INFECTED BLOOD INQUIRY

CLOSING SUBMISSIONS

ON BEHALF OF THE HAEMOPHILIA SOCIETY

INTRODUCTION

1. This submission is made by the Haemophilia Society ("the Society") on its own behalf, and on behalf of its members, to include those designated with Core Participant status in the Infected Blood Inquiry ("the Inquiry") and represented by Eversheds Sutherland (International) LLP. It is made in accordance with paragraph 4(b) of the Inquiry's Statement of Approach – Submissions at the end of oral evidence (issued by the Chair on 1 April 2021, reviewed and re-issued as amended on 18 March 2022 and supplemented with a "Further note" on 30 May 2022), which states that core participants should provide written submissions that:

   "i. set out the core participants' position (if they have one) as to the factual findings which the Chair should (or should not) make;

   ii. set out the recommendations which the core participants invite the Chair to make, including recommendations as to compensation; and

   iii. set out the core participants' position (if they have one) as to why particular recommendations should, or should not, be made."

2. The Society is the only UK-wide charity for all those affected by a genetic bleeding disorder. It was established in 1950 to help people with genetic bleeding disorders to lead fulfilling lives, make informed choices and to support and inspire others.[1] As part of the inquiry's investigations, the Society's role during the contaminated blood scandal is being scrutinised. The Society has always welcomed scrutiny of its role, and that of other organisations, in order to ensure that this investigation is thorough and effective.

[1] WITN6392001/3, paragraph 7

Only then can the victims of the contaminated blood scandal get the truth and justice that they deserve. The Society has played its full part in helping this to happen.

3. The Society's approach throughout the Inquiry has been to support the work of, and to assist the Inquiry. This Closing Submission is now provided to assist the Inquiry in its consideration of relevant matters. It is structure as follows:

   a. Section A: This section sets out submissions on factual findings that the Chair should (or should not) make in relation to the topics under the heading "The Role of The Haemophilia Society" in the Inquiry's Amended List of Issues (at paragraphs 359 to 370).

   b. Section B: This section addresses some of the topics that the Chair has noted he would find most useful for core participants and recognised legal representatives to focus in their final written submissions on. These topics are included within the list at paragraphs 8 to 13 of the "Further note" dated 30 May 2022 ("the Chair's "Further Note" on Closing Submissions"), attached to the Inquiry's Statement of Approach – Submissions at the end of oral evidence. In preparing its submissions for this section the Society was guided by the responses to a survey issued to its membership; this was used to identify areas in which they considered particularly important that we respond.

   c. Section C: This section addresses recommendations that the Society wishes the Chair should make.

4. This Closing Submission is intended to be read alongside the evidence given to this Inquiry by current and former staff and trustees of the Society, including:

   a. Witness statements of the Society's current Chief Executive, Kate Burt;[2]

   b. Witness statements and oral evidence of current and former Society Trustees and staff members including David Watters,[3] Simon Taylor,[4] Peter Wetherell,[5]

[2] WITN6392001; WITN6392268
[3] WITN3429001; Transcripts of evidence of David Watters to the Infected Blood Inquiry, 10, 11 and 12 February 2021
[4] WITN4500001; Transcript of evidence of Simon Taylor to the Infected Blood Inquiry, 26 May 2021
[5] WITN3912001; Transcript of evidence of Peter Wetherell to the Infected Blood Inquiry, 25 May 2021

Andy Cowe,[6] Keith Colthorpe,[7] Paul Sartain,[8] Barry Flynn,[9] Eileen Ross,[10] Elizabeth Carroll,[11] Karin Pappenheim[12] and Roderick Morrison.[13]

5. In Section A, the Society makes submissions in relation to the following topics:

Section A1	Information/knowledge about risks of infection associated with blood products
Section A2	Actions and decisions taken by the Society
Section A3	Advice provided to the Society
Section A4	Relationship between the Society and the UKHCDO
Section A5	Relationship between the Society and pharmaceutical companies
Section A6	Representations made to Government by the Society on self-sufficiency and imported blood products
Section A7	Statements on Factor treatments
Section A8	HIV Litigation
Section A9	Advice or information provided about hepatitis

6. In Section B, the Society makes submissions in relation to the following topics:

Section B1	Response of Government
Section B2	Consent, communication, candour and transparency
Section B3	Viral inactivation
Section B4	Treatment, care and support
Section B5	Self-sufficiency
Section B6	Decision-making of the Committee on the Safety of Medicines ("CSM") and its Biologicals Sub-Committee ("CSM(B)")

7. In Section C, the Society makes recommendations in relation to the following topics:

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[6] WITN3647001
[7] WITN4430001
[8] WITN1013001
[9] WITN4208001
[10] WITN10500001
[11] WITN3078001; WITN3078005; WITN3078007
[12] WITN4504001; WITN4504009; WITN4504010; WITN4504011; WITN4504012; Transcript of evidence of Karin Pappenheim to the Infected Blood Inquiry, 27 May 2021
[13] WITN5252001

Section C1 Submissions on non-financial recommendations relating to:

- Public Inquiry Reform
- Redress for Avoidable harm
- Consent
- Continuing scrutiny of recommendation implementation
- The Irish Experience
- Access to current treatment and up to date information
- Ongoing longer term assistance
- Research on future care and palliative care
- Training and education
- Education about the contaminated blood scandal
- Apology / Memorial

Section C2 Compensation

8. The Inquiry is asked to bear in mind, when reading these submissions, that during the decade 1985 to 1995 the Society's board was decimated by deaths from contaminated blood. At least three trustees died in 1991 alone and Rev Tanner told Lord Archer that, "*At one time I conducted the funerals of six of the twelve members of the Executive of the Haemophilia Society within two years*".[14] His son Mark, who had severe haemophilia A, was born in 1955 when "*there was no treatment for bleeding episodes, except bed-rest, cold compress on swollen joints, with Russell's Viper Venom at hand as a coagulant for extreme external bleeding*".[15] He described how Mark's life, and that of the whole family, was transformed by cryoprecipitate in the 1960s, and then home treatment with Factor VIII concentrate in the 1970s. It was these breakthroughs, he said, that enabled his son to attend university, obtain a Master's degree, and start on the path to becoming a distinguished sculptor. Mark Tanner's death in 1998, like that of many others, was preceded by failed treatment with Interferon, and years of frailty and health crises. He died as a result of HIV infection and Hepatitis C leading to liver cancer.

[14] ARCH0002998/2
[15] ARCH0002998/1

9. The Society would like to say to the Inquiry, and to each person infected and affected by contaminated blood, that it was not separate to its members, it was its members. It was run by patients for patients: those who formed the Executive Committee were individuals who shared, with the members they served, the same group of doctors, and such information, advice, choices and treatments, as were made available to them all. They suffered, or watched the children they loved suffer, the same appalling treatment induced illnesses and deaths. The Society does not seek not to be judged; it does seek to be judged in this light.

SECTION A: SUBMISSIONS ON FACTUAL FINDINGS IN RELATION TO TOPICS UNDER THE HEADING "THE ROLE OF THE HAEMOPHILIA SOCIETY" IN THE INQUIRY'S AMENDED LIST OF ISSUES (AT PARAGRAPHS 359 TO 370)

SECTION A1: INFORMATION AND KNOWLEDGE ABOUT RISKS OF INFECTION WITH BLOOD PRODUCTS

10. This section addresses paragraph 359 in the Inquiry's Amended List of Issues, which is, "*What information and knowledge did the Haemophilia Society as a matter of fact have during the relevant period about the risks of infection associated with blood products?*"

A1.1 Information and Knowledge

11. Many Society board members, trustees and members of staff, were themselves victims or had contaminated blood victims in the family. They were either themselves infected with HIV, Hepatitis C or both; Hepatitis B, Hepatitis D, vCJD, or their family members and loved ones were. Many of them died as a result of infected blood. This has been stated in evidence by witnesses including David Watters,[16] Simon Taylor,[17] Peter Wetherell,[18] Andy Cowe,[19] Keith Colthorpe,[20] Karin Pappenheim[21] and Roderick Morrison.[22] The dates of death and obituaries in various editions of the Society's publication 'The Bulletin' speak for themselves.[23]

12. In her witness statement, Kate Burt refers to an un-redacted version of a table of staff and trustees of the Society during David Watters's tenure, which was exhibited to his statement.[24] Mr Watters was employed by the Society between 1981 and 1994. Where individuals were employed or were trustees outside of these dates, Mr Watters has also included details of those dates for completeness. The table shows that:

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[16] WITN3429001
[17] WITN4500001
[18] WITN3912001
[19] WITN3647001
[20] WITN4430001
[21] WITN4504001
[22] WITN5252001
[23] WITN6392001/41, paragraph 95
[24] WITN6392001/42, paragraph 96; WITN3429006

a. Out of the total 30 staff members and trustees listed, 16 were either themselves infected with HIV and/or Hepatitis C or had a familial link with someone that was infected.
b. Of the 25 trustees listed, 15 were either themselves infected with HIV and/or Hepatitis C or had a familial link with someone that was infected.[25]

13. The Society's trustees were at times in an invidious position as a result of their infected status and trying to do what was best for its members. Simon Taylor, who was co-infected with HIV and Hepatitis C as a result of receiving infected blood products, gave evidence about the period of time when his strong view was that the Society could not afford to prioritise the Hepatitis C campaign, even though to do so would have been in his interests personally.[26]

Sources of Information and Knowledge

A1.A Information from the Doctor/Patient, or Parent of Patient, Relationship

14. The table exhibited to David Watters's statement[27] shows that the Society executive Committee members were people with haemophilia or parents of people with haemophilia. They had the information provided to them from the doctors and haemophilia nurses and others at their treating centre. The position taken by many of the consultants treating individual committee members at the Society is available to the Inquiry through the letters, reports, research papers and other documents written by the consultants.

15. Almost all of the consultants giving evidence to the Inquiry have expressed the view that people with haemophilia knew the risks of US Factor concentrate and, additionally, knew of the general hepatitis risk: they were told, it is said. Even to the extent patients, and the Society, were told, (and many infected an affected witnesses have said that they were not) those clinicians providing this evidence, have confused or conflated

[25] WITN6392001/42, paragraph 96; WITN3429006
[26] Transcript of evidence of Simon Taylor to the Infected Blood Inquiry, 26 May 2021, T78: 4 – T80: 6
[27] WITN3429006

knowledge of risk, with understanding of risk. Telling patients there is a risk, and providing medical information in such a way that it can be understood, used and weighed by a patient as part of a shared decision making process about what if any treatment to accept, are two different matters.

16. The United Kingdom Haemophilia Centre Directors' Organisation ("UKHCDO") position and that of the Reference Centre Directors, the UK Government, and the World Federation of Haemophilia ("WFH") was that the risk of getting AIDS from Factor concentrate, US or domestic, was or was likely to be significantly less than the risks of untreated severe haemophilia. As a result of what appeared to be global unanimity, there was no obvious alternative source of credible information about the balance of benefits and risks available to the Society and/or its members.

17. In the 1980s, the medical establishment, which included Government, at best minimised the risk of people with haemophilia being infected with AIDS, and at worst denied them by making such an unequivocal treatment recommendation. This recommendation was not balanced by any recognition that the asserted balance of benefit and risk could be wrong, and that there was a reasonable and respectable body of opinion that considered that the risk of infection with HIV/AIDS from Factor concentrate was much higher than the majority allowed. Further, it was not accompanied with any or any real treatment choice.

18. In the years that followed the AIDS crisis, lessons that could have been learned about the need to inform haemophilia patients of their treatment related diagnosis in a timely and compassionate way, and about the need to be open and honest with them about what was known, unknown, and uncertain were not learned. The same errors were repeated when the fact that Hepatitis NANB had the potential to be fatal was widely recognised.

19. Doctors asserted to patients that the risk of dying with no treatment outweighed the risk of infection with HIV/AIDS from Factor concentrate.

A1.B Patient Experience

20. In the 1979 edition of The Bulletin[28], John Prothero contrasted his experience of the WFH Congress he attended in July 1979 with that he attended in Moscow ten years earlier:

"Haemophiliacs were then treated with plasma and the lucky ones with cryoprecipitate, where it applied. Everyone looked forward to treatment which would encompass the use of concentrates rather than the other bulkier materials….The increasing use of concentrates has as a natural consequence, led to the introduction of home treatment therapy. Possibly this is the greatest single development of all time in the active care of haemophiliacs. Patients' and parents' lives have changed completely: worries about speed of treatment have gone: sleepless nights are almost a thing of the past: crippling and pain has largely disappeared: new vistas have opened and haemophiliacs can travel world wide with confidence." [29]

21. Many born before cryoprecipitate was introduced as a treatment had experienced lives of pain and disability. For at least one person with haemophilia, the benefits of treatment with cryoprecipitate made cryoprecipitate transmitted hepatitis a price worth paying.[30] Even after the introduction of cryoprecipitate and Factor treatment people still suffered pain and impacts on their lives. As Paul Sartain said in his statement to this Inquiry, *"In my view, my parents and/or I did not think to ask about risks because my treatment (Cryoprecipitate or Factor VIII) was to ease the pain and suffering from a bleed. Many times as a young child I would have countless nights of disturbed sleep, pray for the pain to go away and/or violently shake my head until I was so dizzy and feeling nauseous that I would slump back onto my bed in a state of stupor".*[31]

22. Cryoprecipitate had extended lives and lessened morbidity but home treatment with domestic fridge stored, soluble, self-injectable Factor VIII was transformative. Professor Egli, giving the opening address to the 1980 Bonn Conference, took the view

[28] HSOC0022869/5
[29] HSOC0022869/5
[30] HSOC0022901/2-3
[31] WITN1013001/5, paragraph 21

that there was only one body of people who could understand the burdens and the benefits:

"*Only in our recent lifetime have we been able to extend life expectancy. The second major sequela of the disease, the damage of the joints, remains. Today the extent of this crippling is frightening for many haemophiliacs throughout the world. What this means as to training, career opportunity, psychological stress, briefly everything that we understand as the "quality of life", can only be said and understood by those who are subjected to this disease and by his relatives.*

....our approach must be aimed not at treating a bleeding that has occurred, but rather to prevent such bleeding from occurring." [32]

23. People with haemophilia did understand that this transformation came at a high price to the taxpayer. The health economics of treatment for severe haemophilia in particular has been, and remains, highly relevant to patients. Though they have a right to long and healthy lives, people with haemophilia feel a responsibility to be net contributors to society. The same 1979 edition of The Bulletin published a report of Professor Ingrams' DHSS-funded study of home treatment for 28 patients in London and Oxford. Though the NHS cost of providing a home-therapy program was only slightly less than the cost of hospital outpatient treatment, the social costs left the Professor and his team *"in no doubt of the overwhelming advantages of home treatment as part of the management of severe haemophilia"*. The greatest benefits were "*savings in time lost from school and work, a greater sense of security, and increased capacity for planning ahead.*"[33]

24. In the 1970s, 80s and 90s, the Society was run by haemophiliacs or parents of haemophiliacs. The path from plasma to cryoprecipitate to home treatment was one they had walked, or seen their children walk. This is the context in which, it is submitted, it is appropriate to consider the actions taken by the Society in relation to the new treatment threat posed by AIDS and the growing understanding of the treatment threat posed by what came to be known as Hepatitis C.

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[32] HSOC0022896/4
[33] HSOC0022869/1-2

A1.C Publications

25. Mr Watters told the Inquiry that the Society received The Lancet and the British Medical Journal ("BMJ"), they were rarely read, but if an article was spotted or drawn to the attention of staff, it would be circulated in a weekly mailing to trustees.[34] Several pieces first appearing in The Lancet were republished for the benefit of members in The Bulletin.

26. For example, the January 1972 edition of The Bulletin reprinted an editorial from "The Practitioner".[35] This discussed use of commercial blood banks as a major source of infected blood in the US. It quoted J Garrott Allen's 1970 publication in the Annals of Surgery on the incidence of hepatitis in patients having open heart surgery treated with commercial and voluntary blood. It provided members with the important information that the higher incidence of hepatitis in those treated with blood that had been paid for, was explained by the fact that those paid donors came from prisons, Skid-Row or were addicted to drugs or alcohol.

27. That information was reiterated in the 1980 publication "Haemophilia Home Therapy" by Peter Jones. This advised readers that all human blood carries risk of hepatitis and linked that risk particularly to commercial concentrates from paid donors.[36] The 1974 1st edition of "Living With Haemophilia", and the 1978 "UKHCDO Home Treatment Booklet", also mention hepatitis as a treatment risk.[37]

28. Mr Watters told the Inquiry that the Society had close relationships with Mr Veitch at the Guardian and The Sunday Times both of which would keep the Society informed.[38] The 1982 Bulletin No 1 Edition 32 reprinted A Veitch's piece from The Guardian on 5 August 1981 about Hepatitis Non-A Non-B Hepatitis.[39]

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[34] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T23: 13-18
[35] HSOC0022713/3
[36] HSOC0001636/5-6
[37] RLIT0000041/84-85; WITN1013007; WITN1013001/5, paragraph 18
[38] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T64: 14-22
[39] BART0002327_001/6

A1.D UKHCDO

29. The Society attended HCDO/UKHCDO meetings from 1974 onwards. There are good reasons to conclude that what information about hepatitis and HIV/AIDS they took away from these meetings, was probably limited and incomplete.

30. Mr Watters thought that the Society did not receive either the minutes of UKHCO meetings and its working parties, or copies of the reports being discussed.[40] Although there are occasional records of the Society invitees making a verbal contribution, Mr Watters said that they were there as "*observers rather than participants*".[41]

31. Without the minutes and reports under discussion, many of the meetings would have been difficult for the Society's attendees, all of whom were not medically qualified, to follow. There might have been little hard information that they could sensibly take back to the Executive Committee.

32. That said, the Society would have felt reassured that it had access to discussions of internationally high quality (see Professor Tuddenham's description of the UKHCDO[42]). For example, it would have been well aware, in 1983, that there was no member of the UKHCDO, and no Reference Centre Director, who disagreed with Professor Bloom's advice in May 1983 that patients with severe haemophilia A should continue to use US imported Factor VIII concentrate. At the same time, the UKHCDO was not a source of answers to the treatment dilemmas facing patients and parents of patients. It was "*a gathering of colleagues and a talking shop*".[43]

33. When asked his opinion of Professor Savidge's view of the UKHCDO as a club run by the *"ten or so main players"*, Dr Winter disagreed. He said that:

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[40] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T52: 18-19 & T67: 15-20 and Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T4: 4-14
[41] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T52: 18-19 & T67: 15-20 and Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T4: 4-14
[42] Transcript of evidence of Dr Tuddenham to the Infected Blood Inquiry, 22 October 2020, T82: 12-25 & T83: 1-15
[43] Transcript of evidence of Dr Tuddenham to the Infected Blood Inquiry, 22 October 2020, T84: 25 & T85: 1-12

"...I think we should state UKHCDO was generally regarded by the other haemophilia societies and doctors and other countries as actually being a model of its kind. There isn't really any other country where haemophilia doctors came together and collaborated to such an extent that every patient with an inherited blood disease in the country was registered, we knew the number of patients with the condition, we knew the severity of the condition, we knew whether they had an inhibitor, we knew whether they were on home treatment, we knew whether they were alive or dead. No other country had information like this and every time you went to a World Federation meeting, people would say, you know, your system you have in the UK is light years of what we have in our country. We have nothing like it.

Then, in addition to that, as we've seen already, it was a very active organisation, in addition to all the day-to-day work we were doing. At any one time, there would be six, seven, eight working parties in specialist areas. So I thought the UKHCDO was a very good thing. Of course, there were personalities involved, of which Professor Savidge was a large one." [44]

A1.E Civil Servants

34. Mr Watters described roughly monthly meetings with DHSS civil servants whose office was round the corner from the Society's premises in the early 1980s. Before the advent of HIV/AIDS, the main topic of conversation was supply and self-sufficiency.[45] These meetings continued after 1983 when HIV/AIDS hit, and it is clear there was the opportunity for the Department to share its knowledge with the Society (see Haemofact September 1983[46] "*The Society has established and maintained close liaison with all relevant personnel and departments of Government in order to keep all or members informed of developments...")*.

35. The Inquiry is asked to find that during the relevant period, the Society had a legitimate expectation that civil servants would be open and transparent with the Society about

[44] Transcript of evidence of Mark Winter to the Infected Blood Inquiry, 1 October 2020, T115: 1 – T116:6
[45] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T35:2 – T36:6
[46] PRSE0004474/2

information it had relevant to people with haemophilia. Further, that if civil servants and Government came into possession of information that indicated that people with haemophilia or their partners or children were at risk, they would take steps to ascertain whether that information had been provided to the Society and, if it had not, would have disseminated the information to the Society without delay.

36. That expectation was legitimate for several reasons. The withholding of such information would have been unethical and contrary to Government's duty to keep the population safe. It would also have been obtuse: if the civil service and Government had information relevant to the safety of people with haemophilia, the Society was an efficient and, to the tax payer, cost-free means of communicating that information to at least a section of the bleeding disorder community.

