does ***not*** wish to put HGH as exclusion clause in literature. - Can be caught by net of previous medical treatment.

DOH does not seem happy about this. US specifically mentions HGH recipients.

New specific statement to allow grant of product licence.

DOH very worried indeed !!!

DOH to issue press release later in the Summer.

3. **H.T.L.V. 1**

Tedder {*Professor Richard S. Tedder, Virologist, UCL}* confirmed that tests all detect positive but also high levels of false positives.

US proposing that PCR is only confirmatory test !!!

NIBSC have looked at plasma pools from U.K.

US - no positive proof yet - suggest might become confirmatory test in UK trial of 100k donors.

NBTS Study (HG) – (Note: HG stands for Dr Harold Gunson, NBTS)

Difficult to select ethnic groups.

R. Tedder *(Professor R. S. Tedder)* - Findings of Abbott test ok - detail

HTLV I + II Du Pont - no good?

Support for unselective study - agreed.

Abbott test performed.

Study should proceed now - **not** delay.

Despite non-specificity.

[S Ortho?] seems to have had results to mandatory donations

Now worried about availability of confirmatory testing.

DOH seem to want to delay the project.

- Requested that project be worked up in more detail by sub-committee.

N.A.N.B

P Mortimer thinks test is seeming something sound. (*Note: Dr P. Mortimer is PHLS)*

Paper to be assembled for committee for discussion next time.

Data on Haemophiliacs data to A Rejman. *(Dr A Rejman = DHSS Secretariat)*

NB. P.F.C. SOP needs to be reminded.

(P.F.C. = Protein Fractionation Centre, Edinburgh and SOP = Standard Operating Procedure.)

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME FOUR

(November 1989)

CONTAINS:

21. Non-A Non-B Hepatitis – that routine screening should only be introduced in the UK after the FDA (USA) have approved the test and urgent pilot studies have been carried out in this country. **Note:** It is interesting how the UK can vacillate over whether or not to implement a test and can stall for time when it suits them.
22. Dr Metters explained that although the Department must bear in mind the possible litigation that could arise from a prolonged delay in the introduction of general screening, the NHS Management Executive would want to know more facts and figures before backing such a move.
23. DHSS (Mr J. Canavan) receives advice from Dr Tuddenham (Haemostasis Research Group) that it may well be that screening donor blood could reduce transmission of NANB (Hep.) in single donor products and some pooled plasma derivatives. **Note: This constitutes advice to the DHSS and thus they knew of this on 17th October 1989.**
24. ANTI-HCV TESTING: Evidence that the ACVSB committee knew in November 1989 (and the Department knew) that 70-80% of haemophiliacs were positive for Hepatitis C: *"In general, 70-80% of patients suffering from treated (or severe) haemophilia were anti-HCV positive."*
25. Ortho / Chiron HCV test not yet licensed by FDA. *"The routine use of the test for blood donations in the U.K. should not commence before FDA licensing procedure is effected."*
26. Clinical Trials of the Ortho (Chiron) ELISA HCV tests were completed by July 1989. (Note: this is early, esp. if Government keep insisting that HCV was only discovered in 1989....)
27. Proof of SNBTS testing 146 Haemophiliacs in Glasgow during the Haemophilia HIV Civil Litigation which commenced in April 1989. The SNBTS found that 63% of the Glasgow Haemophiliacs were positive for HCV with the new Chiron / Ortho ELISA test conducted between September and October 1989, which was over 1 year before the alleged waivers emerged.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME FIVE

(January 1990)

CONTAINS:

28. We are now seeing clear and frequent reference to HCV, as opposed to NANB.
29. HCV Testing: Evidence that the USA's FDA will recommend implementation for single donor products but NOT for fractionated products – "two independent sightings of this of this rumour" but as yet unconfirmed. Quoted from the ACVSB minutes: ***"Importance of policy decision on fate of pre-existing plasma stocks before implementation of test to avoid repeat of HIV story"***. (17th January 1990.)
30. Committee agreed not to introduce test (HCV) in advance of FDA approval but very compelling reasons to implement quickly following U.S. decision.
31. Removal of Crown Protection – clarified that 'transitional arrangements' mentioned in recent SHHD briefing note would permit continued product supply beyond April 1st 1991 until the granting of license.
32. Dr Rotblat/Dr Pruves concerned that BPL 8Y (Factor VIII) license application contains no HIV inactivation data – all manufacturers to supply this data as a condition of license.
33. Dr R. Tedder believes that there is date suggesting majority of HCV positive donations are non-infective and tends to support the argument that removal of HCV+ve donations from plasma pools might **not** be a good idea.
34. **Dr R. Tedder and Dr E. Tuddenham** ***"support the view that HCV testing is a 'single donor' issue and not highly relevant (at the present time) to fractionated products."*** (January 1990). **Note:** HCV was most certainly a fractionated product issue – as we all found out the hard way!
35. Professor Zuckerman: *"The projected cost of this screening test is, at least initially, very high, but considering the overall morbidity of chronic non-A non-B hepatitis (including apparently autoimmune liver disease and hepatocellular carcinoma),* ***and litigation which would be indefensible, the introduction of screening could not be delayed much beyond FDA approval."*** (January 1990).

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME SIX

(April 1990)

CONTAINS:

1. American Association of Blood Banks: Testing for HCV should be introduced as soon as the FDA approves test. Confirmed that approval not yet been given. **Concern about litigation/liability was the main influence on the US Blood Banks.**
2. HCV testing introduced for routine screening in France, Belgium & Luxembourg. Italy had introduced the test on a voluntary basis. (April 1990)
3. **HIV Litigation**: Dr P Mitchell mentions the HIV Litigation and the question it raised about a scheme of ***no fault compensation***. The Chairman (Dr J Metters) said that Ministers had no plans for such a scheme. **Note:** this was 24th April 1990, just a couple months prior to Mr Justice Ognall's Statement of Direction of 26 June 1990.
4. **HCV testing** also now in place in Finland and Australia (April 1990).
5. NIBSC reported that US have not decided yet on whether HCV +ve donations will be included or excluded from **plasma pools**.
6. Dr John Barbara on **HCV**: "The validity of the assay in relation to transfusion is best demonstrated by studies in recipients of clotting factor concentrates prepared from large pools of plasma" "This provides an ideal **'control'** for excluding the possibility that the assay merely detects some non-specific factor in patients with haemophilia..."
7. **Dr Christine A. Lee (now Professor):** "Between 1978 and 1983 there have been 50 haemophiliac studies, 31 of them prospective." "**The majority of multi-transfused haemophiliacs are shown to be positive for HCV antibody**." (Circa 1990) "The use of the Ortho Hepatitis C **assay kit has confirmed anti-HCV seropositivity in all haemophiliacs** with well documented NANB hepatitis." **Note: this was stated circa April 1990 – whilst the UK HIV Haemophilia Litigation was ongoing**.
8. **Spiking**: "This will be achieved by the deliberate addition ('spiking') of significant amounts of a virus to the crude bulk to be purified and to different fractions obtained..." "Indeed confirmation that the product is virus-safe will be given only by long-term post-marketing clinical studies. Recipients of the product should be monitored clinically for seroconversion and for viral illnesses."
9. **Look Back**: Public Health Service recommends against an effort to identify and notify all past recipients of blood components from donors now found to be repeat reactive for antibodies to HCV ("look Back"). AABB, ARC and CCBC endorse this position." Note: This was during HIV civil litigation.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME SEVEN

(July 1990)

CONTAINS:

36. Dr Rejman: The FDA had approved hepatitis C screening and that America had already introduced screening and other countries were following.
37. **RIBA test (HCV) also available** as a supplementary test – (July 1990).
38. ACVSB meeting brought forward so that a decision on the introduction of UK Hepatitis C testing could be reached **and consider again advice to Ministers**.
39. After further discussion the Committee (ACVSB) concluded they should recommend to Ministers that hepatitis C testing should be introduced in the UK, but that first a pilot study using Ortho and Abbott tests was necessary to decide which was the better test for the RTCs. (July 1990). **Note: Suddenly the concept of HCV testing is not so unpalatable – it's suddenly all on, and this rush is not just because of the FDA decision to approve the Hep C test, but probably more due to the arrival of the Abbott HCV test.**
40. The Committee decided that the pilot study should go ahead without delay but that **frozen down samples should be kept** so that donations could be retested later against other tests such as the Wellcome one, as these become available.
41. Any HCV +ve donations would not be used, but retained for research purposes.
42. **Consideration of any look-back procedure was postponed.** (Affects haemophiliacs)
43. **Discussion (unresolved?) of whether it is necessary to test plasma** to minimise the virus load in **plasma pool**.
44. The question of **testing plasma for ALT was deferred** for late discussion.
45. Article April 1990: *"In addition to arousing fears about their own health, donors who are told the new test shows that they are positive will become embroiled in the issue of* ***whether HCV can be transmitted to their sexual partners.***"
46. Question of "**look-back**"(ref. **USA**): Donors found positive in trials not yet notified. Attorneys very uncomfortable with notifying donors and not notifying the patient who may have received blood from that donor's last unit.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME EIGHT

(November 1990)

CONTAINS:

47. Dr Gunson reported that a PSCO based at the Manchester transfusion centre had offered to keep **a detailed database of HCV positive test results**, along the same lines as that kept for results identified as HIV positive.
48. Dr Minor said that there would be a meeting organised by the NIBSC in December to discuss other countries' approach **to HCV testing of plasma**.
49. The chairman recalled the summing up of the last meeting and said that a note had gone to Ministers telling them that the ACVSB was in favour of introducing routine HCV testing in the UK.
50. **The chairman reiterated the recommendation that all plasma should be tested for HCV**. He also emphasised that the reference to a "**no look back**" procedure in the previous minutes referred only to work done on the pilot study. A **decision** on this aspect of routine screening of donors was **deferred** to a subsequent meeting of the ACVSB.
51. A UK wide consensus sought on procedures for **counselling** of donors.
52. **BMJ** Vol 299: "Blood donations are accepted by the National Blood Transfusion Service 12 months after an episode of jaundice or hepatitis in the donor so long as testing for hepatitis B surface antigen yields negative results. In the light of our findings and **recent legislation relating to product liability** we believe that this policy should be reassured and that consideration should be given to testing such donors for hepatitis B core antibody and excluding them if the are found to be positive." (BMJ 9 September 1989)

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME NINE

(February 1991)

CONTAINS:

53. Prof. Tedder: If archival specimens showed no antibodies and were followed up with a negative assay test then 85-90% of these donors could be re-instated. **This suggestion ran counter to the EAGA and UKBTS/NIBSC guidelines**.
54. Dr Minor (NIBSC): Should HCV positive donations be included or excluded from the plasma pool? There was no international consensus. **The Committee agreed in principle that positive donations should be screened out.** Good manufacturing practice indicated that possibly infected units should not be included in a pool. **Note: This issue has a bearing on the ACVSB minutes later on (in Volume 12) where use of non-screened anti HCV +ve plasma is fractionated into Factor VIII & IX right up until 1st January 1994.**
55. Acknowledged that there would be **practical problems with licensed American products as the U.S. did not screen out positive donations**.
56. Consultant in charge of patient to decide which product to use.
57. Discussion of problems of **look-back** and recommends that it **should not be undertaken as a service**, leaving the option for those carrying out research.
58. Prof Tedder: Proposal to study HCV infection in blood donors whose serum contained HCV antibodies, & in the **recipients of their blood products**. Applying to **DH** for funding. Introduction of HCV testing "a unique opportunity since in later years the number of HCV positives was likely to be much less."
59. **CJD Agent / Prions in Blood Donors (DoH Look-back)**: Professor Tedder: "It was possible that the numbers involved were so small that raising the issue could cause disproportionate and unnecessary alarm." **Note: This comment is appalling in light of the serious numbers involved when 176 batches of BPL plasma products became implicated as contaminated prior to 1998.**
60. **Chronic Fatigue Syndrome (ME):** Suggested that Department should introduce routine testing of blood donations for **ME** to prevent transmission of the infection(s) responsible for this disorder to blood transfusion recipients.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME TEN