A1.F International meetings and conferences

37. The Society attended these and relied particularly on information gleaned from the annual conference of the WFH. We know that the President of the WFH Frank Schnabel and Rev Tanner had a close working relationship, and the latter deputised for the former. They must have discussed HIV/AIDS and all known forms of hepatitis but it is not clear that this relationship, or communication between the Society and other international societies for people with haemophilia were a source of additional information. Given the international consensus about the best available response to AIDS, knowledge from international meetings was likely to have been additive and corroborative of the UKHCDO's approach.

38. In October 1980, the Society committee members attended the First International Conference on Haemophilia which was held in Bonn, and which appears to have followed on from that year's WFH Congress.[47] These international meetings highlighted for those attending from the UK the lavish use of Factor VIII in West Germany, the risk of dependence on drug companies, the risk of blood being donated by unsuitable people or those who could ill afford to give or sell their blood, and the

[47] HSOC0022893/1-3

need for the Society to do more to put pressure on the Government to fulfil David Owen's promise of self-sufficiency.

39. Of note is the comparison Ken Milne was able to draw with the organisation of societies internationally:

"*Many societies abroad are, in effect, run by members of the medical profession, and to me this seems an unsatisfactory arrangement, as I think it is important that a haemophilia society be free to take decisions and act on behalf of haemophiliacs quite independently of those having a mainly professional interest in haemophilia.*"[48]

40. The Inquiry has abundant evidence of the decisions made by a wide range of medical and scientific national committees including the Medical Research Council ("MRC"), Central Blood Laboratories Authority, Committee on Safety of Medicines Sub-Committee and many others. There is no basis for a finding that a Society run by clinicians and scientists would or could have done better than the Society did, or avoided the decisions it made. There is also no proper basis for a finding that the addition of an epidemiologist to the Medical Advisory Panel would have resulted in better actions or decisions.

41. David Watters told the Inquiry that there was no regular flow of information between the National Haemophilia Foundation ("NHF") in America and the Society[49]: international phone calls were expensive, all societies were small and under-staffed, and most communication took place at annual meetings. For example, there is no evidence that National Haemophilia Foundation faxed or otherwise provided to the Society its December 1982 advice on how to minimise the risk of AIDS from blood products.[50]

[48] HSOC002289/2
[49] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T2:25 – T3:13
[50] PRSE0002436

A1.G Medical Advisory Panel

42. It appears that although meetings were minuted, the minutes are not available.[51] The Medical Advisory Panel was an important source of information for the Society.

43. When the advice given by individual Medical Advisory Panel members to the Society is considered alongside their communications with others, there is nothing to suggest that the advice that they provided to the Society was biased, or driven by a desire to defend the UKHCDO. With the exception of Professor Bloom, whose motivation for misleading the Society and its members remains unfathomable, the views that Medical Advisory Panel members provided to the Society were, particularly in relation to HIV/AIDS, erroneous but genuinely held.

A1.H Pharmaceutical companies

44. There is evidence that in 1980, the Society had a relationship with Travenol and was aware, in the context of the Society's increasing concern about domestic supply and dependence on imported Factor VIII, that the NHS produced blood product but nothing else; other resources, such as plastic bags and other equipment were purchased commercially.[52]

45. The Society's relationship with Chris Bishop of Armour, and with pharmaceutical companies more generally, is addressed in section A5 of this submission.

46. The provision of information about infection risk by pharmaceutical companies to the Society was incomplete to say the least. Whereas the Society could reasonably and legitimately have expected that civil servants, Government and Centre Directors would share their knowledge about risks to the health and safety of people with haemophilia and their families, its expectations of pharmaceutical companies would have been that their products were safe.

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[51] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T51: 17-24
[52] HSOC0019919_022/2, paragraph 3

47. It is notable that when, in February 1998, there was a discussion of Non-A Non-B Hepatitis in the context of heat-treated products between Ken Milne, Rev Tanner and Chris Bishop of Armour[53], Mr Pettet of Bio Products Laboratory ("BPL") was also present. The Inquiry is also well aware that Alpha could have, but never did, send the Society its 16 March 1983 press release in which that company accepted that the evidence suggested the half-dozen haemophilic patients with AIDS known to the NHF had been infected by Alpha Factor VIII product.[54]

Knowledge and information withheld from or unknown to the Society

48. On 6 May 1983, Dr Galbraith telephoned Dr Sibellas to inform the relevant parts of the civil service about the Cardiff patient who had been treated with US Factor VIII, who had been ill for a month and who now appeared to have the right symptoms and signs for a diagnosis of AIDS.[55] He also called to tell her that the previous night, he had received information from Spain that three haemophiliac patients there who had received US Factor VIII were also thought to have AIDS. It did not occur to either doctor to telephone the Society, or invite the Society to any meeting, top level or otherwise. This is just one example of so many of a siloed approach to public health that was so distant from patients as to seem wholly unconnected to them. Patients were simply left out.

49. Diana Walford said that the infrastructure for translating the Secretary of State's responsibility for ensuring safe delivery of NHS treatment was "*like rubber levers. The levers were not fit for purpose*".[56]

50. As to Centre Directors specifically, on 24 August 1994, Graham Barker of the Society wrote a politely, but strongly worded letter, based on evidence collected from members around the country attending different centres, to Dr Colvin, then Chair of the

[53] HSOC0015355
[54] CBLA0000060_067
[55] DHSC0002227_021
[56] Transcript of evidence of Diana Walford to the Infected Blood Inquiry, 21 July 2021, T194: 1-6

UKHCDO.[57] What Mr Barker said about the withholding of information and knowledge from the Society and its members applies as much to HIV/AIDS as it did to Hepatitis C. The letter is evidence not just of the fact that information and knowledge was withheld, but also of the fact that the medical profession had not learned from the mistakes it made in the 1980s. Nothing improved in terms of provision of information to patients and shared decision making. Patients were tested without their knowledge let alone agreement and then not told of the results, and then, once again, falsely reassured:

"*We can see no reason why patients should not have been informed of their HCV status as soon as the result was known. They should not have had to ask for this information….*

We accept that at present there is little information about hepatitis C, but our experience suggests that many centres were not even passing on what little information is available. A frank admission by the centre staff that they did not know all the answers would have been better than a brief comment that there was nothing to worry about."

51. There are instances, most of them authored by Professor Bloom, of the Society being misinformed. The Executive Committee minutes of 14 June 1983 which record, erroneously, that the "confirmed" Cardiff patient was back at work are one example.[58]

52. More generally, information that would or could have benefitted the Society's members was withheld from the Society, either deliberately or unthinkingly. Some examples are:

    a. Ken Milne had forged a working relationship with Mr Godfrey at DHSS (see their correspondence in October 1981 about the former's blood products paper).[59] When, in June/July 1982 Mr Godfrey knew of problems with US Factor VIII and AIDS, there is no evidence that he alerted Mr Milne to the risks.
    b. On and after 16 March 1983, the Society was not informed by either Professor Bloom or Alpha of the information in the Alpha press release warning clinicians that Alpha product might transmit AIDS.[60]

[57] HSOC0005110
[58] HSOC0029476_024/2
[59] DHSC0002213_004/1-2
[60] CBLA0000060_067

c. BPL's decision, made on 18 April 1983, that it would adopt a *"wait and see"* approach and had ruled out reversion to cryoprecipitate was not communicated.[61]

d. Dr Spence Galbraith's recommendation on 9 May 1983[62] that there be a ban on importation of US Factor VIII was not shared with Reference Centre Directors or the UKHCDO and was not communicated to the Society.[63] When they were put to him, Professor Tuddenham agreed with all of the points made by Dr Galbraith and told the Inquiry that had this letter had wider exposure, he was "*sure it would have had some effect*".[64]

e. 23 June 1983 the Council of Europe recommendation[65]: Mr Watters told the Inquiry that this was not brought to the Society's attention by civil servants, Government or anyone else.[66]

f. The Association of Scientific Technical and Managerial Staffs ("ASTMS") had a relationship with the Society (see its letter to David Watters of 23 May 1983[67]) but did not share with it Dr Foster's letter about AIDS, which he rushed out from his hotel room in Stockholm, and which was of such obvious relevance to the safety of people with haemophilia.[68]

g. Neither the UKHCDO, Armour nor anyone else invited the Society to the meeting of the Haemostasis Club on 17 March 1986, convened by members of the UKHCDO and members of the pharmaceutical industry to discuss Non-A Non-B Hepatitis and varying heat-treated products.[69]

Broad understanding of risk prior to the end of 1982

53. The Society knew that treatment derived from commercial blood was inherently more unsafe than treatment derived from volunteer blood.

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[61] CBLA0001697
[62] CBLA0000043_040
[63] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T8-10
[64] Transcript of evidence of Dr Tuddenham to the Infected Blood Inquiry, 22 October 2020, T102: 8
[65] PRSE0000372
[66] Transcript of evidence of David Watters to the Infected Blood Inquiry, 10 February 2021,T40: 19-25 & T41: 1-5
[67] ASTM0000041
[68] ASTM0000039_001/3-4
[69] HCD0000015_059

54. It was this knowledge, coupled with the moral imperatives embodied by the World Health Organisation resolution,[70] that impelled its constant campaigning for self-sufficiency and for the most efficient use in the UK (by plasmapheresis and adoption of a rational blood policy) of voluntary donations.

55. The Society shared its knowledge of this fundamental information about safety with its members.

56. The January 1972 Bulletin informed members of the increased infection risk from commercial, as opposed to volunteer derived, blood and blood products (see "Publications" above).

57. Bulletin Edition 29 No 1 1979[71] restated that risk. It reprinted the BMJ article "*Freeze Dried Factor VIII Concentrates and the NHS*" (published in the BMJ on 25 November 1978). This stated that:

"*…haemophilia centre directors generally agree that most if not all of the material used to treat haemophilia in Britain should be freeze-dried concentrate, preferably made within the NHS*".

"*Besides the problem of cost there is also growing concern about the increased risk of transmitting hepatitis with commercial factor VIII concentrates prepared from large pools of plasma. Blood collected from paid donors (the source of most commercial concentrates) is 10 times more likely to contain hepatitis B virus than is blood collected from unpaid donors by national blood transfusion services.*"

58. Dr Mark Winter informed the Inquiry that all Society members were taught that NHS treatment was preferable to US concentrate, and Mr Watters said that "*NHS concentrates were seen as pure as the driven snow, really*".[72] The Inquiry is asked to reject Dr Parapia's evidence that the Society told its members that "*BPL material was*

[70] WITN1055190

[71] PRSE0001004/4

[72] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T79:15-16

inferior product".[73] That suggestion runs counter to the evidence of all other witnesses. Whilst some patients found the commercial companies' packs easier to use, there is no evidence of patients asking for US Factor VIII in preference to NHS product, or being resistant to treatment with NHS product.

59. Mr Watters agreed with the question put to him that the Society had some awareness of collections in the UK of blood from prisoners and military donors.[74] There is evidence that the Society knew that US commercial blood banks collected blood from prisoners and that that was one reason why the risk of infection from US product was higher than the risk with NHS donated blood derived product. However, there does not appear to be documentary evidence that the Society was aware of NHS product being derived from prison/military collected blood at the time that the practice was current.

60. The well attended 12-14 March 1982 Group Seminar Proceedings (report published in the Bulletin in February 1983)[75] discussed hepatitis Non-A Non-B Hepatitis. Dr Colvin informed members that that infection was commoner following the use of large pool concentrates particularly in the treatment of mild haemophiliacs who had had few injections in the past. He said that:

"*…the vast majority of patients with symptoms recover within a week or two but there is growing evidence that mild inflammation of the liver can continue after clinical recovery and the long term consequences of this are not yet clear.*"

61. He went on to give advice that was equally applicable to AIDS:

"*As no specific treatment is available for hepatitis, the most important method of control is prevention. Cryoprecipitate or DDAVP and tranexamic acid are useful for the treatment of small bleeds and for minor surgical procedures in mildly affected patients and it is worth trying to limit the number of batches of concentrate used when this form of treatment is necessary."*

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[73] WITN0785003/9, paragraph 37
[74] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T80: 1-4
[75] BART0002325/1 - It is of note that this publication also records (BART0002325/6) that of 5000 haemophiliacs, only 1500 belonged to the Society

What did the Society know about HIV/AIDS from 1 January 1983?

62. The evidence available shows that nearly all of the information which came to the Society as an organisation (as opposed to committee members as patients or parents of a patient) came from the media, clinicians, or other international meetings.

63. Following a report about AIDS in the Observer on 16 January 1983, which had caused concern with calls coming from as far away as The Hague[76], David Watters wrote to Professor Bloom that same day seeking guidance and "an early date" piece for The Bulletin so that the Society could keep members informed.[77]

64. The first 1983 Edition of The Bulletin contained an extensive and detailed Q&A with Dr Kernoff.[78] (Dr Kernoff was the treating consultant of The Bulletin's editor, Clive Knight).[79] It is undated. Logically, however, the 'interview', if it was an interview, rather than Dr Kernoff writing both the questions and the answers, must have preceded the Society's 1983 AGM on 23 April 1983. That is because the AGM was not reported until the second 1983 Edition of The Bulletin which was published after the Stockholm conference at the end of June/beginning of July.

65. The Society's third residential seminar took place at Durlston Court Hotel in Bournemouth over a weekend in March 1983. The Society has been unable to locate a record of these proceedings but it is possible that the interview with Dr Kernoff took place there and then.[80]

66. One question and response was:

"*Q Could British haemophiliacs get AIDS?*

[76] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T87: 12-23
[77] BPLL0001351_071
[78] PRSE0004120/11-12
[79] Transcript of evidence of David Watters to the Infected Blood Inquiry, 10 February 2021, T: 14-15
[80] HCDO0000279_030/3

A *Of course it's possible. But I'd still expect AIDS to remain a rare disease. The idea that there's an epidemic of AIDS amongst haemophiliacs is ludicrous.*"

67. Given the rapidity with which Mr Watters wrote to Professor Bloom after the Observer article, and the obtaining and publishing of comprehensive information from Dr Kernoff in the first Bulletin of 1983 (likely to have been published prior to 23 April 1983 for the above reason), and Professor Bloom's address to the AGM on 23 April 1983 which addressed AIDS, it would be fair to conclude that the Society acted promptly in seeking advice when the threat of AIDS was first reported in the UK mainstream media. It provided its members with an early opportunity to ask questions from a consultant well-qualified to answer them.

68. At least one member attended the April 1983 AGM prepared to ask about AIDS. The second 1983 Edition of The Bulletin[81] records that a question was asked about the forthcoming Horizon television program on AIDS billed as "the Gay, Black, Haemophiliac's Disease" (a reference to the Horizon documentary "Killer in the Village").[82]

69. It appears that AIDS was not discussed at the Society committee meetings in early 1983. When asked why, David Watters told the Inquiry that he and Clive Knight had difficulty in persuading trustees and the Executive Committee that this was going to become a problem and he recollected the two of them discussing this at the Kennedy Hotel, but could not remember when.[83]

70. The Inquiry will know that there was a meeting at that venue on 8 October 1983.[84] Professor Bloom had given a presentation in the morning, also attended by Dr Rizza and Dr Aronstam, and the Chair thanked David Watters and Clive Knight for their initiative in producing Haemofact, the second edition of which had been published two

[81] BBCO0000004/5
[82] MDIA0000158
[83] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T92: 11-25 & T93: 1-4
[84] HSOC0019923_006

weeks earlier on 22 September 1983.[85] (Haemofact No 1 was deemed to have been the Professor Bloom letter of 4 May 1983).[86] It could be Executive Committee members were still not accepting that AIDS was going to be a problem, even after the information about AIDS published in the first and second editions of that year's Bulletin and the Stockholm conference. However, that fits with contemporaneous evidence and the abundant testimony that people with severe haemophilia believed, at that time, that the AIDS risk was so small and/or distant that this was simply not a problem that was going to affect them.

71. Mr Prothero's post-Stockholm letter of 15 July 1983 to Dr Colvin[87] enclosing a paper on AIDS given by S Dietrich, gives a keen insight into that trustee's understanding of the threat. The letter exemplifies a likely widespread, mistaken belief amongst many patient attendees that the risk was minimal, coupled with a fatalistic attitude that there was nothing to be done but accept it. Mr Prothero reported that:

"*The main feeling I got from people was that the minimal risk was, at present, just one more that severe haemophiliacs had to accept, along with the other risks they accept already in their treatment, if they wished to avoid the inevitable outcome of reducing treatment frequency or levels. It seemed the issue had, by later in the Congress, become a political and emotional one, a little removed from the cool and realistic appraisal that one, perhaps optimistically, had anticipated!*"

72. Thereafter, the Executive Committee may have accepted that the risk was not minimal, and there was mounting evidence that AIDS was going to be a problem for the bleeding disorder community in the UK. However, such cool and realistic appraisal as it was able to conduct, was predicated on the message consistently sent out by Government and the UKHCDO that untreated haemophilia was a greater danger than AIDS. Further, that running the risk of getting AIDS from Factor VIII large-pool manufactured concentrate was preferable to any reduction in treatment frequency or levels. The Executive Committee believed that advice throughout the period of time before AIDS free treatment became available and the Society echoed that advice when writing to its

[85] PRSE0004474
[86] DHSC0001228
[87] BART0002363

members, whilst reminding them that their treatment decisions were a matter for them and their doctors.

What did the Society know about Non-A Non-B Hepatitis?

73. The Society Executive Committee members attended UKHCDO meetings when Dr Craske in particular often spoke about hepatitis generally and Non-A Non-B Hepatitis. How much of what was discussed was understood by the observing Society attendees (who had neither the reports being discussed nor the minutes of meetings) is unclear. But at a minimum, the Society knew of the existence of Non-A Non-B Hepatitis.

74. At the two day November 1979 UKHCDO meeting, Dr Craske spoke about the Hepatitis Working Party's interest in data collection, "*He already had some evidence that there were different Non-A and Non-B viruses and that the presence of the different viruses in therapeutic material might be related to different methods of fractionation.*" Without the data, it would not be easy to continue with the work. There was discussion about the BMA asking GPs to oppose names of patients going into computer files and Mr Polton, on behalf of the Society, said that all haemophiliacs knew their names were held in Centre files and he did not think that members would object to their names going into a computer file.[88]

75. During the 12-14 March 1982 Group Seminar Proceedings Dr Colvin spoke about Non-A Non-B Hepatitis being commoner following the use of large pool concentrates, "*the vast majority of patients with symptoms recover within a week or two but there is growing evidence that mild inflammation of the liver can continue after clinical recovery and the long term consequences of this are not yet clear*". [89]

76. The minutes of the 10th Meeting of the UKHCDO Hepatitis Working Party held on 13 September 1982[90] records that Dr Craske's Prospective study of Factor VIII and Factor IX associated hepatitis had had MRC and DHSS funding refused. But a preliminary

[88] PRSE0001461/10 & 12
[89] BART0002325/3
[90] CBLA0001618/2, paragraph b)

study had been able to go ahead "*with the help of funds from the Haemophilia Society*". The minutes record that nine out of nine patients who had not previously had Factor VIII or Factor IX developed Non-A Non-B Hepatitis. The Society has not found, and the Inquiry has not heard, evidence that the Society understood that the preliminary study it was funding was proposing to use previously untreated patients as subjects, nor whether it was told directly and by Dr Craske of the results of the study.

77. At the Society AGM on 23 April 1983, Professor Bloom advised those present that open wounds were an infection risk and that "*when people have been exposed, there is a high risk that they may develop non A or non B hepatitis…This work implied that there was more than a 90% chance of contracting non-A, non-B hepatitis after first treatment with NHS or US commercial factor VIII concentrate*".[91] It is unclear whether he was reporting the results of Dr Craske's preliminary study or information gleaned from the "secret" Immuno meeting in January 1983.

78. On 9 January 1984, Ken Milne's Blood Products Sub-committee draft report discussed Non-A Non-B Hepatitis and stated that "*British material is no better (and may be worse) than imported material in this respect*".[92] The evidence base for this statement is unclear but it is clear that Mr Milne knew that NHS Factor VIII was not less risky than imported US Factor VIII concentrate in relation to Non-A Non-B Hepatitis.

79. At a Blood Resources Working Party meeting on 3 February 1988 between Mr Pettet of BPL, Mr Bishop of Armour Pharmaceutical, Mr Milne, Rev Tanner and Mr Watters of the Society, Mr Bishop advised that, "*It is commonly accepted that the pasteurisation process dispels HIV and that the <u>real</u> problem for all production of concentrates is no [sic] NaNb.*".[93]

80. A 1988 Bulletin report, written by Dr Colvin, of the July WHF Congress in Madrid[94] stated that, "*Inevitably the issue of hepatitis received less attention than that of AIDS but it remains a serious cause of illness and we heard some preliminary information on*

[91] PRSE0000411/5
[92] HSOC0011702/2
[93] HSOC0015355
[94] PRSE0000056/13, paragraph 2

potential treatments from Dr Dusheiko who has been working with Dr Peter Kernoff at the Royal Free Hospital."