(May 1991)

CONTAINS:

61. **The Committee considered ALT testing**. It was thought that ALT was used as means of identifying other non A non B hepatitis. It was agreed that ALT test were not specific for HCV and there was poor correlation between HCV antibody and ALT. (Not sure if this relates just to a trial or to actual policy.)
62. **Anti HBc Testing of Blood Donors with a History of Jaundice**: It was further agreed, however, that donations from those where positive anti-HBc was know should be deferred from cellular use. The Committee was to further consider their inclusion in **fractionation** once a summary of the position in the **U.S. was known**.
63. The **Lancet 1991**: "However, it might not be possible to wait for more specific tests in the UK; common regulations for the European Community as well as the **Consumer Protection Act with the introduction of product liability** have increased the pressure on the blood transfusion services to test blood donations for Anti-HCV. **Unfortunately, many haemophiliacs have already been infected with HCV.**" (The Lancet Vol 337: March 30, 1991)
64. **Ad Hoc Working Party on Biotechnology**: "However, despite that fact that recent progress in the methods used for the preparation of coagulation facts have considerably improved that safety of this category of **plasma derivatives, seroconversion for HIV antibody has still occasionally been reported in recipients."**
65. **Hep B Infections:** "In a ***recent*** [circa 1991?] incident a HBsAb suspect donation was included in a plasma pool. This led to a thorough investigation to check whether **haemophiliacs** were at risk of infection." Some haemophiliacs found not to be vaccinated against hep B, & their immune status was unknown to their treating doctors.

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME ELEVEN

(October 1991)

CONTAINS:

66. **Screening of Non UK plasma in blood products:** CSM approves a recommendation that blood products licensed in the UK should be made from HCV screened donations. It seemed probable that the US would follow suit.
67. **Cut-Off Date**: Dr Lane said that the date of **1.1.93** was **not practical** for all the products manufactured by **BPL**. Concerns were expressed that the suggested date would lead to the disposal of valuable collected material, and make self-sufficiency more difficult to achieve. (**Note:** It's October 1991, the UK has had plenty of time to achieve self-sufficiency if they ever really intended to – it's been 17 years since the 1974 pledge.)
68. **Re-admittance of Donors Not Confirmed HIV Antibody +ve**: No definite conclusions to be drawn from EAGA. No common approach in Europe.
69. **HTLV-I Study (BTS)**: The Secretariat to **seek legal and ethical** advice on look-back studies and commission a cost/benefit analysis of HTLV-1 testing.
70. **HTLV-I Study (BTS)**: "Routine screening of all blood donations for HTLV antibodies was introduced in the USA in late 1988 and shortly thereafter in Canada." "The economic impact of screening and the other effects that screening would have on the blood supply should at the same time be ascertained." "If routine anti HTLV screening were to be introduced in the UK, up to 100 donors per annum might be expected to be confirmed positive for anti-HTLV."
71. **Article in the Independent:** The NHS BTS "admits receiving and passing on between 1,000 and 2,000 donations a year of blood infected by hepatitis-C..." ***Delay in Introducing HCV Test*:** "The BTS intends to begin screening for the virus next month. But a test for hepatitis-C has been available since 1989 and lawyers say the delay could amount to negligence." (7th August 1991) ***Mention of HIV Settlement*:** "This year, the Government gave an out-of-court settlement of more than £82m to 1,200 haemophiliacs infected with HIV from contaminated supplies of the blood-clotting agent Factor 8". (7th August 1991)

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME TWELVE

(February 1992)

CONTAINS:

72. **Non-HCV Tested Plasma** remains under discussion within C.P.M.P.
73. **UK expressed doubts that the cut-off date is acceptable** for all blood products released to market being derived from anti-HCV screened plasma.
74. **EC Directive on Blood Products**: The UK had successfully agreed that quality of starting materials and screening were the elements which gave the highest quality standards to finished blood products.
75. **ALT Testing**: ACVSB to advise Ministers that there is no requirement to introduce routine ALT or HBc screening of blood or plasma donations. "The case for introducing ALT testing was that it may identify donors in the early stages of HCV infection." There was **no** European requirement for ALT screening. **Note: Why are they so reluctant to take the lead internationally?**
76. **HTLV-I**: Routine screening not considered necessary. (Broadly consistent with Europe (except France) and the U.S.). Justification for this position is based upon cost/benefit analysis of screening & likely impact on donors.
77. **Virally Inactivated Fresh Frozen Plasma (VIP)**: VIP was being produced in Europe and should be considered for use in this country. "Further attempts to persuade colleagues that this was a **central issue** relating to the **safety of blood supply** failed." (Dr. RJ Perry, PFC Director. 24 **February 1992**.)
78. **Use of Non-Screened Anti-HCV Positive Plasma** in **UK** Factor VIII and IX products right up until 1st January 1994. *"Further to the agreed need for the screening of blood donors for Hepatitis C, and the question which had arisen with regard to medicinal products derived from unscreened blood placed on the market before the 1.1.93... should they be withdrawn, or in the interests of continuity of supply, could they remain on the market during a certain period?"* **Note**: The issue of whether to screen plasma for HCV has been dragging on since the Fifth meeting of the ACVSB in January 1990. **There is no excuse for the use of HCV +ve plasma in UK blood products as late as January 1994.**

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME THIRTEEN

(July 1992)

CONTAINS:

79. **HTLV Testing**: "*Members were now asked in the light of all the information available about advice the Committee should offer* ***Ministers*** *on whether screening of donated blood* ***and plasma*** *for the presence of the HTLV antibody should be introduced in the UK.*" (2 July 1992).
80. **Gaps in Knowledge about HTLV**: "The incidence of transmission by blood transfusion indicated that though very low it could be one of the major routes".
81. **No case for selective screening for anti-HTLV**.
82. **Cost** was a major factor in considering anti-HTLV screening. "*Members noted the conclusion of* ***the economic appraisal of anti-HTLV testing*** *that it would represent* ***relatively poor value*** *compared with other health service* ***interventions***."
83. **Legal Advice:** "Members noted the legal advice that a decision to recommend against anti-HTLV testing would **not** expose the Secretary of State to **charges of negligence** should a patient transfused with HTLV infected blood come to harm as a result of the infection." (9th July 1992).
84. **Recommendation to Ministers**: Committee agreed that at present there was an insufficient case to support the introduction of routine screening of donated blood **and plasma** for the presence of the HTLV antibody. (9th July 1992)
85. **ALT Testing**: ***"There will be no introduction (meantime) of ALT testing."*** (25th February 1992. John D Cash (SNBTS) writing to Mr David McIntosh.)
86. **Virally Inactivated Fresh Frozen Plasma**: Liaison between NBTS & SNBTS regarding development of UK clinical trials of VIP, using products derived from UK blood donors **but processed in Europe**. Such a programme should lead to products being available which are **appropriately licensed**.
87. **Use of Anti-HBc Positive Donations:** John Cash of SNBTS writes to Dr H. Gunson of the NBTS stating that he was fascinated to see that the ACVSB agreed on 29 Oct. 1991 that screened donations testing **positive** for **anti-HBc** as cellular components and RTC other issued products should be excluded from use (i.e. discarded) **but plasma for fractionation could be accepted!**