81. The same edition also carried a two page article by Professor Manucci et al reprinted from "Hemophilia World": *Evaluation of the Safety of Heated Antihemophilic Concentrates*. This referred to Non-A Non-B hepatitis as being a "*formidable problem related to the use of large-pool concentrates*" with a 100% frequency in those not previously transfused. It discussed wet and dry heat-treating techniques.

82. The Inquiry asked Simon Taylor what had prompted the Society to concentrate on hepatitis in 1991. He was unsure and explained that his memory of events during that period was poor. The documents may assist. The General Secretary's report to the Executive Committee dated 4 December 1990 records that there had been a meeting in Liverpool held over the weekend of 23-25 November 1990.[95] A paper on hepatitis had been presented (this does not appear to be available and it is not clear who wrote it). One of the purposes of the weekend meeting was for the local Groups to set the Society's priorities for the next year. One of the priorities set by the Groups was hepatitis.

83. Minutes of a meeting of the Society's Council held on 25 November 1990 at St George's Hotel, Liverpool provide more detail, "*The nine Workshop leaders were invited to present their suggested priorities for the coming year. In these presentations, it was generally agreed that the campaign for HIV compensation should continue as the highest priority of the Society*". In addition, "*the quality of care offered to people with haemophilia in the UK was the top priority for the Society*". A close second was the NHS Review. And in third place was support for Groups and "*the problems of hepatitis for people with haemophilia who were suffering severe liver damage*".[96]

84. The May 1991 Edition of The Bulletin carried a long piece on Haemophilia and Liver Disease by Dr Hay which reported that about 15% of patients would develop cirrhosis

[95] HSOC0024242
[96] HSOC0019923_034

which "*does carry a significant mortality*" and thus left readers in no doubt that this was a virus that could kill. The conclusion stated:

"*For older patients, it* [haemophilic liver disease] *is usually not an active concern since most will have mild liver disease. A minority of patients are at risk from more serious problems and may require treatment with alpha-interferon however, even though the role of such treatment is still under investigation.*"[97]

85. At the Member Services Committee of the Society on 18 May 1991, no doubt following on from the Liverpool meeting, Mr Milne reported that a Project Team consisting of Mr Taylor, Mr Dickason and Mr Watters had been set up to look at ways in which the Society's work in the field of hepatitis could be furthered; Dr Winter had agreed to being consulted if necessary.[98]

86. At the AGM on 1 June 1991, "*The Chairman declared that one of the Society's main concerns in the future was that of hepatitis and the ways in which it would affect people with haemophilia.*" Professor Lee gave the keynote address at the AGM and her subject was "Haemophilia and Hepatitis Past, Present and Future".[99]

87. The minutes of a meeting of the Members Services Committee on 2 November 1991 report on the findings of the Hepatitis Project Team which had looked into the effectiveness of hepatitis vaccines.[100] Christine Lee had suggested a conference of hepatitis specialists and haematologists, and Mr Watters proposed that it might be done in conjunction with the British Liver Foundation. Mr Dickason mentioned that Dr Charlie Hay had suggested publication of a hepatitis fact sheet.

88. There was then a meeting of the Executive Committee on 14 November 1991 and the minutes record that Mr Milne reports that the Hepatitis Project Team had completed its

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[97] HSOC0022975/13
[98] HSOC0010274/6, paragraph 11.1
[99] HSOC0022976/9-10
[100] See paragraph MS91.4 [The of Minutes of the Member Services Committee dated 2 November 1991 have been disclosed by the Society to the Inquiry but do not appear on Relativity; this document has been re-submitted to the Inquiry at the date of this Closing Submission.]

brief, "*having contacted experts in the field and having received comprehensive reports on the current thinking on the subject, the Team had concluded that hepatitis should not be a major concern for the Society. 80% of people infected with HCV and HBV would show no clinical signs and the treatments available were limited: the understanding of the progression of liver disease could only be established through liver biopsies, now considered unethical.*"[101]

89. That was not the end of the matter, however. Minutes of a meeting of Council on 29 February 1992 state that a comprehensive report on hepatitis had been submitted (this does not appear to be available) and the promised fact sheet would be forthcoming before long. The Society was keeping an eye on the matter and on litigation.[102]

90. The November 1992 minutes of the meeting of Council Meeting state that an in house leaflet on hepatitis had just been produced.[103]

91. The No 2 Edition of the 1993 Bulletin carried a report from the Berlin AIDS conference and under the sub-heading "HIV and Hepatitis C" and stated that, "*A group of people with haemophilia who were both HIV+ and Hep C+ were studied, and it was seen that HIV accelerated the onset of liver problems. This is early days yet, but it is an area that will have to be watched carefully.*"[104]

92. The Bulletin No 3 in 1993 carried a piece on viral transmission of Hepatitis C and HIV and a long article on "*Haemophilia and hepatitis* C" from the British Society for Haematology and annual scientific meeting.[105] This reported on Dr Telfer's research at the Royal Free. It said that 60% of patients who contract hepatitis as a result of blood transfusion go on to develop chronic hepatitis and 20% of those patients "*develop cirrhosis over the course of a decade, often with resulting liver failure and hepatocellular carcinoma*". (As 20% of 60% is 12%, Dr Telfer's research would appear to corroborate Dr Hay's figure of 15% developing cirrhosis published in the May 1991

[101] ARCH0002721/3, paragraph 36.1
[102] HSOC0019923_038/4, paragraph (viii)
[103] HSOC0019923_040/4, paragraph C92.32
[104] HSOC0022993/8
[105] HSOC0022994/9

Bulletin). The article ended with a quote from Dr Telfer that, *"This is a disease that is still early in its evolution... Over the next two or three decades we may be seeing many more patients presenting with liver failure.*" There was also a page with some advice about what to do about litigation concerning Hepatitis C.

93. Update No 3, published in September 1993 said that the Society continued to get enquiries from members "*concerned about hepatitis in all forms but especially HCV*" and that it had just finalised a booklet.[106]

94. On 12 March 1994, the Society held the first of a series of meetings on hepatitis. In the same month, four leaflets on hepatitis produced in conjunction with the British Liver Trust were available and it is reasonable to assume that they were being written and printed in 1993. The Society launched its Hepatitis C campaign in March 1995.

95. The documents available to and created by the Hepatitis Project Team in 1991 are not all available. It's reasons for considering that it had completed its brief at the end of 1991 were not obviously wrong, and hepatitis had been a second third priority for the Groups at the Liverpool weekend in November 1990. The Society continued to keep Hepatitis C under review and prioritised this issue as more information became available and there was persistent concern amongst members. It knew that hepatitis could be a fatal disease and that it was likely to be a growing problem. It produced a fact sheet in November 1992, regularly provided members with information in 1993, started a series of meetings on hepatitis in 1994 and embarked on a new campaign in March 1995. The Inquiry is asked to find that the Society's actions in relation to Non-A Non-B Hepatitis were reasonable. Indeed, the Inquiry may feel that the Society did more than any part of the NHS healthcare system, including Government, to inform one at risk section of the population about this growing threat.

[106] HSOC0022995/1

SECTION A2: ACTIONS AND DECISIONS TAKEN BY THE HAEMOPHILIA SOCIETY

96. This section addresses paragraph 360 in the Inquiry's Amended List of Issues, which is, "*What actions and decisions were taken by the Haemophilia Society in relation to the use of infected blood products during the relevant period?*"; "*Should different actions or decisions have been taken?*" and "*What difference might this have made?*".

What actions and decisions were taken by the Haemophilia Society in relation to the use of infected blood products during the relevant period?

97. The context in which the Society's actions and decisions need to be seen prior to the move out of Trinity Street[107] was provided by David Watters:

> "*...because of the evidence presented in the press every day and the problems being encountered once again by haemophilia -- people with haemophilia in the community, because in those days we were still at 16 Trinity Street, I notice, which meant there was me and one secretary, two telephone lines, and they rang off the wall from about 8.30 every morning until 5.30/6.00 every evening, and in between times I was required to deal with everything else.*"[108]

Campaigns and Policy Decisions

98. The Society always campaigned for self-sufficiency. It did so for reasons of patient safety and ethics, and because self-sufficiency made financial sense and was, and could and should have been presented as, a win-win for the taxpayer.

99. The Society always campaigned for treatment that it believed was the best possible, best meaning most effective and safe.

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[107] HCDO0000279_003/16 [Note that information about the Society's new address has been redacted from the version disclosed to Core Participants.]
[108] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T47: 25 & T48: 1-9

100. The Society always campaigned for increased supplies of the best possible treatment.

101. The Society tried to encourage a focus on a rational blood policy that made the most efficient and economical use of voluntary blood donations, a precious resource which was in limited supply. The Society attempted to help increase supply of concentrate treatment, despite its attempts being sometimes rejected, thwarted or discouraged by Government, and kept its membership informed of shortages of cryoprecipitate.

102. The Society's objectives were (as expressed in a meeting of the Society's Council on 22 November 1975), "*always to plug gaps in the NHS, and especially to find haemophiliacs still receiving no proper treatment*".[109]

103. The Society's active attempts to draw attention to shortages of concentrate and to increase the supply of concentrate included the following:

a. As early as January 1965, Mr Polton of the Society liaised with Dr Maycock and offered to recruit donors to give blood which could be hypothecated to the production of AHG – this offer was rejected with regret.[110]

b. Throughout the 1970s and afterwards, the Society used its own funds to plug gaps in the NHS. The Society made or facilitated grants so that hospitals could purchase equipment to make cryoprecipitate.[111]

c. At a Society Council meeting held on 24 October 1970[112] it is noted that Margate Haemophilia Centre asked for a grant to buy a refrigerated centrifuge to make cryoprecipitate, "*they had an excess of blood donors in the area and would be able to supply other hospitals with cryo if they were able to make it*". On this occasion, the Society resolved to suggest an application to another body which may be interested first.

d. At the Society's third Council meeting held on 17 March 1973 at which Messrs, Polton, Prothero, Tanner, Biggs, and Dormandy were all present, there was a discussion on the availability of cryoprecipitate, noting that the system was not

[109] HSOC0019918_009/2, Section 4, paragraph 4
[110] HSC0100025_026/2, paragraph 2
[111] HSOC0016116_015/3 and HSOC0016116_019/4
[112] HSOC0016116_019/4

understood and that a detailed questionnaire was needed. Mention of Sir George Godber's notice on commercial concentrates (6.3.73) is also made.[113]

e. In August 1974 The Bulletin refers to a letter from Dr Rosemary Biggs (published in the Lancet and reproduced in The Bulletin) which stated that 90% of UK patients are "*receiving less than the optimum treatment for their complaint*". The Bulletin also notes that the Society offered help to one hospital by way of voluntary workers to help in increasing the production of cryoprecipitate, but were turned away.[114]

f. At a Society Council meeting on 14 September 1974 the Society approved a grant to Cardiff Haemophilia Centre of £912 to cover the salary for 6 months to a Scientific Officer to assist Professor Bloom plus £1,000 for purchase of a platelet aggregation meter and other equipment.[115]

g. In November 1974 the Society Bulletin again refers to the shortages of Factor VIII and notes that there has not been any indication of action from the authorities.[116]

h. On 25 April 1976 at a Society Council meeting a grant was approved to Dr Hill, now appointed director of centre at Children's Hospital, of £4,000 to enable him to buy equipment which he could not get "*through the usual channels*".[117]

i. On 18 September 1976 at a Society Council meeting there is a report of Sister Aston's work as co-ordinator for haemophilia in domiciliary practice; it is noted that patients on home treatment had risen from 18 to 35 and 12 more were expected. She had discovered there were now registered with the North East Thames Region 240 haemophilia patients.[118]

j. On 18 October 1978 K. R. Polton sent a letter to Minister, Mr Moyle MP reminding him of David Owen's self-sufficiency promise and stating that there is now shortage of Factor VIII, pointing out that some people are only offered cryoprecipitate home treatment if they can self-fund a home freezer and the Society recently had to assist in this regard.[119]

DHSC0100025_026

[113] HSOC0016116_029/3, paragraphs 5 to 6
[114] HSOC0022701/1-2, paragraph 2
[115] HSOC0016116_036/1, Section 4, (1)
[116] HSOC0022698/1, paragraphs 1 to 3
[117] HSOC0019918_011/2
[118] HSOC0019918_012/3-4
[119] DHSC0003722_150/1-3

104. Actions aimed at focusing on value for money to the taxpayer of moving from cryoprecipitate to concentrate, and encouraging implementation of a rational blood policy and the most efficient use of every unit of donated blood, included:

a. In May 1975 the Society and Sunday Times campaign to get more funding for home treatment on the grounds it would make economic sense. Dr Peter Jones drew attention to the fact that some concentrate was sitting unused because regional bodies had discretion whether to provide it or not, the Government position being that it did not fund drugs centrally.[120]

b. 18 June 1975, a BBC Radio 4 transmission with John Prothero who stated that the cost to the tax payer of funding concentrate is less than continuing with cryoprecipitate.[121]

c. On 11 December 1975 there was a meeting between the Society and Government: Dr Owen, Mr Draper, Rev Tanner, Mr Polton with Government (G E Grimstone). Topics discussed included: concern that the self-sufficiency target was too low, and whether greater use of plasmapheresis could be a solution – a thought based on the MRC's report. It was agreed that there would be annual meetings between officials and the Society.[122]

d. In April 1976 David Owen addressed the 3rd European Regional Congress of WFH and states his intention that the UK will be self-sufficient.[123] In his statement he says this was likely arranged through the Society.

e. In April 1977 The Bulletin reported on the MRC Report for April 1975-March 1976. The Bulletin says that the "*number one interest for 1977 and, perhaps, in succeeding year*" is "*the effort to ensure an adequate supply of concentrates*".[124] The MRC report provided not only a date for NHS self-sufficiency in Factor VIII, ie the middle of 1977, but also the most rational use of blood as a means to achieve it. Use of whole blood to treat a patient who needs only a defined part derived from it is wasteful. That report deals with blood and quotes the report as stating the urgent need to replace cryoprecipitate with concentrate, and the NHS aiming to have a "rational" blood policy and to achieve self-sufficiency in Factor VIII by the middle of 1977.

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[120] HSOC0006284
[121] HSOC0008606/1-3
[122] DHSC0100006_093/1 and DHSC0100006_104
[123] LDOW0000084
[124] HSOC0022508/1

f. Neither target was achieved. On 17 December 1980, Ken Milne wrote to Dr Lane on behalf of the Society which had lately become concerned at the large amounts of Factor VIII concentrate being imported into the UK from commercial sources. The Society's wish was to see increased plasma fractionation capacity in the UK. The Society was setting up a small working party and rather than seek second hand advice from its medical advisers, was writing to seek advice from Dr Lane directly.[125]

g. The concern about limited supply and increasing reliance on commercial concentrate was referred to at the start of the January 1981 in the Society's 1980 Annual Report.[126] It may well be that this action followed the UKHCDO's decision to send a strong resolution to the DHSS about increasingly inadequate supplies of NHS Factor VIII at the meeting on 30 September 1980.[127]

h. On 21 October 1981, the Society had a meeting with Dr Vaughan, Minister of State for Health, and discussed the Society's concern that the NHS was so reliant on expensive imported blood products. Dr Vaughan assured the Society of the Government's commitment to self-sufficiency, and told them that the upgrade of Elstree would double Factor VIII production by the end of 1982.[128]

i. Throughout the years that followed, the Society tracked closely the work done at Elstree. It did what it could to hold Government's feet to the fire, but it had no power. The Inquiry is invited to conclude that there is no evidence that there would have been a greater supply of AIDS-free NHS product between the advent of AIDS and the advent of heat-treated product, had the Society campaigned harder or differently for self-sufficiency and greater use of plasmapheresis.

The Society's Support For Importation of Licensed Factor VIII Concentrate

105. In January 1985, Professor Bloom suggested to Mr Watters that "his committee", apparently the UKHCDO, *"has always been under pressure from patients and from the Society to seek increased funding for the purchase of commercial Factor VIII"*.[129] He

[125] CBLA0001220
[126] HSOC0022906/1
[127] BART0002485/6
[128] DHSC0002211_062/1, paragraph 1
[129] BPLL0001351_103/1, paragraph 3

said the same thing five years later, at a UKHCDO meeting on 21 September 1990 when self-sufficiency was declared to have been achieved, "*in 1979 to '85, when he was Chairman, all the Haemophilia Centre Directors and The Haemophilia Society were pushing the Department of Health to purchase imported products.*"[130]

106. These words themselves are not factually inaccurate, but the effect of the incomplete statements is misleading. Professor Bloom omits the fact that he was instrumental in advising the Society and patients to continue to use commercial Factor VIII throughout 1983-1985. He was never an advocate for adhering or reverting to cryoprecipitate, neither did he seek strongly to promote reduction of home treatment or prophylaxis for those with severe haemophilia A, nor exclusion of children and people with mild haemophilia from treatment with imported commercial products. It was Professor Bloom himself who was the author of the Society's first advice about use of commercial product in the face of AIDS. He was not "pressurised" either into giving that advice, or himself purchasing such treatment for his patients.

107. Further, his statements do not explain *why* the Society and patients sought funding for the purchase of imported commercial Factor VIII both before and after January 1983. Some explanatory facts are set out below.

108. The Archer Inquiry found as a fact that in 1974, "*senior doctors, supported by the UK Haemophilia Society, asked the Government to fund the purchase of commercial Factor concentrates from the United States, where they had been licensed in the previous year*".[131]

109. That finding is likely to have been based on Dr Peter Foster's evidence.[132] He told Lord Archer that the doctors and the Society urged that action on Government "*on the grounds that 90% of patient were receiving inadequate treatment*".

110. That figure, and the timing, dovetails with the Society's reproduction, in the August 1974 Bulletin[133], of correspondence in The Lancet about treatment insufficiency. This

[130] HCDO0000015_021/3, paragraph 2
[131] ARCH0000001/25, paragraph 4
[132] ARCH0002320/5, paragraph 3
[133] HSOC0022701/1

included a letter from Dr Biggs stating that because of a shortage of material, 90% of UK patients were "*receiving less than the optimum treatment for their complaint*", that essential but non-urgent operations were being cancelled, and there was delay in putting patients on home treatment.

111. Questions were put in the House of Commons on 9 July 1974 and there was a statement from Dr David Owen. The Government accepted that supply of NHS Factor VIII was "*at present insufficient for the optimum treatment of haemophilic patients*", but sought to provide reassurance by stating that in the interim, two product licences had been issued to two firms and, unusually, central contracts were arranged to facilitate purchase of the imported material by health authorities.[134]

112. The August 1974 issue of The Bulletin also noted that discontent in the NHS did not help in finding a problem to the solution. When the Society had offered a hospital assistance with volunteer workers to increase production of cryoprecipitate, they were told such help might be resented by technical staff and could result in industrial action. (The Bulletin then went on to consider that response from the viewpoint of an "overworked, underpaid" hospital worker. This ability to empathise and consider a human situation from perspectives antithetical to the needs of people with haemophilia is, it is submitted, an example of the Society's institutional, "middle of the road" approach generally: thoughtful, respectful of others, non-combative, and solution focussed.[135])

113. There is no doubt that from at least 1972, the Society knew – and informed its members - that US commercial blood products carried an increased risk of infection.[136]

114. This is likely to be a policy area where the direction taken by the Society was informed by the personal experiences of trustees and members. For example, Chris Hodgson described to Lord Archer the transformative effect of his first infusion of commercial Factor VIII in 1973.[137]

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[134] HCDO0000392_035
[135] HSOC0022701/2, paragraph 2
[136] HSOC0022713/3, paragraph 3
[137] ARCH0000001/15

115. The August 1974 Bulletin spoke of access to injectable home concentrate being capable of "*saving a life or preventing the crippling of a young child*".[138] The avoidance of crippling injuries and orthopaedic surgery in children was Dr Swinburn's rationale for supporting the immediate purchase in Southampton of concentrate imported from the US.[139]

116. All of the Society's actions in relation to supporting importation of blood products known to be riskier than domestic products were carried out *in the context of imported products being a necessary and justified, licensed and Government funded stop-gap pending attainment of self-sufficiency*. The same Bulletin records the April 1976 WFH 3rd European Regional Congress at which Dr David Owen, then Minister of State, gave an assurance that self-sufficiency was the policy of the DHSS. He had already acknowledged the increased risk of infection from commercial blood products, and the moral hazard inherent in the worldwide trade in blood in the December 1975 "World In Action" television programme.[140]

117. On 23 February 1975, Radio Four's "World This Weekend" broadcast the Society's Secretary describing the excruciating pain of a bleed in a joint, and his personal experience of a bleed on holiday in Wales where cryoprecipitate was sent by night-time motorcycle dispatch rider but, as a result of the time lapse, treatment was only sufficient to hold the situation rather than treat the bleed.[141] Dr Owen, then Secretary of State, was interviewed and discussed spending £0.5 million and anticipated achievement of self-sufficiency in probably two to three years.