ACVSB

(Advisory Committee on the Virological Safety of Blood)

VOLUME FOURTEEN

(September 1992)

CONTAINS:

88. **Legal case**: Dr Gunson reported that a case was being brought against North West RHA by a patient who had acquired HCV before the test was introduced.
89. **HCV Screening of Plasma**: Papers ACVSB 14/2 and 14/3 give different views of the English and Scottish fractionators on whether plasma which is HCV screen positive but RIBA negative is acceptable for fractionation.
90. **Plasma for Fractionation**: "*Dr Lane said that the HCV testing criteria for releasing cellular components for transfusion should apply to plasma for fractionation. He accepted that this was not a wholly scientific argument and it would mean turning down plasma with a high probability of being safe.*" "*Viral inactivation procedures did not change this view.*"
91. **Plasma Safety**: "Dr Gunson and Dr Mitchell took the view that there was **no** safety reason for discarding the plasma." (September 1992).
92. **Plasma Pools & PCR Testing:** "Virologists pointed out that PCR testing in plasma pools of 500 units would not be reliable."
93. **Public Perception**: "The Chairman said that he was satisfied that there was **no real safety** issue involved." "The argument was one of scientific evidence indicating that this plasma posed no significant risk of transmitting HCV infection being set against the problems of **public perception** that would arise from treating differently the cellular components & **plasma** coming from the same donation." "*...difficult for Ministers to convince the Public...*"
94. **Virally Inactivated Fresh Frozen Plasma**: ACVSB Virologists thought that *pooled* VIP would not necessarily be safer than FFP drawn from UK donors.
95. **Parvovirus Contamination of Blood Products**: Parvovirus Bl9 DNA was detected in **TWO-THIRDS** of separate batches of non-heat-treated factor VIII and IX concentrate manufactured from plasma donations unscreened for B 19 DNA. "*Dry heat treatment of 8O°C for 72 hours reduced but did NOT always eliminate detectable B19 from factor VIII concentrate...*" **This is horrifying!**
96. **Size of Plasma Pools** used for manufacture were 3,000-10,000 plasma donations. (i.e. with reference to Parvovirus B19 contamination of blood products).

Who's Who in the Minutes of the Advisory Committee on the Virological Safety of Blood (ACVSB)

Dr E. L. Harris Chairman of ACVSB (April 1989-July 1989.) Deputy Chief Medical Officer (DCMO) from 1977 until 31.07.89. The role of the DCMO is to assist the Chief Medical Officer in formulating advice to DH Ministers and to Ministers in other Departments.

Dr Jeremy Metters Takes over as Chairman of ACVSB from July 1989. Deputy Chief Medical Officer (DCMO) from 02.08.89. From January 1989 to August 1989 he was Senior Principal Medical Officer, (SPMO) MED SEB, later MED ISD (the DH Medical Division responsible for International Health and scientific services). From August 1989 to September 1993 Dr Metters was one of three Deputy Chief Medical Officers. As DCMO, Dr Metters saw most DH submissions on BSE / CJD in draft before they were submitted to Ministers and usually had the opportunity to comment on these. As DCMO, from August 1989 until September 1991 he reported to Sir Donald Acheson, the Chief Medical Officer.

Dr S. Lader Senior Medical Officer (SMO) at the Department of Health on Histopathology from 02.03.89. Attended ACVSB for item on Human Growth Hormone.

Dr A Rejman Senior Medical Officer (SMO) at the Department of Health on Haematology from 1st March 1989. Later, Clinical Haematology, Leicester Royal Infirmary.

Dr Hilary Pickles PMO Principle Medical Officer (Grade 4) and Branch Head in 1989 with lead responsibility of directly assisting the CMO Sir Donald Acheson. She worked in Med SEB/B and Med ISD3 and held Departmental Lead on BSE between 1988-1990 and professional lead between 1988-1991. She was joint secretary to the Southwood Working Party and Tyrrell Committee. SEAC observer until 1991. Dr Pickles sat in on 9 of the 14 ACVSB meetings. She is now MD of Hillingdon PCT.