118. Mr Prothero's interview on BBC Radio Four's "Today" programme [142] on 18 June 1975 explained the context in which, and the reasons why, the Society supported the treatment of people with haemophilia with US commercial blood products that it knew to be inherently riskier than NHS concentrate. In summary:

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[138] HSOC0022701/2, paragraph 1
[139] HSOC0000006/5
[140] HSOC0000006/3
[141] HSOC0000006/3
[142] HSOC0008606/1-4

a. cryoprecipitate was a crude treatment kept and used in hospitals;
b. it was also in short supply and not as effective as the concentrate alternative;
c. there were few hospitals so haemophiliacs had to travel long distances;
d. in that time, "a lot of damage can be done to joints";
e. alternative, soluble, fridge stored, home treatment was more effective than cryoprecipitate, faster acting and more convenient for the patient;
f. it made economic sense for the taxpayer because the saving in time meant that patients with a bleed could get back to work more quickly;
g. the NHS had not kept up with and should increase production as quickly as possible; and
h. in the interim, Government should provide funds to buy the commercial products that it had licensed.

119. When Professor Bloom came to look back in 1985 and 1990, it seems that he sought, indirectly, to disavow the advice he had given the Society and its members to keep using imported US Factor VIII. He took no responsibility for what he had done, neither did he acknowledge the significant and influential role he played in promoting the importation, prescription and use of US contaminated product in the AIDS years. Instead, he sought to distance himself from his own actions by pointing the finger at other Centre Directors, the Society and patients.

120. In contrast, in 1985 and 1986 the Society's position remained the same. In the first Edition of the 1985 Bulletin,[143] its editor, Clive Knight, explained why it had not been published for a year, "*In 1984 the sheer volume of extra work in our office, generated largely by AIDS, and the shortage of cash available to the Society, led us to stop production of the "Bulletin"*. On the front page, David Watters covered a familiar story - the "*AIDS Problem*" in the context of persisting product shortages and delayed self-sufficiency. He wrote, "*And although the press has been dramatizing the AIDS problem and the risk of imported blood coming into this country, I think it is very important not to forget that without the imported product the quality of life of those who need Factor VIII and Factor IX would have been much poorer.*" Writing in the 1986 Bulletin in his

[143] DHSC0000696

Note from the Editor[144], Clive Knight responded to a view expressed to the Society that these comments were misleading in relation to Factor IX and "*may have alarmed Christmas disease sufferers*", and reported the fact that "*some 20 UK users of Factor IX had seroconverted by August 1985*."

121. The Society acknowledges, with significant regret, the absence of any documents directly addressing how the Executive Committee, including Rev Tanner, felt about the decisions it made in 1983-1985. After heat-treated product became available, the Society threw itself into campaigning for at least a modicum of swift financial relief for all people with haemophilia. The trauma was AIDS was swiftly followed by the realisation of near universal infection with Non-A Non-B Hepatitis and the growing realisation that many more would die. That resulted in further hard-fought campaigning.

122. This necessary and productive activity must have enabled infected Executive Committee members to feel that they were engaged in work of benefit to the bleeding disorder community. We can never know whether the campaigns were, in whole or in part, a conscious or unconscious form of atonement. However, all of the evidence suggests that if and when members of the Executive Committee of the AIDS years looked back and reviewed their actions on behalf of the Society, and their personal decisions, they felt, even when ill and dying, that they did the best they could for the membership in impossible circumstances and could not have done more or better.

123. The extent of Professor Bloom's betrayal of them was not known in their lifetimes. The Inquiry's presentation on Professor Bloom has been shocking and profoundly upsetting for some of the Society witnesses who have given oral evidence.

Should different actions or decision have been taken?

The Advice to Keep Taking US Factor VIII

[144] DHSC0002164/3

124. The Society undoubtedly relied on Professor Bloom. However, its reliance on him was not, or not solely, as an individual consultant, but more importantly perhaps, as the Chair of the most authoritative body in the UK in relation to the treatment of people with haemophilia, the UKHCDO. To put it another way, had he been no more and no less than a consultant treating haematologist with a research interest in the treatment of people with haemophilia, the Society would have relied on him less and may well have turned elsewhere in May 1983 when it needed advice on AIDS very quickly.

125. In May 1983, the Society must have believed that through Professor Bloom, it was getting not just his advice, but the advice of the UKHCDO. The evidence to the Inquiry has shown that that belief was well founded and justified; there was no member of the UKHCDO who had any significant disagreement with Professor Bloom's 4 May 1983 advice.

126. As will be illustrated later, the advice from Professor Bloom, circulated by the Society on 4 May 1983 did not reflect the true position, or his true state of knowledge. The Society is now aware, but then was not, of the content of a letter sent by Dr Evatt to Professor Bloom on 7 March 1983. It is instructive to compare the content of that letter, which we now set out in full, with the text of Professor Bloom's advice to the Society, which follows:

Letter from Dr Evatt to Professor Bloom, dated 7 March 1983

Thank you for your recent inquiry concerning the AIDS Syndrome. I will be happy to present an update on the current status of AIDS in North America during the Stockholm meeting. As you can imagine, AIDS is having a major impact on the treatment of hemophiliacs here presently.

The evolution of the epidemic is occurring with a frightening pace. We now know of over 1150 total cases in the United States. To give you an example of rapidity of development, approximately 80 patients with AIDS reported to us during the month of December; in January - 120; and in February the number is approaching 20% above

that level. In fact, about 40% of the cases have been reported to us in the last 3-4 months.

We presently have 13 confirmed hemophiliac patients with AIDS in the United States. One of the patients has Factor IX deficiency and one is bisexual. In addition 5 more highly suspect cases are under investigation. The incidence rate has been increasing in hemophiliacs and the epidemic curve paralays that of the total epidemic curve. The first case appeared in a hemophiliac in January 1982; a total of 9 were reported by December. Of those, 8 died in 1982. From preliminary data obtained from a nationwide surveillance, the AIDS syndrome was the second cause of death among hemophiliacs in 1982 in the U.S. (hemorrhage was the largest cause of death.) AIDS has developed in both mild and severe hemophiliacs. Ages have been 7 to 62 years. The clinical course has been rapid after the onset of an opportunistic infection. Most have had Pneumocystis pneumonia and none have had Kaposi sarcoma. All have received Factor VIII concentrates, and all but one have received other blood products such as plasma or blood transfusions. Common lots among the concentrates have been rare. We have accumulated a large amount of clinical data on these patients, and it is very similar to that seen in other cases of AIDS. We are performing a longitudinal study of the immune status on hemophiliacs in Georgia and have performed immune studies on approximately 50 randomly selected hemophiliacs and compared them with patients who have chronic active hepatitis, or with patients undergoing chronic renal dialysis (to represent another group which receives chronic transfusions). Preliminary data suggest that one half of the hemophiliac population has T cell abnormalities and, in fact, 13% are markedly abnormal (in the range that we see with the AIDS patients). Patients with chronic active hepatitis, or patients undergoing chronic renal dialysis are not significantly different than normal. These patients will be followed and by the summer we should be able to give a status report on this study. Other additional groups are being added.

Transfusions as a source of AIDS infection is another cause for concern here. Approximately 12 patients have developed AIDS following blood transfusions. These cases are under intensive investigation by us. Of these patients, half are male and half are female. They appear to be located in the high incidence area of AIDS, i.e., New

York, San Francisco, and Los Angeles, locations where we would expect the majority of donors with AIDS to be.

I hope this information is useful to you. I suspect it is a matter of time before you begin to see cases in the United Kingdom.

We have been aggressively trying to isolate a virus in the laboratory. So far, results have been negative. CMV is frequently isolated, however, DNA probes suggest that they are all different strains.

Look forward to seeing you this summer. If you have any further questions, please do not hesitate to ask.[145]

Text of the letter from Professor Bloom to the Society, dated 4 May 1983

Reports from America of the acquired immune deficiency syndrome (AIDS) in persons with Haemophilia are causing anxiety to members of this Society and to their relatives. Haemophiliacs, their parents and doctors have always balanced the quality of life and the dangers from bleeding against the risks of treatment. We are no strangers to infective diseases, such as hepatitis, which can be transmitted by factor concentrates. Recent evidence indicates that in this respect at any rate concentrates prepared from British blood are not necessarily safer than those prepared in the United States. Even so we welcome the fact that the government is investing over twenty million pounds in the Blood Products Laboratory (i.e. Factory) at Elstree so that this country shall become self— sufficient in blood products. Bearing this in mind it is important to-consider the facts concerning AIDS and haemophilia. The cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products. The number of cases reported in American haemophiliacs is small and in spite of inaccurate statements in the press we are unaware of any proven case in our own haemophilic population. Neither have any cases been reported from Germany where massive amounts of American concentrates have been used for many years. Nevertheless the situation is being closely monitored

[145] BPLL0001351_021

by the Haemophilia Centre Directors and in a more general way by the Communicable Disease Surveillance Centre in London. In addition the importation of licensed blood products has always been strictly monitored and controlled. Thus whilst it would be wrong to be complacent it would equally be counter—productive to alter our treatment programmes radically. We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation.[146]

127. The contrast in tone and content between these two communications is stark.

128. The Society also wrote to Professor Bloom in July 1983 after Stockholm, asking him to revisit his May 1983 advice and tell them whether it was *"still sufficient without any amendment"*.[147] Professor Bloom responded by suggesting that although the WFH's guidelines were not strict enough there was no point in circulating the membership again. [148] And he did not go on to take the opportunity provided to him by the Society to explain that he had devised his own policy for the treatment of his patients in Cardiff,[149] which was more stringent and protective of patients with severe haemophilia, than the UKHCO guidelines and those of the WFH. The information he did provide he said was not to be shared with the membership.[150]

129. The Society held Professor Bloom in high esteem. As well as being a clinician and a research scientist of repute, he was a member of almost all relevant national committees. The positions it was aware that he held would reasonably have caused the Society to believe that Professor Bloom's view was respected by his clinical and scientific peers, and sought after by civil servants and decision makers at the highest level of Government. It proceeded on the basis, having no reason to do otherwise, that he was a trustworthy source of unbiased, reliable information. It could also reasonably have held the view that if there was important information about AIDS relevant to people with haemophilia that came to Professor Bloom's attention, and which he was free to pass to the Society, he would do so without delay and not withhold it. It is submitted that each of these views or beliefs were eminently reasonable at that time. As Mr Wetherell put it, *"I think we're a*

[146] DHSC0001228
[147] DHSC0001246
[148] CBLA0000062_053
[149] WITN4029002
[150] CBLA0000062_053

very deferential and grateful little community, and we trusted people to give us the best advice possible at the time".[151]

130. The Society's reliance on Professor Bloom was not misplaced but the trust it reposed in him was.

131. During the Inquiry's oral presentation on Professor Bloom, Counsel to the Inquiry referred to the Society's reliance on Professor Bloom and the way his May 1983 advice shaped the Society's policy and impacted on the membership. The Society accepts that it can be fairly criticised in that regard. However, it asks the Inquiry to note that in mid-1983, the Society did obtain, from a different source, information that was nuanced, presented in a tonally different way, and which carried a significantly more cautious message than Professor Bloom had given out. The information referred to, is the piece by Dr Pinching, consultant immunologist at St Mary's Paddington, published in Bulletin Edition 33 No 2 1983.[152] This edition is undated but it came out after the conference in Stockholm which ended in early July 1983. Dr Pinching was not on the Medical Advisory Panel, was in no way a Society regular contributor, and he was not on the UKHCDO. The Inquiry is asked to find that the Society was prompted to seek the article from Dr Pinching because the Mail on Sunday article published on 8 May 1983 which quoted him as saying:

"*I wouldn't dream of giving a patient American blood products. We have to find an alternative immediately.*"[153]

132. The evidence given to the Inquiry suggests that Dr Pinching was the only doctor known to the Society to be reported as saying that he would not dream of giving a patient US product because of AIDS. In approaching him, and with relative haste, the Society acted responsibly and proactively, by seeking out what it could have anticipated would be an independent counterpoint to Professor Bloom of benefit to members.

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[151] Transcript of evidence of Peter Wetherell to the Infected Blood Inquiry, 25 May 2021, T64: 5-7
[152] PRSE0000411/11
[153] PJON0000001_101

133. On 10 February 2021, drawing together the strands of 1983 evidence discussed with him, Counsel to the Inquiry put to Mr Watters the following proposition:

"*The Society could have said, in the course of 1983, to its members: AIDS is a condition which is probably transmissible by blood. It's a disease with a high mortality rate and known long incubation period. We don't know how many people might end up being infected but you may wish to explore alternatives to treatment with factor concentrates with your clinicians.*"[154]

134. The Inquiry is asked to find that the Society did say this to its members. Dr Pinching's article in Edition 33 of The Bulletin - "*The Acquired Immune Deficiency Syndrome (AIDS)*" - said all of these things to the Society's members, and provided a significant amount of additional important and reliable information. Dr Pinching said the following (bold emphasis added):

"***AIDS may be due to an infectious agent, transmitted by intimate contact or blood product inoculation****...the agent is* ***probably a virus****...****A particular problem is that there appears to be quite a long period (months or years) between exposure to the causative agent and the person becoming ill; during this time he/she may be infectious****...the* ***tests available ...are extremely non-specific****...the disease carries a* ***high risk of mortality****...****no cure*** *has yet been found...AIDS has affected roughly 1 in 1,000 haemophiliacs in the USA, and* ***two patients in the UK****. The* ***immediate source of infection in such patients is thought to have been FVIII concentrate, derived as it is from thousands of donors****. On the other hand, this new and* ***to some extent theoretical hazard of using concentrates has to be set against the enormous benefits of such concentrates in haemophiliacs, especially for home therapy****...****FVIII concentrate from the USA may be the most likely to contain the AIDS agent****, however, the risk is probably small and no source can be regarded as completely free from risk...The present balance of opinion among haemophilia centre directors in the UK therefore is that imported FVIII concentrate should continue to be used for those selected patients already receiving it: ie severely affected haemophiliacs with frequent bleeds, and* ***excluding children and those with mild disease****....The* ***source of FVIII concentrates***

[154] Transcript of evidence of David Watters to the Infected Blood Inquiry, 10 February 2021, T70: 9-16

***will need to be kept under constant review**, as will blood donor policy both by the medical profession and the relevant industrial concerns, to minimise or eliminate the risks.*"[155]

135. He ended his article with the observation that the risks of AIDS "*need to be kept in a proper perspective*". As the Inquiry has observed, many clinicians enjoined people with haemophilia to keep AIDS in perspective. And at the meeting on AIDS on 3 June 1983 central bodies found helpful "*the part played by the Society in keeping AIDS in perspective*".[156]

136. The Society was acting on the advice it was provided with directly and indirectly by attendance at UKHCDO meetings. Though the perspective was never defined by the NHS or any member of it, the advice to all severe haemophilia A sufferers with frequent bleeds was that they should continue to use US Factor VIII treatment even though he knew that there was a risk that in doing so they would contract a fatal disease for which there was no treatment and no cure.

137. Dr Pinching couched his advice in more careful, nuanced terms than did Professor Bloom. And importantly, he gave advice about those people with haemophilia who should not be using US imported Factor VIII. But for severe A patients, his advice was identical to Professor Bloom's.

138. Whilst the Inquiry has heard evidence about a handful of clinicians who did not prescribe concentrate other than cryoprecipitate or who wanted to consider greater use of cryoprecipitate, there was never a time when any clinician or scientist publicly endorsed reversion to cryoprecipitate, a temporary suspension of imported US product, or a ban on its prescription.

139. The perspective the Society, its members and all people with haemophilia were encouraged to adopt by doctors, scientists, public health experts, civil servants,

[155] PRSE0000411/11-12
[156] DHSC0002229_030/3, paragraph 24

Government and the entire healthcare system, right up, until the time that heat-treated AIDS free Factor VIII was available, was that for severe A sufferers, getting AIDS from US Factor VIII concentrate was a risk worth taking.

140. It is instructive to look closely at the Society's 33rd Edition of The Bulletin (1983) No. 2. It evidences the differing speed at which doctors treating people with haemophilia were getting information. It also demonstrates the difficulty for the Society in providing its members with accurate and reliable information, when the nature of this threat to people with haemophilia was so new, and a matter on which all patients were totally dependent on medical science for answers. As to the incidence of AIDS in the UK haemophilia population, this edition told readers three different things: there was a rumour that a British homosexual who was a haemophiliac had AIDS but this was not definite (Professor Bloom – at best incomplete), there was no case of AIDS in Britain or Western Europe (Dr Forbes - incorrect), and there were two haemophilia patients with AIDS in the UK (Dr Pinching – correct). Dr Pinching's article appeared as the last of four items touching on AIDS in Bulletin Edition 33.[157] The first three, in order, were:

a. Professor Bloom's talk to members at the AGM on 23 April 1983:
"*I am unaware of any definite cases in British haemophiliacs although cases are occurring in British homosexuals and it is rumoured that one of these has haemophilia. The Haemophilia Directors' Organisation is conducting a comprehensive survey…so that firm data may be available in due course.*"[158]

b. The Q&A session with assembled members:

A member of the audience referred to the forthcoming BBC Horizon program on AIDS (the Gay, Black, Haemophiliac's Disease) and says, "*this unfortunate association in the Radio Times must be upsetting for haemophiliacs*".[159]

[157] PRSE0000411/11
[158] PRSE0000411/3
[159] PRSE0000411/5

Professor Bloom responded that, "*It is unfortunate that haemophilia has been linked with AIDS. Apart from that we must not overlook the AIDS problems. One of my patients may have a mild form of it*",[160]

Dr Forbes then said, "*The problems in the US are not prevalent anywhere else. It has not occurred in Britain or in Western Europe*".[161]

c. Andy Cowe's account of Stockholm. He reported attending the meeting addressed by Dr Aledort and Dr Evatt. The inference can safely be drawn from what he does not report that he did not distil from Dr Evatt's address the learning points identified by Dr Peter Forbes, despite reporting that, "*A most important resolution on AIDS was proposed and adopted by the General Assembly, AIDS was clearly a major topic of discussion at the Congress, and hardly a session passed without some reference to this problem.*"[162]

Better Use of the Pinching Article

141. Although the information Dr Pinching provided to severe haemophilia A sufferers with frequent bleeds did not differ from Professor Bloom's, his tone was more cautious than reassuring, and he emphasised the need for constant vigilance. He also gave the Society strong steers as to areas on which it could usefully focus in future: the source of Factor VIII concentrates, and blood donor policy.

142. An option open to the Society, following publication of Dr Pinching's article, was to return to it and highlight to the membership the key points of his opinion, whilst making it clear that this was one clinician's opinion, and not medical advice. Had it done so, information from Professor Bloom would have been balanced by a perspective which took as its starting point that: AIDS was probably transmitted by blood and blood products, it was probably a virus; product made from large pools of blood posed a higher risk of transmitting AIDS than cryoprecipitate, AIDS had a long incubation period during which those infected were infectious, and a high mortality rate. The

[160] PRSE0000411/5
[161] PRSE0000411/5
[162] PRSE0000411/10

Society could also have done, in the 1980s, what it does now, namely remind readers that it does not give advice, publish established guidelines, and recommend that patients discuss them with their doctors. Publishing the UKHCDO guidelines would have been sensible. And the Society could and should have refrained from making statements, such as that in the editorial of the next edition of the Bulletin, "*All things considered, haemophiliacs have no reason to be worried about using commercial concentrates*".[163] Dr Pinching's core message was that there were reasons to be worried.

143. In August 1983, presumably not long after Edition 33 was published, Dr Pinching was appointed Scientific Secretary to the MRC Working Party on AIDS, of which Professor Bloom was also a member.[164] The Society could, and perhaps should, have continued to seek Dr Pinching's views. It could, for example, have asked him to speak to the membership about AIDS on 8 October 1983, rather than turning to Professor Bloom again. That said, even with the benefit of hindsight, many of the Society's members struggle to accept that returning to Professor Bloom was an action that was outside the range of reasonable responses to the crisis situation facing members at the time. Dr Pinching did not treat people with haemophilia. And it was clear from the article he wrote for The Bulletin, that his advice to those with severe A disease was not to stop using US imported Factor VIII concentrate (as the Mail on Sunday had reported) but to continue to do so if that was what the treating clinician recommended. For severe patients then, who formed the majority of the membership[165] and who were the group of haemophiliacs most at risk because of their frequency of bleeds and dependency on Factor VIII concentrate, his advice was the same as Professor Bloom's. The Society had provided Professor Bloom and all Medical Advisory Panel members with the medical and scientific papers presented at Stockholm WFH conference which Professor Bloom had attended. Professor Bloom *did* treat people with haemophilia and on this issue, he continued to speak for the whole of the UKHCDO. The Society reasonably believed that when it went to the Professor, it was obtaining for its members the most informed, scrutinised, and authoritative advice in the country.

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[163] PRSE0002925/2, column 2
[164] MRCO0000373_089
[165] Transcript of evidence of David Watters to the Infected Blood Inquiry, 10 February 2021, T6: 2-5

144. What impact might the actions at paragraph 141 above have had? Members might have been better informed and they might have been left with a heightened sense of the risks and the need to be vigilant. They may have been more empowered to ensure that they, or their children, were not treated with large pool concentrates unnecessarily. If asked to speak, would Dr Pinching have said anything substantially different to the membership in October than Professor Bloom did? The tone may well have been less reassuring. But Dr Pinching was not advocating a reversion to cryoprecipitate, a suspension of imports of US Factor VIII, or even a cessation of home treatment. As referred to above, his advice to severe haemophilia A patients did not differ from Professor Bloom's.

145. On 27 September 1983, Dr Pinching, Professor Bloom and others met and prepared a report for the British Society for Haematology "AIDS" Working Party. This report stated that the transmissible agent of AIDS was "*possibly a virus*". In his article for The Bulletin, Dr Pinching had used the word "probably". If he was accurately quoted in the Mail on Sunday on 8 May 1983, there is evidence of his confidence about the nature of the infective organism decreasing and his view changing over the 4-5 months that followed.

146. However, there is evidence that in his address to the Society members on 8 October 1983, Professor Bloom's tone was more pessimistic than it had been in April. Mr Peter Wetherell had listened to Professor Bloom speak at the AGM on 23 April 1983, was also present at the meeting on 8 October 1983 and answered the Inquiry's questions about his written account.[166] His evidence gives a strong sense of the mixed messages Professor Bloom provided and does much to explain the Society's inaction in relation to the May advice:

"*For the very first time we were getting sort of intonations from Professor Bloom that treatment should be limited, in stark contrast to the previous stated position at a meeting of The Haemophilia Society membership, in relation to home therapy.*

[166] WITN3912001/11, paragraph 32 and Transcript of Evidence of Peter Wetherell to the Infected Blood Inquiry, 25 May 2021, T45-53

….

I know Professor Bloom tried to give some sort of reassurances about sexual transmission, and it was unlikely that women could contract it. But I think, you know, frankly, I mean, some eyebrows went up around the room at that point. You know, it was now there as an issue for members to reflect upon, and this terrible crisis of treatment and the risks associated with treatment…

Professor Bloom was still basically saying, "Look, it may not be as bad, but it could be bad". You know, in other words he was pretty much holding to his position in relation to I think the treatment therapy programmes going forward."

147. When it was suggested to Mr Wetherell that one finds no sense of any grappling with the difficulties in the Society's Council meeting minutes relating to 8 October 1983[167], he said that, "*we didn't have the ability, seemingly, to explicitly discuss, I think, how we were feeling about it as individuals.*"

148. The minutes of the MRC Working Party's meeting on 20 December 1983 record a report from the CDC of "*the case of the wife of a haemophiliac who had recently developed AIDS, suggesting that the disease may be transmitted by heterosexual contact*". Both Professor Bloom and Dr Pinching were present at that meeting. This was hard information that Professor Bloom knew, and Dr Pinching must have realised, would be of the greatest concern to people with haemophilia and the Society's members. There is no suggestion that the discussion was confidential and each of them could and should have made that information available to the Society immediately.[168] There is no evidence that either of them did so.

149. Had Professor Bloom and others provided information to the Society within their possession, with an indication of what was known to be factually accurate, what intelligence came from a reliable source but was uncertain, and what was intelligence

[167] HSOC0019923_006 and Transcript of evidence of David Wetherell to the Infected Blood Inquiry on 25 May 2021, T53: 18-22
[168] DHSC0002239_079/2

of dubious or unknown quality, the Society would have been better placed to make its own, informed evaluation of the situation. But there was not that openness and candour.

150. That said, the Society takes responsibility for its decisions. It could have referred back to the article that Dr Pinching wrote for the 1983 Bulletin. It either did not digest all of what he was saying or if it did, it forgot about it. Thus, even in the December 1984 and April 1985 editions of Haemofact, the Society was advising "*everyone with haemophilia – however mildly affected – to continue to accept medication as prescribed by medical staff*", without the caveat that unless there was good reason to do so, people with mild haemophilia should not be treated with large-pool concentrated Factor VIII.[169]

151. The Executive Committee's belief – which in retrospect appears more of an article of faith - that any form of haemophilia was more dangerous than AIDS, seems to have taken hold on 4 May 1983 and been close to unshakeable thereafter. Professor Bloom's May 1983 advice was formative, and the Inquiry is asked to find that each member of the Executive Committee would have had that advice reinforced at consultations with his treating doctors. The UKHCDO and WFH guidelines did not change over time and that constancy would reasonably have encouraged confidence in the Executive Committee that it remained on the right track. But perhaps the two main reasons why the Society's policy did not change between the start of the AIDS crisis and the advent of heat-treated product, were the lack of any real alternative for severe haemophiliacs, and the reliance of patients on their doctors. The Executive Committee members had grown up, or seen their children grow up, before there was any effective replacement therapy. Cryoprecipitate had been transformative and provided the hope of longer, fuller lives, but it was restrictive for most patients. Self-injected treatment at home was not only liberating, but it delivered that hope. People with severe haemophilia would probably only have been convinced that abandoning Factor VIII concentrate was the right thing to do if a clear public health message had been sent out, by Government and the UKHCDO, that no treatment was better than unsafe treatment. The consistent actions and health advice of both, were that untreated haemophilia was a much bigger

[169] DHSC0000673/1, paragraphs 5 & 7, DHSC0000673/22 & 25

threat to patient safety than AIDS. AIDS was a new health emergency. The Society and patients trusted Government and doctors to give them considered, balanced advice about what to do. They were given the advice they were given and they allowed themselves to be led by it. Should the Society have done differently and better? This central question is one that it continues to wrestle with and finds itself not well placed to answer.

Other action that the Society Could have taken

152. The Society has listened and learned from the modern governance and scrutiny measures outlined by Sir Alex Chisholm[170] and "red teamed" this issue. It has looked back from the viewpoint of 2022 with a modern understanding of the dangers of groupthink. These were, in the 1980s, and remain particularly acute for the Society. It remains a small charity overseen on a voluntary basis by a board which is largely comprised of patients or parents for patients and parents. That governance structure has inbuilt advantages and disadvantages. The disadvantages include conscious and unconscious factors which put obstacles in the path of Mr Prothero's "*cool and realistic appraisal*".[171] Congenital illness may shape character so that truly independent evaluation of treatment risk is difficult; generational memory also plays a part. And there is the ever-present fact that people with haemophilia depend on the NHS not just for their health but for their survival. Particularly for parents of child patients, even now there may be difficulties in challenging a consultant.

153. All that said, the Society accepts that in 1983 the Society had set itself the goal of providing good quality, reliable and objective information about treatment and treatment risks. In pursuit of that goal, and in addition to the matters set out above, it could have:

    a. Not published any medical advice about AIDS
    b. Advocated a suspension of imports of US Factor VIII
    c. Advocated a return to cryoprecipitate

[170] Transcript of evidence of Alex Chisholm to the Infected Blood Inquiry, 14 November 2022, T45: 6 – T46: 10
[171] BART0002363

d. Advocated temporary cessation of prophylactic treatment and/or home treatment until more was known about risk
e. Undertaken a survey of members' views on the action or position that should/should not be taken by the Society
f. Asked members of the Medical Advisory Panel directly: *Do you have any information, reliable or not, relevant to the risk of AIDS from Factor VIII concentrate whether US and domestic, that you have not shared with the Society?*

154. As to 152(a), even with the benefit of hindsight, The Society does not consider that declining to say anything in response to the Mail on Sunday's May 1983 article and members' immediate response to it, was an option it could reasonably have taken. Nor can it believe that it was unreasonable, that weekend, to ask Professor Bloom for the guidance the membership was seeking.

155. As to 152(e) a survey of members would not have been reasonably possible in that timeframe. Further, for the reasons explained below, there is no basis for finding that the Executive Committee was out of touch, nor that a survey of members, many of whom were living in fear and dealing with impossible situations, was reasonably required.

156. As to 152(f), in hindsight, asking the above question of Medical Advisory Panel members would have been illuminating. But these were relationships of trust. There is, it is submitted, no basis for a finding that it could or should have occurred to any member of the Executive Committee to question whether these eminent clinicians – or their treating doctors - might be withholding reliable information about AIDS which it could benefit Society members to know.

Reversion to Cryoprecipitate/reduction in use of concentrates

157. As to 152(b), (c) and (d), there is no evidence that the Society had any mandate from the membership for a campaign that would have limited access to self-injected, soluble Factor VIII concentrate. There is no reason to believe that the Executive Committee

was out of touch with the membership. Mr Watters gave evidence of constant phone calls and letters about AIDS, there were lectures and an annual residential seminar over a weekend, the AGM, and Council meetings two or three times a year. The Council was made up of representatives of a nationwide local Group network and earlier in these submissions (at paragraph 82) the Society has provided evidence of the Groups setting the charity's priorities for the next year. There can be no doubt that the Council meetings would have provided feedback to the Executive Committee about members' views and experiences. Had there been a sizeable number of members who wanted the Society to campaign for, or send out a message to members about, any of: a stop on US Factor VIII, a reversion to cryoprecipitate, or a reduction in home treatment, the Executive Committee would have known about it.

158. Even if the Society had campaigned on those issues, it is unlikely that the campaigns would had any traction. Government had already made its mind up that it would do everything to maintain supply of concentrate, even if that meant accepting US stocks derived from pre-March 1983 collected blood. There were no calls from the treating clinicians, Centre or Reference Centre directors to suspend importation of US Factor VIII at any time, and the UKHCDO considered, and decided against, a reversion to cryoprecipitate. When the AIDS threat became known, the Society continued with its policy of supporting importation of US Factor VIII. As explained below in section A6, the sole reason for support of continued importation was the Government's continuing failure to attain its goal of self-sufficiency and resulting dependence, of the NHS and its patients, on US commercial blood banks. Although the UK Government found the Society's pragmatic support for continued importation useful, there is no basis for a finding that the Society's opposition to Government policy would have changed Government's mind. Government had no Plan B. Throughout the period 1982 to heat-treated product for all in 1985, there was not only not enough UK Factor VIII concentrate to meet patients' needs, there was not enough cryoprecipitate. The UK Government's dependence on the US was total.

159. As early as 18 January, Dr Walford had decided that the value of using Factor VIII and Factor IX outweighed the hazards of transmission of AIDS.[172] Thereafter, no action was taken to prepare for a scenario in which that decision turned out to be wrong.

160. By 3 May 1983, the Department had already formulated its proposed "*line to take*". This was that, "*at present, haemophilia experts in this country take the view that to ban the imports of US FVIII would be to place haemophiliacs at greater risk from bleeding than they would be from acquiring AIDS.*"[173]

161. Dr Craske's view was that there was insufficient evidence in May 1983 to support Dr Galbraith's proposal that US Factor VIII be withdrawn from clinical use in the UK.[174]

162. As to reversion to cryoprecipitate, even after the Council of Europe meeting where that was discussed and a step that other European countries were considering, Dr Gunson did not consider such a move feasible in the UK.[175]

163. Dr Walford explained that the Government would have looked at what action was being taken in America where there were more AIDS cases[176] where the FDA and Congress decided against withdrawal of blood products because of concern about the effect on people with haemophilia of immediate curtailment of treatment.

Impact and harm caused by the Society

164. The Society accepts, that it is possible that had it had adopted the more cautious, questioning approach advocated by Dr Pinching in The Bulletin, rather than seeking to reassure members, the health outcome for some patients may have been different. There is much that the Society could say in its mitigation: those matters, some of which have been touched on in this submission, will not be lost on the Inquiry and will be returned to in our oral submissions.

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[172] DHSC0002223_088
[173] DHSC0003824_173/1
[174] WITN4461127/1
[175] Transcript of evidence of Diana Walford to the Infected Blood Inquiry on 21 July 2021, T28: 14-25 & T29: 1-14
[176] Transcript of evidence of Diana Walford to the Infected Blood Inquiry on 20 July 2021, T183: 1-17

165. Clear information that there was a risk of getting AIDS from US Factor VIII, that children and patients with mild haemophilia should not be treated with large-pool concentrates, as per UKHCDO guidelines (whether US or NHS) absent a specific reason, and that severe haemophiliacs should be cautious and consider alternatives or a reduction in treatment with large-pool concentrated Factor VIII would have helped. It would have provided material that parents, for example, could have used to challenge consultants seeking to prescribe Factor VIII concentrate to children for no good reason, and in breach of UKHCDO guidelines.

166. A list of questions to ask your treating doctor may have helped. Questions such as:

a. Knowing what you know, if you were me what would you do?
b. Is cryoprecipitate safer for me with this bleed than a single injection made from large-pool concentrate?
c. If I want cryoprecipitate in future, can you get it for me?
d. When will there be an AIDS free injectable treatment?

167. Publications that empowered patients by emphasising their right to treatment choice, and that listed questions for treating consultants could have helped. Those patients of Dr Chisholm who were unwilling to take up US Factor VIII concentrate for fear of AIDS, for example, might have been emboldened to demand cryoprecipitate and that choice could have been lifesaving.

168. In the September 1983 Haemofact, the Society could have warned members that their centre might be using stocks of US Factor VIII made with higher risk blood and that they should ask questions and ask for post-FDA regulation manufactured treatment.

169. Had the Society sent its members the clear message that the risk of AIDS was real, and information about how to avoid that risk, and minimise such AIDS risk as each patient or parent decided was unavoidable, its members might have taken comfort from knowing that they had taken all the protective steps they could have taken, and may, perhaps, have been relieved of a burden of guilt.

170. The Society has apologised to the community for its shortcomings, and its remorse remains profound, and it will say more about this in oral submissions.

SECTION A3: ADVICE PROVIDED TO THE HAEMOPHILIA SOCIETY

171. This section addresses paragraph 361 in the Inquiry's Amended List of Issues, which is, "*Who provided advice to the Haemophilia Society?*"; "*Was the Haemophilia Society over-reliant on the advice of Professor Bloom?*" and "*Should the Haemophilia Society have sought advice from others and if so, whom?*"

Who provided advice to the Haemophilia Society?

172. The answer to this question is a matter of record and the Society's sources of information are addressed in A1.

Was the Haemophilia Society over-reliant on the advice of Professor Bloom?

173. Evidence shows that clearly the Society was reliant on Professor Bloom. However, the reliance it placed on him was not, or not solely, as an individual clinician, but rather as the Chair of the most authoritative body in the UK in relation to the treatment of people with haemophilia, the UKHCDO.

174. Had there been dissent, or division, in the UKHCDO that the Society was aware of, its reliance on Professor Bloom would have been clearly misplaced. It would then have been misrepresenting to members that his advice was the unanimous view of the UKHCDO when it was not. But the Society was not aware of any difference of view amongst UKHCDO members, and all of the evidence the Inquiry has heard is that the membership spoke as one in relation to the balance of risk and the steps that should, and should not, be taken to minimise risk.

175. The Society and the medical profession held Professor Bloom in high esteem. He was a clinician and a research scientist. He was a member of almost all national committees concerning AIDS. The multiplicity and elevated nature of the national groups to which he contributed, and which relied on his expertise, can only have added to the Society's belief that his views were respected and sought after by civil servants and Ministers. The Society was a very, very small charity and this very eminent figure in the field of haematology and AIDS gave it his time for free. The Society likely considered itself fortunate to have such a friend.

176. That said, there came a time when the Society should have been capable of questioning whether Professor Bloom's advice that there was no conclusive proof that AIDS was transmitted by blood remained accurate, and to think harder about whether it had been right to wait for proof. The fact that it did not do so is evidence of over-reliance, in the sense of reliance that adversely affected the ability of the members of the Executive Committee, individually and collectively, to think calmly and objectively about the more nuanced information available to it. In comparison to Dr Pinching's article, which started from the point that AIDS was probably transmitted by blood, Professor Bloom's advice to the Society and its members was simplistic and inappropriately confident.

177. Professor Bloom recommended individuals for appointment to the Medical Advisory Panel. The Panel was composed of Reference Centre Directors, they rarely disagreed with Professor Bloom's line. Mr Watters accepted that by taking advice from these sources, the Society disabled itself from scrutinising the treatment policies and recommendations of UKHCDO. He agreed that it should have sought a more balanced membership of the Medical Advisory Panel to hear disagreement and dissent, that voices of rising stars such as Dr Mark Winter were not heard, and that the Society was too trusting of the Medical Advisory Panel.[177]

178. There was the additional problem of many Panel members being London based (though Medical Advisory Panel members included eminent specialists from Northern Ireland, Scotland and Sheffield and the Society had strong links with Dr Peter Jones in

[177] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T53-54: 16-25 & 1-7

Newcastle (where the Northern Group held its own conferences). Haemophilia treatment was and is a small world, and there was a clear risk of groupthink.

179. Professor Tuddenham was a Medical Advisory Panel member from 1978-1986. He explained how he and Dr Kernoff were co-directors at the Royal Free Hospital where there were twice weekly multi-disciplinary meetings.[178] When advising the Society, he would have brought to Medical Advisory Panel meetings information from the whole department, including laboratory staff, a psychosocial worker, social worker, nursing and medical staff. Sheila Sherlock was also at the Royal Free Hospital and had established a unit there studying Non-A Non-B Hepatitis. Further, Professor Tuddenham was a Reference Centre Director and therefore attended those meetings, notably that held on 4 February 1983 when AIDS was first discussed (this meeting was also attended by Professor Bloom).

180. Although Mr Watters's concession was rightly made, it is not obvious that the fact that the Medical Advisory Panel members were, or were colleagues of, highly thought of specialists at Reference Centres was a disadvantage when it came to expertise in HIV/AIDS and Hepatitis C. Had there been a cohort of younger haematologists working in smaller centres outside London which held different views in relation to either infection, then exclusion of that perspective and reliance on Professor Bloom and the Medical Advisory Panel would have been a vulnerability. But this was not the case.

181. Though some may have felt histone overly reassuring, (Dr Parapia, for example) there was no Reference Centre Director who disagreed with the advice Professor Bloom gave the Society in May 1983. And no centre director or Reference Centre Director supported even a temporary ban on the use of US Factor VIII, even in 1984.

182. Further, the Society's relationship with the Medical Advisory Panel was not intended to be a one-way street: the Society was entitled to expect that Medical Advisory Panel members would pass information about AIDS and Hepatitis C as they came by it. Professor Tuddenham could have contacted the Society and provided a more balanced view than Professor Bloom's. In contrast to Professor Bloom, by October 1983 he

[178] Transcript of evidence of Professor Tuddenham to the Infected Blood Inquiry, 22 October 2020, T12: 9-14 & T14: 4-16

considered that there was "*very strong circumstantial evidence*" that commercial blood products transmitted AIDS.[179]

183. That said, had the Society approached Professor Tuddenham for advice in 1984, his advice would not have been different to Professor Bloom's. Professor Tuddenham was at the Reference Centre Directors' meeting on 10 September 1984[180] by which time there were 20 AIDS cases in the UK and HTLV-III[181] had been identified: the Reference Centre Directors made no change to the early 1983 treatment recommendation.

184. Moreover, in December 1984, there was a specially convened Reference Centre Directors' meeting[182] at which Dr Kernoff suggested not telling patients about their diagnosis unless they asked to be told.[183] The minutes record a discussion about whether patients should be told of a positive diagnosis. Differing views were expressed and agreement reached that each clinician would decide for each case, *"but in general to provide information if asked for"*. It was then agreed that heat-treated product, "*if freely available*" should be given to positive patients, and that negative patients "*must*" be treated with heat-treated material. Dr Kernoff commented that a 70% of haemophiliacs were positive, therefore telling them or not telling them of their test result "*may be considered irrelevant*". Professor Tuddenham described the decisions made as "*pretty vague*" aa they left the advice given to patients as a matter for the judgment of individual clinicians.[184]

185. In fact, the Chairman's (Professor Bloom's) summary was not quite so vague. He summary of what the meeting had concluded was that informing patients of their test result should not be automatic, and they should only be told if they asked for the result. It does not seem to have occurred to anyone at this meeting that if treatment with heat-treated product was consequent on the test result, and if the patient did not ask for the result and therefore was not told of it, they might also be treated in the absence of their consent.

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[179] Transcript of evidence of Professor Tuddenham to the Infected Blood Inquiry, 22 October 2020, T106: 22-24
[180] HCDO0000416/1
[181] HCDO0000416/8-9, section 8
[182] PRSE0000890/4-5
[183] HCDO0000394_117/5
[184] Transcript of evidence of Professor Tuddenham to the Infected Blood Inquiry, 22 October 2020, T113: 4-6 & T109-110: 6-25 & 1-12

Should the Haemophilia Society have sought advice from others and if so, whom?

186. Sir Brian asked David Watters whether the Society should have appointed an epidemiologist to the Medical Advisory Panel. The Inquiry is asked to find that it was reasonable for the Society not to take that step. It had links with Dr Tedder and Dr Pinching and no member of the Panel ever suggested that there was a gap in expertise.

187. It is noteworthy that when the Reference Centre Directors met on 14 February 1983 and discussed AIDS,[185] they decided to invite an immunologist to join the Hepatitis Working Party which was involved with the AIDS syndrome. As already discussed, The Society obtained and published in the post-Stockholm 1983 Bulletin an article on AIDS from the immunologist Dr Pinching.

188. The Committee on the Safety of Medicines Biologicals Sub-committee did not have an epidemiologist present when, in July 1983, it discussed and decided against Dr Galbraith's recommendation to suspend importation of US Factor VIII.