Dr H. H. Gunson National Director NBTS (National Blood Transfusion Service). Dr Harold Gunson was appointed as Director in 1988 when the National Directorate of the NBTS was formed. He then became National Medical Director when the NBTS was replaced as from 1st April 1993 by the NBA, with full central authority. Dr Gunson remained in this post until his retirement in July 1994. Dr Gunson was chairman of another high powered committee, the UK Advisory Committee on Transfusion Transmitted Diseases ('ACTTD').

Dr R. S. Lane Director of Blood Products Laboratory, Elstree. **Note:** Clearly this doctor is not merely "a lab technician" as he told Susan Watts of BBC Newsnight in response to the "Spiking" of Factor VIII allegation which was in the TaintedBlood Accusations Document. Dr Lane played it down and he just worked in

the Lab – but he forgot to mention sitting on this high-powered Committee and also being the director of BPL !

Prof A. Zuckerman London School of Hygiene and Tropical Medicine. Now Dean of the Royal Free Medical School and member of the World Health Organisation's Advisory Panel on Viruses.

Dr P. Mortimer PHLS (Public Health Laboratory Service). Now Consultant Virologist, PHLS Virus Reference Division, Central Public Health Laboratory, Colindale.

Dr R. Mitchell PHLS (Public Health Laboratory Service)

Dr J. Garrett NIBSC (National Institute of Biological Standards & Control)

Professor R. Tedder Virologist, University College London. Now Consultant Virologist, Royal Free and University College Medical School, London.

Dr E. Tuddenham Director of Haemostasis Research, Faculty of Medicine, MRC Clinical Sciences Centre, Imperial College of Science. Now Professor and Director of the Royal Free Haemophilia Centre.

Dr R T Wensley Haematologist. University Department of Clinical and Laboratory Haematology, Manchester Royal Infirmary, Manchester

Dr G. P. Summerfield Consultant Haematologist, Middlesbrough General Hospital

Dr R. J. Perry Director, Protein Fractionation centre Edinburgh.

Dr P. Minor Head of the Division of Virology, NIBSC, (National Institute of Biological Standards and Control). Note: Dr Philip Minor is a Research Virologist. Now Deputy Director of NIBSC board and a member of the Advisory Committee on Dangerous Pathogens. Dr Minor was recently at the centre of the Haemophiliacs Blood Samples scandal as reported in the Observer: **"Doctors at NHS hospital carry out 'mad cow' analysis without permission"** where a British scientist (Dr Minor) told the FDA that haemophiliac blood samples taken from the Royal Free Hospital in London would be 'provided for variant CJD analysis'. He described the samples as 'a bit of serendipity' that could provide 'icing on the cake' for testing the development of an effective blood test for the disease.

Dr F. Rotblat Department of Health – Observer. DH Senior Medical Officer; Medical Assessor to the Biologicals Sub-Committee of the Committee on Safety of Medicines, until 1990. Dr Frances Rotblat was a Haematologist who joined the Medicines Division of the DHSS in 1985 as a Senior Medical Officer (SMO) in the New Drugs Section. Reported to Dr Isaacs, (PMO). In 1986, asked to take up responsibility for biological products. Spent 7 years in Medicines Division carrying out laboratory based research into haemophilia and blood products. Aware, at this

time, of the iatrogenic transmission of CJD by pituitary derived human growth hormone. The only SMO in MB3A specialising in Biologicals. Responsible for new chemical entities during most of their time in MB3A. Medical assessor for the Biologicals Subcommittee. Sat on CSM committed in March 1989. Principal Assessor to the Safety, Efficacy and Adverse Reactions Subcommittee of the CSM, 1990-95.