189. The difficulty was not that epidemiology had in its scientific armoury tools unavailable to haematologists, virologists and immunologists, which, if deployed, would have interpreted the data so as to differentiate between what was coming out of the tap and what was in the pipeline: it did not. The difficulty was that even the highest level, the most eminent national committees with the greatest reach in terms of ability to co-opt top level advice from all necessary scientific and medical disciplines and informed by data from across the world, conflated risk and incidence and failed to foresee the coming epidemic which Dr Evatt correctly predicted in March 1983.

190. Drs Evatt and Galbraith could all see that the number of infections and deaths in the US (and Spain) were just the tip of the iceberg. Dr Foster was one of the few, perhaps the only, UK healthcare professional attending Stockholm who had ears to hear what Dr Evatt was saying. It appears that he felt his primary duty, in attending the Stockholm conference, was to provide information relevant to the safety of ASTMS members, most of whom did not suffer from haemophilia. He was more detached from the storm

[185] HCDO0000411/5

engulfing patients and their doctors, and that objectivity is likely to have been one of the factors that enabled him to hear and understand what attending members of the UKHCDO could not, or, in the case of Professor Bloom, it seems would not.

191. Had the ASTMS shared Dr Foster's Stockholm letters with the Society then it is difficult to believe other than that it would have proceeded differently. It is likely that it would have asked Dr Foster to write for The Bulletin and asked him, and the ASTMS, for permission to publish his letters. It would certainly have asked the Medical Advisory Panel members for their views about Dr Foster's interpretation of Dr Evatt's predictions. And it may have contacted Dr Evatt. The Society was capable of independent thought. It is reasonable to conclude that armed with Dr Foster's clear summary of what Dr Evatt had tried to get across at Stockholm, it would have sought to test the medical consensus instead of accepting it, and taken a more assertive approach in its meetings with Government.

192. The Society came away from the Stockholm conference with the understanding that the US, the UK and no doubt other large countries such as Canada were all approaching the threat of AIDS in the same way. There was no, or at least no obvious, source of a different perspective to whom it could have turned.

SECTION A4: RELATIONSHIP BETWEEN THE HAEMOPHILIA SOCIETY AND THE UKHCDO

193. This section addresses paragraph 362 in the Inquiry's Amended List of Issues, which is, *"What was the relationship (financial and otherwise) between the Haemophilia Society and the haemophilia centres/UKHCDO? What impact did such a relationship have on the Society's actions and decisions?"*

What was the relationship (financial and otherwise) between the Haemophilia Society and the haemophilia centres/UKHCDO?

194. We submit that it is important first to consider the context in which the UKHCDO was established and the wider societal position at the time. Both haemophilia and Von Willebrand's disease were and are rare diseases. Many haematologists have given

evidence to the Inquiry about the fact that the treatment of people with haemophilia formed only a small part of their day to day work. As an inevitable consequence of this, the number of scientists and clinicians specialising in research into, the development of treatment for, and the delivery of treatment for bleeding disorders were few.

195. We do not propose to repeat the evidence the Inquiry has heard as to how and why haemophilia treatment centres were developed, nor why the HDO, later the UKHCDO, were established, but in broad summary these developments arose because of the need to bring together specialists dealing with treatment disorders from across the country to aggregate their endeavours.

196. Therefore once established, throughout the relevant period, the UKHCDO and its predecessor were regarded, not only by the Society but generally, as the definitive source in the United Kingdom for information and guidance about bleeding disorders and their treatment.

197. The Society has had medical advisors, or a "Medical Advisory Panel" since its inception. Most members of the Society's Medical Advisory Panel were members of the UKHCDO.[186] In this section, the Society submits that historically, it relied heavily on the expertise of its Medical Advisory Panel because it did not have the clinical expertise or expertise within its staff or board members. Due to the limited number of specialist haemophilia clinicians in the UK already referenced, the Society's options in respect of obtaining alternative advice and assistance was extremely limited. The key impact this had is that during the 1970s and 1980s, the Society issued statements reassuring its members about the risks of AIDS and indicating that factor treatments were safe (as described further in section A2 of these submissions relating to actions and decisions taken by the Society); and the Society lobbied Government to continue allowing the import of products from the USA (as addressed in section A6 relating to the Society's representations to Government about self-sufficiency). This advice, given to the Society's members, was based on and reflected advice issued at the time by the UKHCDO and by the Government.

[186]WITN6392001/69, paragraph 162; WITN6392268/72, paragraph 162; WITN3429001/103,paragraph 237

198. The UKHCDO was established in 1968 and is *"an association of medical practitioners who work within the Haemophilia Centre's of England, Scotland, Northern Ireland or Wales and have an interest in the care of people with haemophilia or other inherited bleeding disorders*".[187] The Society's Medical Advisory Panel, was an informal panel[188] whose function was to "*provide advice in relation to the clinical aspects of managing and treating haemophilia"* and which *"consisted of clinicians who were national, and in some cases world, experts in all aspects of haemophilia care."*[189] This was a panel of *"leading clinicians in the field whom the Society could turn to whenever necessary to request their opinion and advice in relation to developments in the treatment of haemophilia."*[190] The Medical Advisory Panel were also responsible for dealing with grant applications for research projects.[191] Most members of the Society's Medical Advisory Panel were members of the UKHCDO.[192]

199. To understand how and why the Medical Advisory Panel was established, the Inquiry may wish to refer to the evidence given by former staff and Trustees of the Society.[193] The statement of Kate Burt sets out a number of relevant extracts of evidence.[194]

200. The Society has a long history of drawing on advice from varied disciplines,[195] including through the publication of articles by authors from multidisciplinary backgrounds in its historical publication, *The Bulletin*.[196] As the Society did not have the expertise or resources to review scientific journals and papers it relied heavily on the expertise of its Medical Advisory Panel.[197] The Society sought information and answers to members' questions from clinicians and scientists who were experts in their fields.[198] Many fitting that description were members of the UKHCDO.[199] This relationship is illustrated well the witness statement of David Watters (who was employed by The Society between 1981 and 1994):

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[187] http://www.ukhcdo.org/about-us/
[188] WITN3429001/13, paragraph 34
[189] WITN4500001/11, paragraph 61
[190] WITN3429001/13, paragraph 32
[191] WITN6392001/82, paragraph 196
[192] WITN6392001/69, paragraph 162; WITN6392268/72, paragraph 162; WITN3429001/103,paragraph 237
[193] WITN3429001/13, paragraph 34; WITN3912001/6, paragraph 14; WITN6392001/73-74, paragraphs 175 to 177
[194] WITN6392001/73-74, paragraphs 175 to 178
[195] WITN6392001/78, paragraphs 185 to 195
[196] WITN6392001/78-79, paragraph 185
[197] WITN4500001/11, paragraph 61
[198] WITN6392001/69, paragraph 162
[199] WITN6392001/69, paragraph 162

"... At a time when the scientific world was confronted with a new virus, and there were so many unknowns, The Society had little option but to rely on the members of its Medical Advisory Panel. A number of the members of the Medical Advisory Panel were also members of the UKHCDO. Therefore, they were not only discussing issues at Medical Advisory Panel conferences or meetings, they were also discussing things in the context of the UKHCDO. In the event that members of the Medical Advisory Panel became aware of a development, I anticipate that they would discuss those matters amongst themselves outside the Medical Advisory Panel meetings. However, I cannot be certain. That was just the sense I got."[200]

201. Before 1991, the Medical Advisory Panel was consulted by the Society on an *"ad hoc basis"*[201] and it was not until the recommendations of a review by the Society of the Medical Advisory Panel were implemented that the Medical Advisory Panel became a more formal part of the structure of the Society.[202] A report prepared by David Watters dated 7 November 1991 describes that the size of the Medical Advisory Panel varied throughout the years and consisted, *"to some extent at least, of "favoured" Reference Directors plus, more recently [to 7 November 1991], other Centre Directors."*[203] The same report noted that the *"problems with the present position were identified as the size of the Panel; the lack of terms of reference; the inability of the Panel members to adjust to an advisory role; the inability of the Society to capitalise on the valuable resource available to it"*. One of the proposed Terms of Reference set out the shift to a personal advisory role that the Society wished for members of the Medical Advisory Panel to have, as distinct from their role as members of the UKHCDO, *"Members of the Medical Advisory Panel are expected to give the Executive Committee of The Society their best personal and unbiased opinion as distinct from reporting the policy of the Haemophilia Centre Directors' Organisation or any other body with which members of the MAP are singularly or collectively associated."*[204]

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[200] WITN3429001/103 paragraph 237
[201] WITN4500001/11, paragraph 59; Transcript of the Inquiry Presentation on Professor Bloom and the Cardiff Haemophilia Centre, 8 October 2020 T34:13 – T35: 4
[202] WITN4500001/11, paragraph 59; WITN3429001/14, paragraph 36
[203] HSOC0010470/1
[204] HSOC0010470/1

202. The Inquiry has heard evidence from David Watters that *"[t]he relationship between the Society and the UKHCDO was, on the whole, respectful and cooperative… There was regular contact between the Society and the UKHCDO, there was an ease of contact and an appreciation of each other's roles"*.[205] There is no evidence that the relationship became too close, indeed with the benefit of hindsight it has become apparent that the UKHCDO could have been more open with the Society at the time, but at that time there was no reason for the Society to think that they were not passing on all the information that they had.

203. As noted above, the relationship between the Society and the Medical Advisory Panel was not without its frustrations. David Watters paints the following picture:

"My view of the UKHCDO however, was that it was very secretive. It published its annual statistics, which we always received, but of course they were virtually always incomplete because Geoff Savidge (St Thomas's Haemophilia Centre) would not contribute towards them. It was therefore always very difficult to rely on any statistics from the UKHCDO as we were aware that they were incomplete and lacked information from one of the biggest Centres in the UK. I believe that the UKHCDO could have worked more closely with The Haemophilia Society. Possibly, the fact that we had to have our own Medical Advisory Panel speaks to the fact that the relationship between The Society and the UKHCDO was not perfect and we needed this additional support".[206]

204. An exhibit to the statement of Kate Burt sets out the membership of the Medical Advisory Panel in the 1980s.[207] Kate Burt's statement refers to a selection of documents which relate to appointments to the Medical Advisory Panel;[208] and sets out evidence given by former staff of the Society about selection of members of the panel.[209] The composition of the panels throughout the years are also set out in the Society's Annual Reports.[210]

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[205] WITN3429001/32, paragraph 72
[206] WITN3429001/104, paragraph 238
[207] WITN6392164B.
[208] WITN6392001/76-78, paragraph 183
[209] WITN6392001/75-76, paragraphs 179 to 182
[210] WITN6392009 to WITN6392058 and WITN6392143

205. Members of the Medical Advisory Panel were also at times, appointed as members of the Society's committees and/or went on to be appointed as trustees. For example, Minutes of the meeting of the Council of the Haemophilia Society on 24 November 1991[211] record at page 3 that Brian Colvin had accepted an invitation to join the Policy Committee; and that Mark Winter had joined the Members Services Committee. Both Brian Colvin and Mark Winter were members of the UKHCDO.

206. Notwithstanding the heavy presence of UKHCDO members on the Medical Advisory Panel, this did not give rise to any financial relationship between the Society and the UKHCDO. These were voluntary roles, and the only payment that would have been made to members of the Panel would be the reimbursement of expenses for travel where they had been necessarily incurred in connection with the role.

207. The Society did attend a number of meetings of the UKHCDO, although it is apparent that it was not invited to each and every discussion. The first documented reference of the Society seeking to attend UKHDCO meetings is recorded in the minutes of the meeting of Council of The Haemophilia Society on 25 November 1972 which states that, *"[a]t Dr Kuttner's suggestion the Council agreed that a request be made to Dr Biggs for the Society to be allowed to send one or two observers to any future Centre Directors' meetings."*[212]

208. No historical documents have been identified as to the purpose of the Society's attendance at the UKHCDO meetings. However, in her witness statements, Kate Burt sets out some of the reasons as to why the Society attends UKHCDO meetings today, which include, *"to understand the current issues and thought processes of the UKHCDO; how the centres operate; and what is on their agendas."*.[213] It is reasonable to assume, we submit, that this was also the original purpose of attendance.

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[211] WITN6392180/3
[212] WITN6392186/4
[213] WITN6392001/86, paragraph 206

What impact did such a relationship have on the Society's actions and decisions?

209. The Inquiry has heard evidence in respect of how the Society sought the Medical Advisory Panel's advice and relayed such advice and information to its members.[214] In her first statement to the Inquiry, Kate Burt addresses the topic of the Society's engagement with clinicians, and sets out a number of historical documents which may assist the Inquiry in relation to ascertaining the role the Society played in providing medical advice to its members. [215]

210. The Society acknowledges that some of its members are angry and disappointed by actions taken by the Society in the past in relation to medical advice that it published to its members. The Society always made it clear to members that anybody using treatment made from human blood was at risk of being infected with hepatitis. However, in 1983, 1984 and 1985, even as evidence to the contrary was growing, it did provide information to its members that the risk of getting AIDS from Factor VIII concentrate was "tiny",[216] and that any form of haemophilia was more dangerous than AIDS. The information the Society gave its members was based on guidance from the UKHCDO.

211. Peter Wetherell (who was the Local Chairman of the Cambridge branch of the Society in 1981 and an Executive Committee Member of the Society from 1983 to 1990) gave evidence to the Inquiry that the *"judgement of the Executive Committee was informed by the advice of the* Medical *Advisory Panel at all times."*[217] Similarly, David Watters said, "... *I cannot recall any instances where the Society relied on its own judgement when deciding whether or not to formulate a policy on the basis of the Medical Advisory Panel's advice; or when the Society did not follow the Medical Advisory Panel's advice; or when members of the Medical Advisory Panel disagreed with the advice of the Chair of the Panel; or when the Society did not follow the advice of the Chair of the Medical Advisory Panel. As far as I recall, the situations simply did not happen. As*

[214] WITN6392001, section 3; see also Transcript of evidence of Professor Christopher Ludlam to the Infected Blood Inquiry, 3 December 2020, T80: 2-25
[215] WITN6392001/69-87, see Section 3: Relationship with clinicians
[216] CBLA0000004_024/1; PRSE0004474/2
[217] WITN3912001/6, paragraph 18

stated at paragraph 35 above, the opinion of the Executive Committee in 1982 was that the Society would ignore the advice of the Medical Advisory Panel "at [its] peril".[218]

212. Simon Taylor (who was an Executive Committee Member/Trustee of the Society from 1998 to 2002) gave evidence about the context in which the Society relied on advice from the Medical Advisory Panel:

"I would like to bring to the Inquiry's attention a range of matters that provide a deeper context to how the Haemophilia Society acted over the period I was involved with its work.

The Society was always a very small charity, with limited income and resources. It was not until the appointment of David Watters in about 1980, that the Society had any full time staff.

The level of funding was severely limited, and was mostly in the form of community fundraising, such as raffles, indeed I believe that for a time the Christmas Raffle was the largest single source of income, local events, individual fundraising efforts etc. This changed somewhat as the impact of the HIV epidemic amongst the haemophilia community grew and government grants, grants from charitable trusts and commercial donations became available.

At no time was the Society in a position to pay for its own scientific and medical expertise, and so at all times it had to take on trust, the advice given to it by clinicians and scientists within the haemophilia community. The Trustees were all lay individuals in this connection.

The Society had to make policy, and take decisions, based on the medical and scientific advice available to it as a group of lay individuals. As is frequently the case

[218] WITN3429001/23, paragraph 52

with emerging threats, this advice was frequently confusing, conflicting, incomplete and with hindsight, some of it was incorrect.[219]

213. Again, for context, it should be remembered that the vast majority of the Society's Board members would have either had a bleeding disorder of their own, or a family member so affected, and so they would have brought to their discussions their own experience of dealing with the medical profession. This would have provided another sense check that advice being received was not out of step with wider views in the UK at the time.

214. It is also established that the Society had a good relationship with the World Haemophilia Society and with other similar organisations around the world. Had different information or advice been emanating from those organisations, then that would have informed challenges from the Board to any conflicting advice from the Medical Advisory Panel, informed by the UKHCDO. That this did not occur demonstrates that the advice the Society received and adopted reflected the wider position at the time, not just a UKHCDO centric view. The Society regarded its responsibility as being to keep its members updated as to current thinking on the issue of interest to them.

215. In January 1983, Dr Peter Kernoff published an article in the Society's publication, The Bulletin, which stated that the links between AIDS and concentrate therapy for haemophilia were *"very tenuous"*.[220] Dr Kernoff was at this time a consultant haematologist at the Royal Free Hospital in London, a member of the UKHCDO and became a member of the Society's Medical Advisory Panel in 1988.

216. In May 1983, in response to particular stories about AIDS in the media, the Society issued to its members a letter composed by leading haemophilia clinician, Professor Bloom. Professor Bloom, who was chairman of the UKHCDO at the time, a senior member of the Society's Medical Advisory Panel and a member of the Central Blood Laboratories Authority, was contacted by the Society[221] and provided a letter that

[219] WITN4500001/67, paragraphs 335 to 339
[220] PRSE0004120/12
[221] Transcript of evidence of Chris Ludlam, 3 December 2020, T80: 3–21

offered reassurance about the level of any risk posed by AIDS, and asserted that it would be counter-productive to alter treatment programmes radically. His letter stated that the number of AIDS cases reported in American haemophiliacs was small and it was not aware of any proven case of AIDS in the UKs haemophilic community nor were there any cases reported from Germany where "*massive amounts of American concentrates*" had been used for "*many years*". The Society published this document of 4 May 1983 to its members reassuring patients that the new factor treatments were safe and to continue using them. [222] This document reproduced the advice of Professor Bloom, who was considered an authoritative expert by the Society (and the Government and others),[223] at the time and whose recommendation appears to have been shared by all other clinicians who have provided evidence to the Inquiry.[224]

217. Similarly, a Society publication, 'Haemofact' dated 22 September 1983 reinforced this message, stating, *"The advantages of treatment far outweigh any possible risk. Balance the risks for yourself, but we would state again that the risk of AIDS is tiny compared to the risks from uncreated bleeding episodes."*[225] This advice, which was mirrored in an article published in the Guardian in the same month[226] was a continuation of the same policy, as provided by the UKHCDO.[227] Peter Wetherell (who was the Local Chairman of the Cambridge branch of the Society in 1981 and an Executive Committee Member of the Society from 1983 to 1990), gave evidence that, *"There had been no, as I recall, any reason to revise the policy at that stage. I mean, we didn't know the circumstances, I say, of this individual in Bristol. We didn't know the circumstances of the individual in Cardiff, other than that they were haemophiliacs. And of course, there was also, I think, in the back of our minds, a feeling that it may not have been the mere fact that it been a haemophiliac…"* [228]

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[222] HSOC0003360
[223] Transcript of Inquiry Presentation on Professor Bloom and Cardiff Haemophilia Centre, 8 October 2020, T37: 2-10; See also press release from the Department of Health and Social Services dated 20 February 1985 which notes they have set up an Expert Advisory Group. Professor Bloom being listed as one of those experts, WITN4461005
[224] See for example, Transcript of evidence of Dr David Bevan to the Infected Blood Inquiry, 12 January 2021, T96: 16 – T97: 23; Transcript of evidence of Francis Eric Preston to the Infected Blood Inquiry, 2 November 2020, T47: 23 – T75: 1-5; WITN4106001/23, paragraph 50; WITN0841038/36-38, paragraphs g – h and WITN0841007/39, paragraph 1; WITN3456002/94-5, paragraphs 277 to 279
[225] CBLA0000004_024/1; PRSE0004474/2
[226] PRSE0004533
[227] Transcript of evidence of Peter Claude Wetherell to the Infected Blood Inquiry, 25 May 2021, T40: 20 -T41: 9
[228] Transcript of evidence of Peter Claude Wetherell to the Infected Blood Inquiry, 25 May 2021, T40: 20 -T41: 9

218. On 13 May 1983, there was a special meeting of the UKHCDO at St Thomas's Hospital, chaired by Professor Bloom. This was arranged specifically to discuss recent publicity about AIDS and the consequent *"considerable anxiety to haemophiliacs and their medical attendants as well as to the Department of Health"*. It was agreed that there was insufficient information available from the US experience to warrant changing the type of concentrate used in any particular patient and there was insufficient evidence to warrant restriction of the use of imported concentrates in view of the immense benefits of therapy.[229] Four days later, on 17 May 1983, Professor Bloom wrote to Dr Diana Walford about this meeting raising an outstanding point about the possibility of high-risk American Factor VIII being imported to the UK and concerns of the possibility that stocks held will be preferentially exported.[230] There is no evidence that Professor Bloom relayed these concerns to the Society. On the same day, the Society wrote to an official at the Department of Health and Social Services recording its wish to meet a minister as soon as possible after the election, with one of their concerns being, *"No ban on the importation of American concentrates meantime"*.[231]

219. In 1984, the Society's publication, The Bulletin (Edition 32, Number 1), published an article by K.E. Milne which stated, "*We have no evidence as yet [as] to whether AIDS may be acquired more readily from commercial Factor VIII than from the NHS product but, of course, if AIDS becomes established in the UK then NHS blood and plasma supplies are just as likely to transmit AIDS as commercial concentrates. All things considered, haemophiliacs have no reason to be worried about using commercial concentrates."*[232] K.E. Milne became Vice Chair of the Society's Executive Committee later that year and held this position until June 1993.