Mr S. J. Sloggem Department of Health – Observer. Pharmaceutical Officer, DH Medicines Division, Market Towers, 1989. Mr J Sloggem is part of the Licensing Division of the Committee on the Safety of Medicines in 1998.

Dr J. Purves Department of Health – Observer. DH Senior Principal Pharmaceutical Officer, 1985-90. Dr John Purves was a Superintending Pharmacist in MB5A. He was the pharmacist with the lead responsibility for Biologicals and a number of pharmacists responsible for the pharmaceutical assessment of Biologicals reported to him. Dr Purves was the Pharmaceutical Assessor to the Biologicals subcommittee of the CSM. Unit Manager, Biological Unit, Medicines Control Agency, from 1990.

Dr A. M. George DCMO Welsh Office. Observer. Dr Alain Michael George was one of two Deputy Chief Medical Officers (Grade 4 post) at the Welsh Office having been there since January 1982. As DCMO Dr George deputised for the Chief Medical 0fficer and had responsibility for Public Health and Environmental Health issues and the Regional Medical Service. A number of Senior Medical Officers (Grade 5) reported to Dr George and two were involved on BSE and CJD.

Dr Ruth Jacobs SMO (Senior Medical Officer), Health Professional Group, Welsh Office. Observer for the Welsh Office (replacement)

Dr E. J. Ludlow SMO, Welsh Office, from January 1991 – Observer. Also a specialist in public health and communicable disease.

Dr A. McIntyre Dr Archibald McIntyre PMO, Principal Medical Officer, Scottish Home & Health Department (SHHD) – Observer.

Dr H. Flett Observer for DHSS Northern Ireland.

Mr M. Fuller Observer - Procurement Directorate of the Department?

Dr A. Keel Observer. Now Deputy Chief Medical Officer, SEHD and member of Working Group of the Scottish Medical and Scientific Advisory Committee (SMASAC).

Mr J. Canavan Department of Health Secretariat HS1A. Also DH Administrative Secretary.

Mr M. H. Arthur Department of Health Secretariat.

Miss P. Reenay Department of Health Secretariat

Mr J. F. Rutherford Department of Health Secretariat

Note about **Dr Christine A. Lee** (now Professor) – although she didn't actually sit on the ACVSB Committee or attend any ACVSB meetings, she submitted a crucial paper (on HCV) for the Sixth meeting of the ACVSB in April 1990 – which because of the HIV Haemophilia Litigation, amongst other things – was a delicate time. Dr C.A. Lee started research in haemophilia at the Royal Free Hospital in London in 1983. She was appointed Consultant Haematologist in the Haemophilia and Haemostasis Unit at the Royal Free in 1987; she became centre Director at the Royal Free in 1991. Now retired from that post, she sits on the Executive Board of NIBSC (the organisation recently mentioned in the Observer article over controversial blood samples from haemophiliacs.)

Department of Health Power Structure

REPORTING ARRANGEMENTS

28.3.88 – 24.7.91

CMO	Sir Donald Acheson	
DCMO	Dr E Harris	– 31.7.89
	Dr J Metters	2.8.89 –
SPMO	vacant	– 13.2.89
	Dr J Metters	14.2.89 – 1.8.89
	Dr G Jones	2.8.89 – 24.9.90
	Vacant	25.9.90 –
PMO	**Dr H PICKLES** (branch head)	
SMO	Haematology	K Kimber – 30.4.88, vacancy, A Rejman 01.03.89 –
	Histopathology	S Lader – 2.3.89, vacancy, P Furnell 22.5.89 –
	Anatomy Inspector	E Clissold 10.1.91 –
PSO	Microbiology	P Lister – 9.3.89, vacancy, D Harper 1.9.89 – 7.1.91, vacancy, M Nugent 17.6.91 – 4.10.91
	Clinical Chemistry	R Jennings – ?, vacancy, A Hora 12.2.90 –
SSO	Microbiology	A McGinty 23.5.89– - (T/P PSO from 7.1.91)
AO, PES	2 x PES 1-2 x AO	