220. As the Inquiry has heard, on the issue of whether people with haemophilia should have continued to take Factor VIII imported from the US when AIDS was first heard of, the UKHCDO spoke with one voice.[233] Dr David Bevan illustrated this point and provides reasons for why this was the position:

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[229] HCDO0000003_008/2
[230] WITN4461128
[231] PRSE0003827
[232] PRSE0002925/2
[233] Transcript of evidence of Dr David Bevan to the Infected Blood Inquiry, 12 January 2021, T67: 21-24

"... I don't know whether there were any real dissenting voices at UKHCDO. There may have been warning voices but I don't think anybody actually dissented from the general view. Of course, this was informed by the structure of medical negligence thinking at the time, which was based on the Bolam test. So, by and large, I don't have to tell you about the Bolam test, but if you were following the advice of an authoritative group of clinicians in exactly the same field, if you're following their advice to the letter, essentially, it was very difficult to convict anyone of negligence. Whereas, if you had gone off, away from their advice, you would have become vulnerable to claims of negligence. So if anything happened, if anything bad happened as a result of switching people off their concentrate then you would be in open view, sort of thing..."[234]

221. The above reflected the position in which the Society found itself. Dr Bevan gave evidence about the approach of UKHCDO and the generation of haematologists that dominated UKHCDO in the 1970s and early 1980s:

"The AIDS epidemic was a turning point that utterly transformed medical practice in ways analogous to the effect of a World War. The decisions and policies of the generation of haematologists that dominated the UKHCDO and haemophilia treatment in the UK up to this point -- pre-AIDS -- were conditioned by the long period when haemophilia treatment was of limited availability and effectiveness.

Their attitude and reactions were dominated by determination never to withhold treatment and never to run short -- let alone out -- of treatment. This unwillingness to countenance the loss of effective treatment was shared by the Haemophilia Society.

The UKHCDO also took a position in many ways typical of British public health governance: Not to risk over-reaction, not to act prematurely, not to alarm the public, 'the evidence is not yet conclusive', 'we don't yet have proof' -- responses still evident during the early phase of the current Covid-19 pandemic...

It is also true that the FVIII companies 'pulled the wool' over the eyes of medical opinion-leaders at the time...

[234] Transcript of evidence of Dr David Bevan to the Infected Blood Inquiry, 12 January 2021, T67: 21 – T68: 12

However, taking all these things into account, the UKHCDO continued to hold the line, well into 1983, that the evidence of an infectious cause of AIDS was inconclusive, and that action would be premature, long after that position became obviously untenable. However, by then the scale of HIV infection in people with bleeding disorders in the UK was fully established."[235]

222. On 27 March 2017, the Board of Trustees issued a statement on behalf of the Society in which the Society accepted that its actions and statements at the time, while well intentioned and based on the prevailing views of experts at the time, had been shown to be damaging to the community and incorrect. For this, the Society apologised unreservedly.[236] In its statement the Society wrote:

"We want a full public inquiry under the inquiries act as only this could compel witnesses and would shed light on concerns such as:

- *the inappropriate use of known infected treatments on previously untreated patients*
- *why and how British self-sufficiency in blood products was never achieved*
- *why tests to identify infected blood donations were not implemented sooner*
- *when and to what extent the UKHCDO, the Haemophilia Society, the Department of Health and the NHS held and were aware of information on risks and tests for infection with blood borne viruses*
- *why potential methods to heat treat blood products were not fully investigated and implemented sooner*

To facilitate this we want a full and open disclosure of all information held by the Government, or elsewhere, relating to the sourcing, manufacture, procurement, licensing and NHS treatment with contaminated blood and blood products. However, an inquiry must not distract from or delay the implementation of an improved support scheme."

[235] Transcript of evidence of Dr David Bevan to the Infected Blood Inquiry, 12 January 2021, T96: 16 – T97: 23; WITN4106001/23, paragraph 50
[236] WITN6392158/4

223. The Society wishes to refer to and acknowledge the powerful concluding comments that David Watters made in his statement:

"... I have often reflected on the events that happened over 30 years ago, and it is very easy to stand back and think, "oh, you got that one wrong!". Maybe we did, but we could only act on the information that we were being provided with at the time. Whilst we were aware that some clinicians had put all of their patients onto heat-treated factor quite early on, the advice that we were receiving overall from the Medical Advisory Panel was that this was not necessary. I have no recollection of any of the members of the Medical Advisory Panel raising concerns with the advice that the Society was providing."[237]

224. It is worth noting that there is evidence that the Society did not in fact always follow advice given by the Medical Advisory Panel. Minutes of a meeting of the Executive Committee held on 29 July 1993 record at page 6 under the heading "High Purity Blood Products" record as follows:

"Mr Barker reported that the Centre Directors Regional Committee had recommended that HIV positive patients should receive high purity blood products but had made no distinction between monoclonal products and those produced by ion exchange chromatography. There was increasing evidence that it was only the monoclonal products that had a beneficial impact on patients' CD4 cells. In England the new Alpha product was made from an ion exchange process and was cheaper than the monoclonal products. In Scotland and Northern Ireland the main product available was produced from an ion exchange process.

The issue had been discussed at the meeting of Committee B on 15 July 1993 The Committee had felt that the evidence of beneficial effects on the CD4 counts of HIV positive patients with haemophilia should be offered monoclonal products was very strong, but that there was no similar evidence for ion exchange products. Therefore, the Committee recommended that the Society's policy should be that all HIV positive

[237] WITN3429001/104 , paragraph 240

patients with haemophilia should be offered monoclonal products and that this policy should be actively promoted, even if it did not have the full backing of the Medical Advisory Panel.

There was a brief discussion and the Committee endorses Committee B's recommendation. It was further agreed that the decision be presented to MAP and the Panel's advice sought."[238]

225. The Society also wishes to note a letter dated 27 September 2006 from Dr CRM Hay (Chairman of the UKHCDO) to Margaret Unwin (who was Chief Executive of the Society at the time)[239] which illustrates that in circumstances where the views of the Society and the UKHCDO did not align, the Society has not always followed the UKHCDO. The letter was sent in response to the Society's request for the UKHCDO to comment on the Department of Health's report entitled, "Self sufficiency in blood products in England and Wales – A Chronology from 1973 – 1991". In the letter, Dr Hay states the UKHCDO's *"collective view that a public enquiry [sic] into this matter is not in the patients' best interests and is likely to harm rather than enhance patient care"*. Despite the UKHCDO's views to the contrary, the Society continued its campaign for a public inquiry well beyond this date.

SECTION A5: RELATIONSHIP BETWEEN THE HAEMOPHILIA SOCIETY AND PHARMACEUTICAL COMPANIES

226. This section addresses paragraph 363 in the Inquiry's Amended List of Issues, which is, *"What was the* relationship *(financial and otherwise) between the Haemophilia Society and the pharmaceutical companies manufacturing/supplying blood products? What impact did such a relationship have on the Society's actions and decisions?"*.

[238] WITN6392096/6
[239] HSOC0001265

Nature of The Society's relationship with pharmaceutical companies

227. Over the years, the Society has maintained relationships with pharmaceutical companies, which have funded and shared knowledge with the Society. The Society submits that its relationships with pharmaceutical companies have had minimal impact on its actions and decisions. Documents disclosed to the Inquiry demonstrate that the Society was careful to ensure that no product or company was favoured in publications to its members; and funding received was and is publicly documented in the Society's annual report, Executive Committee minutes and documents prepared for this Inquiry.

228. The benefits of maintaining links with pharmaceutical companies are addressed in the first statement of the Society's Chief Executive, Kate Burt.[240] Having links with pharmaceutical companies has benefitted the Society through:

a. Understanding what assets companies have in development;
b. Having a direct line of communication with companies; meaning that the Society could inform the community about any product issues (for example, if there were a problem or batch withdrawal or issue that arose from products);
c. Having an input into development of assets and materials for patients; if companies were looking to develop patient materials, the Society's involvement could give a better patient perspective; and
d. Having an input into what would improve the quality of products.

229. In her first witness statement, Kate Burt notes that the Armourpagers project *"is a good example of the Society working together with a pharmaceutical company and this working well"*.[241] The use of pagers was of enormous value to the community. At that time there were no mobile telephones, and landline telephones were not available to every household and were often shared. When considering events and developments today, the societal context of the time should not be forgotten.

[240] WITN6392001/100-101, paragraphs 240 to 243
[241] WITN6392001/93-98, paragraphs 223 to 231

230. Currently, pharmaceutical companies are occasionally invited to attend the Society's events, such as member conferences. This is because they often produce useful patient facing material. Kate Burt makes this point her first statement to the Inquiry.[242] It is also beneficial for pharmaceutical companies to hear the views of patients.

231. One issue raised in evidence before this Inquiry has been the Society's relationship with Christopher Bishop (who has held a number of senior roles for Armour UK).[243] On 4 November 2021, Mr Bishop gave evidence about his relationship with the Society as a representative of Armour, including about meetings he had with the Society. He said that, *"in general, [Armour] would have kept the Haemophilia Society appraised of scientific developments"*.[244] This is consistent with a reference in the Society's January 1988 issue of The Bulletin, in which there is an article about the Society's Blood Products working party in which Mr Bishop (amongst other representatives of pharmaceutical companies, including Alpha and Cutter), were described as *"good friends of the Society for a long time"* who *"have been helpful"* to the Society. [245] Of course, the extent to which information was fully shared with the Society was within the gift of the company. The relationship therefore relied on elements of trust, and it was difficult at the time for the Society to assess the extent to which that trust was met Indeed, Mr Bishop gave evidence that he did not recall having alerted the Society, in 1985 or 1986, to the possibility that Armour's heat-treatment procedures might be ineffective.[246] This illustrates the reliance that was placed by the Society on information provided by Armour and information that it was told by pharmaceutical companies.

232. Mr Bishop said that in the second half of the 1970s to the first half of the 1980s, he had interactions with the Society *"perhaps once a month or every couple of months"* and that he would have met up with the Society's General Secretary at the time, David Watters.[247] Mr Bishop gave evidence that, broadly speaking, the purpose of those meetings was, "*to discuss the current issues, and perhaps discuss the format of their -*

[242] WITN6392001/93-93, paragraphs 221 to 222
[243] Including as Products and Marketing Manager (1973-79), Sales & Marketing Manager (1979-81), Biologicals Division Manager (1981-87) and Managing Director (1987-1993))
[244] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T16: 25 – T17: 2
[245] HCDO0000279_019/5
[246] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T40: 17–20; T175: 25 – T176: 25
[247] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T39: 16–25

- or the arrangements for their Haemophilia Society meetings, and ways which we could support them in that".[248]

233. The General Secretary's report dated November 1989 prepared by David Watters refers to time spent discussing various issues with Armour Pharmaceutical, *"Members of the Executive Committee will realise that Armour are very much about the business of improving their public image in the UK prior to obtaining a full product licence for Monoclate. I have spent more than a little time with them discussing issues - and extracting money – eg. I understand that they are willing to grant GBP 10,000 for publications costs; that they are keen to meet travel costs to lobby the US Congress; that they are looking into funding the 1990 Executive Conference; and so on. However, this is time consuming and reminds one of the 'there's no such thing a free lunch' maxim!!"* David Watters was asked in his evidence before the Inquiry about his reference to there being "no such thing as a free lunch" and whether he was conscious that there was something that Armour wanted out of the Society. He responded, *" Not really. I was just thinking that I had to work jolly hard during meetings with the companies to present the needs of the Haemophilia Society to them."*[249] It is submitted that this is an accurate description of the relationship.

234. In his statement dated 22 April 2021, Simon Taylor (who was an Executive Committee Member and Trustee of the Society from 1998 to 2002) gave evidence of the benefits of the Society having relationships with pharmaceutical companies:

"There were two primary benefits of having a relationship with both BPL and the pharmaceutical companies. One benefit was the ability to gain an understanding of their products and processes, which was valuable as the Society sought to build its own knowledge and understanding of product safety and innovations. The other was financial, as outlined above, in that they were able to make contributions to events for our members that might not otherwise have been possible."[250]

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[248] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T40: 1–6
[249] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T41: 24 – T42: 5
[250] WITN4500001/27, paragraph 126

235. The Society was careful to ensure that no product or company was favoured in its publications to its members. In her witness statement dated 7 April 2021, Lucy McGrath (who was a hepatitis worker at the Society between 1997 and January/February 2001; and carried out administrative and project work between autumn 2001 to approximately July 2002) confirmed that representatives of pharmaceutical companies had no role in proposing and/or editing and/or selecting material for the Society's publications:

"I recall that pharmaceutical firms supported the Haemophilia Society's work financially, but from memory, firms had no input in terms of proposing and/or editing and/or selecting any material for the publications with which I was involved."[251]

236. Examples of the Society's members receiving benefits from pharmaceutical companies are set out at paragraph 243 of Kate Burt's first witness statement to the Inquiry.[252]

Funding from pharmaceutical companies

237. At present, the Society receives funding from a range of organisations and members of the haemophilia community, including through fundraising by members and volunteers; grant and trust income; corporate income; and legacy income. Like many charities working in the healthcare sector, including haemophilia societies across the UK and Europe and the EHC and WFH, a proportion of that funding comes from pharmaceutical companies. This funding helps support projects such as the Newly Diagnosed Weekends, Talking Red, and Youth Ambassador projects.[253]

238. Without this funding, it would be impossible for the Society to run many of these programmes which provide members with essential support. The Society understands that many people within its community are concerned by any link to pharmaceutical

[251] WITN5428001/10, paragraph 35
[252] WITN6392001/101, paragraph 243; WITN6392210; WITN6392211/3; WITN6392212; WITN6392213/3 and WITN6392214/6
[253] WITN6392001/91, paragraph 212

companies, which is why it is very important to The Society that its sources of funding are made clear.[254]

239. The Society has prepared a document for the purpose of this Inquiry which sets out in as much detail as possible, based on information available, funding received by the Society from pharmaceutical companies from 1970 to 2000.[255] The figures in this spreadsheet have been drawn from the Society's Annual Reports, Financial accounts, Bulletins and Minutes of Meetings. The Society's employees have done their best to prepare an accurate record; but the Society acknowledges that there are inevitably gaps. The gaps in the records arise because of the way that financial records have been recorded has changed over time; and the Society does not have full financial records dating back to the 1970s.[256]

Regulation of funding received from pharmaceutical companies

240. There are strict guidelines relating to donations from pharmaceutical companies to health organisations. Companies must respect the independence of the project and organisation to which they have donated and are not allowed to influence any of its written material.[257]

241. The Society decides which projects it wants to deliver, based on feedback from members and then approaches companies that it feels are best placed to offer financial support to those projects. Often, more than one company will contribute towards a project. At all times the Society maintains its independence. A funding company cannot dictate how a project is run or have any input in its content or outcome; although the Society can and does engage in collaborative partnership agreements, it always retains final sign off and control of what is produced.[258]

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[254] WITN6392001/91, paragraph 213
[255] WITN6392196
[256] WITN6392001/90-91, paragraph 211
[257] WITN6392001/91, paragraph 214
[258] WITN6392001/91, paragraph 215

242. As per clause 27 of the 2019 Code of Practice for the Pharmaceutical Industry published by the Prescription Medicines Code of Practice Authority ("PMCPA"), established by the Association of the British Pharmaceutical Industry ("ABPI") ("2019 ABPI code"), all pharmaceutical companies must declare their sponsorship of "patient organisations", which is how the Society is classed under the code. It must be made clear which company is supporting each programme. The details of funding by individual project can be found on the individual company websites as per clause 27.7. This must be published once a year, although some companies produce this information twice a year.[259] All details of donations are disclosed on the ABPI website and are publicly available. The Society is required to publish details of any publications or event funded by a company and who this is. This has been practice for many years as seen in various Bulletins.

243. Other Haemophilia Societies in the UK also receive donations from pharmaceutical companies. This Inquiry has heard that other societies have contacted various pharmaceutical companies asking for contributions towards events. Donations received by any charity from pharmaceutical companies would need to have been made under contracts in line with the Code of Practice issued by the ABPI. Wherever possible, the Society endeavours to have projects funded jointly to avoid suggestions of bias. In addition, trustees of all charities have a duty to demonstrate to the Charity Commission that they have acted with reasonable care and skill in the best interests of the charity when choosing to accept or reject a donation. The Institute of Fundraising also sets out some good practice guidelines on the acceptance or refusal of donations. Trustees have a duty to act in the best interests of the charity and the Society has always, and continues to, rely on donations to ensure that it can continue with its work.[260]

244. The European Haemophilia Consortium ("EHC") also receives donations from pharmaceutical companies. The EHC's 2002 Annual Report[261] notes at page 8 that the following companies had supported the EHC's work in the form of core funding or by sponsoring the EHC's members' conference: Biotest Pharma GMBH; Baxter Hyland

[259] WITN6392001/91, paragraph 216
[260] WITN6392001/92, paragraph 217
[261] WITN6392197/8

Immuno; Bayer; Shanghai RAAS; Alpha Therapeutic; and Octapharma AB.[262] The Inquiry will also note that other bodies, including NHS bodies, rely on pharmaceutical money to develop resources of benefit to those in the bleeding disorder community.

245. Individual trustees of the Society may also receive funding from pharmaceutical companies, for example to attend an event or conference or in the form of a research grant. These payments are declared at the start of every board meeting. The Society may receive funding for staff to attend relevant conferences and events, both in the UK and beyond, where it can be shown that the Society and its members will derive demonstrable benefit from the knowledge gained.[263]

246. In his statement dated 22 April 2021, Simon Taylor provides the following evidence about the extent of the Society's reliance on financial contributions from pharmaceutical companies manufacturing and/or supplying blood products:

"Funding from pharmaceutical companies of patient groups was common at the time across a wide range of health conditions, many health based charities received funding of this kind. More recently restrictions have been placed on such funding by the Association of the British Pharmaceutical Industry (ABPI), but during the 1980s and 1990s this was considered normal practice.

My view of the blood product companies, which I believe was shared by the Society generally, was one of wary cynicism. We were only too aware that it had been largely their products, and their plasma collection practices, that had caused the infected blood epidemic amongst the haemophilia community. As a consequence, we did not trust them, however we felt little compunction in seeking money from them to help respond to the problems that they had in large caused.

[262] WITN6392001/92, paragraph 218
[263] WITN6392001/92, paragraph 219

Before the HIV epidemic the Society's main sources of income was community fundraising including: the Christmas raffle; an annual Ball; fundraising by local groups; individual fundraising by members etc. As the scale of impact on the Society's work in supporting the community grew, a considerable amount of money was received from the Government in the form of 'Section 64' grants. In addition, a number of pharmaceutical companies provided, on request, contributions to activities and events, however I do not believe that the total of pharmaceutical company contributions ever became a significant proportion of the Society's funding.

The normal procedure as I recall, was that the Society would decide to hold an event, such as a members' conference or an information day, and then approach the pharmaceutical companies to see if they would make a contribution to the cost. I do not recall any examples of the companies approaching the Society with a request to undertake any activity in return for financial support.

I do not recall in detail all activities that companies gave contributions to, they were in main member events as outlined above or participation in WFH or EHC meetings. A number of companies made financial contributions to publications such as The Bulletin." [264]

247. In his statement dated 18 February 2021,[265] David Watters explained the value of financial contributions to the Society and the mechanisms that were in place to ensure transparency:

"Financial contributions were invaluable to the Society in meeting its income objectives. There was an even-handed application process made to each of those companies and to a huge number of charitable trusts. Every year applications would be made to these organisations and an equal opportunity was provided to all to respond as they felt fit, there were certainly no benefits deriving from it. Any funding

[264] WITN4500001/25-26, paragraphs 116 to 120
[265] WITN3429001/89-90, paragraphs 196 to 197

received would be acknowledged within publications. As a charity we were under an obligation to do everything we could to fund the work and not refuse any donations. We were also required, as a charity, to publish the names of those who supported the work.

As stated in the letter provided by Thompsons to the Penrose Inquiry, dated 9 November 2011 [WITN3429029/PRSE0003528] the Society's approach to funding changed considerably during the 1980s and, as the Society employed more staff, its ability to raise more funds increased, which resulted in the pharmaceutical companies also increasing their donations. The letter also explains that "any donation made would have no influence over the conduct of the Society, its attitudes or its communications with its membership. The pharmaceutical companies who were prepared to donate sums to the Society were prepared to do so not in return for promotion of their products."

248. Funding received from pharmaceutical companies by the Society is also recorded in Minutes of Executive Committee meetings, which the Inquiry has had access to. In her first written statement, Kate Burt sets out a selection of documents which record discussions about funding received from pharmaceutical companies. Some entries that are referenced also note caution with respect to the funding and any associated perceived or actual influence on the Society. Relevant documents include:

a. Minutes of the Executive Committee meeting on 4 February 1993,[266] which records discussion about funding from BPL and Porton Products.
b. Minutes of the Executive Committee meeting on 25 March 1993,[267] which records the Society's position regarding assigned sponsorship by Armour Pharmaceuticals, BPL, Porton Products and Octapharma. There is also potential funding indicated to be available from Alpha UK and Immuno. This minute also records that funding had been received from an international federation of plasma producers, noting that, *"The Committee established that the group of*

[266] WITN6392177/4, paragraph 04.4 (a)
[267] WITN6392154/5

plasma producers was a trade consortium with vested interests. It was felt that caution should be exercised in the way the Society accepted and made use of funds from commercial sources, while accepting Mr Taylor's point that the Society would not have been able to be influential in Europe had it not received sponsorship. Mr Clarke proposed that, when taking Sponsorship, the Society adjust its budget accordingly and that the Executive Committee should approve expenditure beforehand. This was noted."

c. Minutes of a meeting of the Executive Committee held on 29 July 1993,[268] which records that David Watters was in discussions with a number of pharmaceutical companies concerning sponsorship in 1994, *"Among the emerging proposals was a specific one from Cutter—Miles (Bayer) to fund a national conference for people with haemophilia, Centre Directors, nurses, social workers, physiotherapists, in fact the entire health care team. The talk had been in terms of £15,000 plus. It was hoped that other pharmaceutical companies would pay for satellite sessions relevant to their own activities. Any direct promoting of products would not be permissible…"*

d. Minutes of an Executive Committee meeting on 7 May 1994,[269] which reports discussions for potential funding from Alpha Pharmaceutical and Proton for sponsoring sessions at the Chairman's Conference.

e. The June 1995 edition of The Bulletin,[270] which notes that the pharmaceutical industry had contributed towards the cost of the year's Adventure & Sport holidays for young people with haemophilia. Alpha Therapeutic, Bayer, BPL, Immuno and Pharmacia had all pledged support.

f. The September 1996 edition of The Bulletin,[271] which notes that publication of the edition was funded by BPL.

g. Minutes of the Board of Trustees meeting on 13 February 1997,[272] which notes that, *"Discussions arose regarding the possible influence on the Bulletin by pharmaceutical companies. The Chairman called for a vote on a proposal by Mrs Norm a Guy, to decide whether the Bulletin was to be a future budgeted item. The final decision, was that the Bulletin would continue to be produced*

[268] WITN6392096/7
[269] WITN6392062
[270] WITN6392189/12
[271] WITN6392190/2
[272] WITN6392191/5

even if sponsorship was not forthcoming. However, companies who help fund the Bulletin via the "Pharmaceutical Industry Fund" will be thanked in each issue. This was seconded by Mr Gordon Clarke and unanimously accepted."

h. The Chief Executive's Report dated 21 March 1997,[273] which sets out monetary support for the Pharmaceutical Industry Fund from BPL; Bayer; Baxter; Centeon; Alpha and Genetics Inst.

i. The 1997 (No. 1) Edition of The Bulletin[274], which acknowledges the financial support received from companies *"whose contributions to [the Society's] Pharmaceutical Industry Fund help [the Society] to provide [its] membership services: Alpha Therapeutic; Bayer; Baxter Healthcare; BPL; Centeon; and Genetics Interest Group.*"

j. An invitation to a local Group meeting on the topic of "Orthopaedic problems in haemophilia" on 23 September 1997,[275] which notes that the event was sponsored by Alpha Therapeutic.

k. The Chief Executive's Operational Report from the Board of Trustees meeting on 25 September 1998,[276] which records that funding from Bayer was used to upgrade the Society's computer systems.

Benefits to pharmaceutical companies for funding the Society

249. In the Inquiry's request under Rule 9 of the Inquiry Rules 2006 dated 17 January 2022, the Society was asked about its understanding of the benefit to pharmaceutical companies of funding the work of the Society. In a statement responding to the Inquiry's request, the Society's current Chief Executive Kate Burt responded, *"I have not seen any documents which answer this question definitively. I can surmise that it may have been for altruistic reasons; understanding customers better, which would lead to producing better materials; or understanding needs of community and to enhancing their reputation."*[277]

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[273] WITN6392192
[274] WITN6392193/2
[275] WITN6392194
[276] WITN6392195/2
[277] WITN6392001/99, paragraph 234

250. The earliest documentary evidence of the Society seeking funding from pharmaceutical companies was in 1975 by way of a direct appeal that was sent to over 1,000 companies. This is recorded on page 2 of the minutes of the Society's Executive Committee on 13 November 1975.[278] Also noted in Executive Committee minutes from the same year (from a meeting held on 11 December 1975) is that, *"a letter has been received from Serological Products Ltd expressing interest in supporting various research projects we had put to them"*.[279]

251. The September 1989 General Secretary's Report[280] suggests that Armour hoped that the Society might have a (small) role to play in facilitating discussions that might lead to image rehabilitation so that it could market Monoclate in the UK. Ken Milne's report of the September 1992 UKHCDO meeting records that Armour was "very interested" in the Society's proposed study with Professor Maynard at York University on health economics and evidencing the benefit of treatment changes and cost/benefit analysis generally.[281]

252. In oral evidence to the Inquiry on 4 November 2021, Christopher Bishop was asked about a document that shows financial contributions being made by pharmaceutical companies, including, but not limited to, Armour, to the Haemophilia Society.[282] This document describes that it extracted information from the Society's annual reports from 1982 to 1999 (inclusive) *"to show provision of funding by manufacturers of blood products and other pharmaceutical companies."* In relation to who within Armour would decide how much Armour was going to pay to the Society in a given year, Mr Bishop said, *"That would be during the budgeting process for the following year and would have been agreed, well, proposed, perhaps by me in the formulation of the budgets for the following year."*[283] He said that the purpose of the funding was for "any or all" of the following categories: sponsorship of the Society's meetings; sponsorship of the Society's publication; a general contribution to the Society's coffers.[284] Counsel

[278] WITN6392206/2
[279] WITN6392207A/3
[280] WITN6392207B.
[281] WITN6392208/3
[282] PRSE0003929
[283] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T40: 20 – T41: 12
[284] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T41: 13–17

to the Inquiry asked Mr Bishop, *"what was Armour's purpose in providing not insubstantial sums of money to the Haemophilia Society?"*. Mr Bishop responded:

"Well, bearing in mind they are a charity and very, very strong supporters of their members and their groups, important for them to be kept up to date on all scientific developments in the interests of their members, and attendance at international and national meetings, you know, would be expensive for them as a charity, and we, along with other companies, felt it appropriate to support that charity."[285]

253. Former Society staff have given evidence to this Inquiry about the benefits to pharmaceutical companies for supporting the Haemophilia Society, including that:
    a. it might help them to avoid criticism for past actions; and that there was no expectation that the Society provide anything in return.[286]
    b. to keep the Society, a patient organisation, that did not have a huge number of members anyway, in existence to assist in contributing to its work; and that there was no expectation that the Society provide anything in return.[287]

254. Documents disclosed to this Inquiry demonstrate that the Society was careful to ensure that no product or company were favoured in The Bulletin. For example, please see the Minutes of the Executive Committee of the Haemophilia Society meeting, 4-5 October 1991:[288]

"28.6 The Bulletin 1991 Issue No 3: Mr Watters reported on a controversy that had arisen over the publication of three articles on monoclonal or high purity products in the recent issue of The Bulletin. Having read them, a few Society members had approached their Centre Directors with requests for the products and this had caused a certain amount of consternation to a few Directors. Dr Elizabeth Mayne had agreed

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[285] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T42: 1–8
[286] See evidence of Simon Taylor, *"[131] I believe guilt might have had a lot to do with it. I have no knowledge of any specific motivations and expectations by any of the companies. I expect they believed that by supporting some of the Society's activities, they might ward off criticism of their past actions, but that is speculation on my part. [132] I do not believe that there was any expectation that the Society would provide anything in return"*, WITN4500001/28, paragraphs 131 to 132.
[287] See evidence of David Watters, *"[205] I think their motivation was purely that of keeping The Haemophilia Society, a patient organisation, that did not have a huge number of members anyway, in existence to assist in contributing to its work. As far as I recall, there was never an expectation that The Society would provide anything in return."*, WITN3429001/89 and 92, paragraphs 196 to 197 and 205
[288] WITN6392061/4, paragraph 28.6

to write an article for the next issue on some of the problems related to the use of high purity products, there by presenting the other side of the argument. The Chairman remarked that the Society might be perceived in certain quarters to be favouring a particular pharmaceutical company, and that such sensitivities ought to be borne in mind in the future. Mr Cowe said that The Bulletin was a forum for debate and should take into account all the medical evidence on a range of issues."

Concerns about the Society's relationship with pharmaceutical companies

255. The evidence of Dr Hilary Pickles (who was Principal Medical Officer (Department of Health) for the Committee on the Review of Medicines (1984-86); the AIDS unit (1986-1988); and MedSEB/B (1998-1991) and other roles) gives rise to criticism of the Society's relationship with pharmaceutical companies. On 12 May 2022, Dr Pickles gave evidence to the Inquiry about a minute dated March 1991 from herself to Mr Harris at the Medicines Control Agency.[289] In this document, she expressed concern about Armour's financial sponsorship of the Society's publication, The Bulletin and the Society's comments about monoclonally purified high purity factor VIII in The Bulletin 1991 (No.1).[290] She said at paragraphs 3 to 4 of the document:

".. 3. I bring to your attention the latest copy of the Haemophilia Society Bulletin. The front page is strongly advocating monoclonally purified high purity factor VIII, in fact being more positive about these products than the haemophilia centre directors. The Bulletin claims to be "unhappy" at the "low take-up of the monoclonal product which is available commercially".

4. On page 11 of the Bulletin is a note that Armour had paid for the Bulletin's publication. I think a warning to Armour from your section would not be out of place. If there is evidence that Armour influenced editorial policy directly, then something more formal would be appropriate…"

[289] DHSC0002472_135
[290] HCDO0000279_009

256. In evidence before the Inquiry on 12 May 2022, Dr Pickles was questioned about this document. Counsel asked Dr Pickles if it was right to understand that the basis for her concern in paragraph 4 (set out above) was about the Armour sponsoring the Haemophilia Society's Bulletin publication. Dr Pickles agreed. [291]

257. Dr Pickles' criticism arises because at page 1 of The Bulletin 1991 (No.1)[292] the Society recommend monoclonally purified high purity Factor VIII (which is an Armour product), in circumstances where Armour had paid for The Bulletin to be issued (as noted on p.11 of The Bulletin). Dr Pickles appears to make two criticisms:

a. that payment may have affected the Society's editorial policy; and
b. that the entry at page 1 might have amounted to promotion of the drug.

258. It is submitted that there is no evidence that editorial policy was affected by this or any donation, and in fact as is apparent from all the evidence referenced in this section, the contrary is actually true; that the Society was very careful to maintain separation between donations and its own activities.

259. This is supported by evidence given by David Watters, that, *"pharmaceutical companies did not assist in proposing and/or editing any articles whatsoever in the Society publications. They never had adverts either within the publications as this was against the code of practice of the Royal Pharmaceutical Society."*[293] He also explained that, *"The pharmaceutical companies sometimes sponsored publications, and this was confirmed by including a short paragraph in the publication to state that the publication had been sponsored by a particular pharmaceutical company. That was not advertising their products. All sponsorship was always offered to all pharmaceutical companies on an even-handed basis. It was up to each company to determine as to whether they wanted to provide any sponsorship, and if so, how much."*[294] David Watters also explained that at the Society's regional days and Annual General Meetings, pharmaceutical companies had the opportunity to have a stand but

[291] Transcript of evidence of Dr Hilary Pickles to the Infected Blood Inquiry, 12 May 2022, T186:14 – T187:18
[292] HCDO0000279_009/1
[293] WITN3429001/39, paragraph 89
[294] WITN3429001/39-40, paragraph 90

not to promote their products; they could respond to questions about their product but there was no direct promotion and advertising of products.[295]

260. This is supported by evidence given to the Inquiry by Christopher Bishop. In response to a question from Counsel to the Inquiry, Jenni Richards KC about whether it was fair to conclude, given that Mr Bishop's role was in sales and marketing, *"that at least one purpose of interaction with the Haemophilia Society would be to -- through the Haemophilia Society to try and promote sales of Factorate",* Mr Bishop said it was "*Certainly not, no. Armour were considered a very valuable member of the team of treating and looking -- well, treating the haemophilia patients, and our association with the Haemophilia Society was part of that ethos."*[296]

261. In response to a question about whether he recalled whether he ever alerted the Society, in 1985 or 1986, to the possibility that Armour's heat-treated procedures might be ineffective, Mr Bishop responded, *"No, I don't recall any discussion like that at all."*[297] Later on the same day, Mr Bishop gave the following evidence about the Society's knowledge 1985 and 1986 about the possibility that Armour's heart-treated product could be infected:

"Q. When I asked you this morning about your interactions with the Haemophilia Society, you said you met them fairly frequently, every month or so it might have been, but you didn't alert them in 1985 and 1986 to the possibility that Armour's heat-treated product could be infected. Why not, and how did that fit with what you described Armour's ethos to have been?

A. It may well have been unofficially discussed, but The Haemophilia Society and, indeed, individual patients, were very, very well informed about their condition and about the -- you know, about the science. You know, more so, I think, than any other specialty. So they, you know, they may well have been -- you know, found out things for their own -- in their own observations.

[295] WITN3429001/29, paragraph 89
[296] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T40: 7 – 16
[297] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T40: 17 – 25

Q. Would it not have been more in keeping with what you describe Armour's ethos to have been, to tell, not unofficially but officially, the Haemophilia Society of the concerns that the heat-treated product might have been infected?
A. No, again, that would have been under the direction of the medical department. I think possibly that -- the concern about the divulging too much unproven information would have been -- had the same impact as the -- Peter Jones' premature statement at that AIDS meeting."[298]

262. In a request under Rule 9 of the Inquiry Rules 2006 dated 17 January 2022, the Society was asked whether any pharmaceutical companies try to influence the Society in relation to: the information provided to members about which blood products to use and/or their safety; submissions the Society should be making to the Government; and whether or not the Society should take a particular course in relation to any of the campaigns they pursued. In a statement responding to the Inquiry's request, The Society's current Chief Executive Kate Burt responded, *"I have seen no evidence of pharmaceutical companies trying to influence The Society in relation to any of the matters listed in this question. Certainly since I started my role at The Society there have been no such attempts."*[299] It is submitted that this remains an accurate reflection of the evidential position before the Inquiry.

SECTION A6: REPRESENTATIONS MADE TO GOVERNMENT BY THE HAEMOPHILIA SOCIETY ON SELF-SUFFICIENCY AND ON IMPORTED BLOOD PRODUCTS

263. This section addresses paragraph 364 in the Inquiry's Amended List of Issues, which is, *"What representations were made to Government by the Haemophilia Society in relation to self-sufficiency and why?"* and paragraph 365 in the Inquiry's Amended List of Issues which is, *"What representations were made to Government by the Haemophilia Society in relation to imported blood products and why?"*

[298] Transcript of evidence of Christopher Bishop to the Infected Blood Inquiry, 4 November 2021, T175: 25 – T176: 25
[299] WITN6392001/102, paragraph 244

264. The Society has a long history of lobbying Government to achieve self-sufficiency. At the same time, the Society recognised the life altering impact of Factor concentrates for people with haemophilia and it wanted people to keep having access to treatment and understood that many were dependent on it. Therefore, it supported the continued importation of Factor concentrates from the US within the wider context that the UK did not have enough supply to meet demand. This was a reasonable position to adopt.

265. Haemophiliacs were dependent on treatment with Factor concentrates and the Society's position (based on advice from the UKHCDO and Medical Advisory Panel) was that the benefits of patients continuing their treatment out-weighed the risks of stopping it. In the late 1970s to early 1980s, the Society's members wanted home treatment for Factor concentrates to be widened. This treatment had changed their lives and this was at a time when it was generally believed that the risk from AIDS and hepatitis was very low in the UK.[300] The average life expectancy of people with haemophilia had been increased through the use of blood products and as a result, *"people with haemophilia were able to enjoy better employment and were better at functioning in society. All of that came about as a result of using Factor concentrates."*[301] The alternative to Factor treatments was cryoprecipitate; but of those adults and school age children with severe haemophilia who had experience of cryoprecipitate and injectable concentrate, few wanted to revert to cryoprecipitate or even considered it as an option.[302] Further, the more units of blood that were devoted to cryoprecipitate production, the fewer would be available to achieve self-sufficiency in injectable concentrate.

266. Over the years, the Society has been well aware of the challenges faced by Government in meeting the goal of self-sufficiency. The Society well understood that an adequate volume of blood donations would be required before self-sufficiency could meet all treatment needs; and it appreciated the need for implementation of a rational blood policy[303]; that is, using all components of blood in the most efficient way, so as to minimise waste and maximise the number of people who could be treated with each donation. The Society was also aware of the practice of collecting plasma in the US and

[300] PRSE0000411/2-6
[301] WITN3429001/47, paragraph 105
[302] PRSE0000411/2
[303] HSOC0022508/1

this provided a further impetus to seek self-sufficiency due to the nature of voluntary versus paid donation in the US. Trustees of the Society took part in the World in Action programme 1975; they were the same ones taking the concentrates.

267. The Society was also conscious that in order to persuade government to meaningfully pursue self-sufficiency, it would need to put forward cost effective arguments.

268. The Government accepted the advice of the World Health Organisation around the infection risks of using foreign blood products to treat haemophilia and accordingly in 1975, Dr David Owen, Secretary of State for Health, had promised in the House of Commons to make the UK self-sufficient in blood products for Factor VIII within 2 to 3 years.[304] Had this occurred, it would have reduced the incidence of infection with HIV of hundreds of those people with haemophilia who died from AIDS. However self-sufficiency was not achieved until many years later.

269. The Society had a Blood Products Committee, whose purpose was "*to keep under review and, in particular, to be constantly on the back of the Department of Health about the achievement of self-sufficiency in the United Kingdom.*"[305]

270. From 1983 onwards, making representations to government was a *"main feature"* of the work of David Watters. David Watters' meetings with civil servants were *"frequent"* and he spoke with them about *"self-sufficiency, progress towards self-sufficiency and the need for compensation."*[306] David Watters gave evidence that achieving self-sufficiency in blood products was a key issue pursued by the Society and that they *"continually pressed"* for it.[307] His evidence was that the risk from blood products *"was evident from the 1970s, hence pressure on Dr David Owen which later led to an assurance broken by successive administrations. The flagship demand was always for self-sufficiency. However, realism came into it with the advent of HIV and AIDS, which meant that we were led to believe that the best thing to do was to continue treating with imported product. Whilst it appears that evidence may have been less*

[304] DHSC0000274/2; DHSC0000279/1; WITN2050036/5
[305] WITN3429001/12, paragraph 30
[306] WITN3429001/63, paragraph 136
[307] WITN3429001/69, paragraph 150

supportive over time, the advice did not change. The conversations continued with the Government and civil servants."[308]

271. David Watters commented that, *"[h]ad we been self-sufficient in the late 70s, I have no doubt, that the outcome would have been very, very different. I do not mean that we would not have been in a situation where we had no Hepatitis and no HIV, but it would be much, much less and that's where successive governments, and successive Ministers of Health really failed us down the line."*[309] Further, he said *"[b]ecause the UK Government failed to meet David Owen's pledge to become self-sufficient by the late-'70's, this meant that we had to import vast amounts of Factor VIII, which proved at too late a date to come from dubious backgrounds."*[310] The Society adopts and echoes these words today and urges the Inquiry to do so.

272. Key actions taken by the Society in respect of their representations to Government around self-sufficiency and the importation of blood products are set out below.

273. A review of the Society's Executive Committee meeting minutes shows that dried concentrates were discussed at the 1969 WFH Congress.[311] Mr Frank Schnabel had had discussions with commercial producers with the idea that they produce concentrates in more countries, reduce the price of Factor VIII and Factor IX, and make their profits primarily from the remaining blood constituents. The Congress agreed with that and agreed to encourage transfusion services to make dried cryoprecipitate concentrate wherever possible.[312]

274. The Society was concerned about the supply of Factor VIII concentrates from at least July 1972.[313] On 10 August 1972, the Society's Executive Committee meeting was joined by Dr Katharine Dormandy to discuss a Society produced report on the topic, and she suggested that the Society liaise with Dr Rosemary Biggs. The Society continued to gather data about shortages at different centres. In 1974, the Society

[308] WITN3429001/51, paragraph 151
[309] WITN3429001/12, paragraph 30
[310] WITN3429001/47, paragraph 105
[311] HSOC0029691_114/3-4
[312] HSOC0029691_114/3-4
[313] HSOC0029671_006/4

supported Dr Biggs' appeal for an increase in supplies and had a letter published in the Lancet.[314]

275. Minutes of the Executive Committee on 10 October 1974 record that there was a meeting with the Society's Medical Advisory Panel (the Department of Health and Social Services ("DHSS") having bought 500,000 units of commercial concentrate) to discuss supply.[315] It was agreed that the Society should request a meeting with officials from DHSS to discuss the position with regard to concentrates and Dr Biggs and Professor Ingram agreed to prepare a case for the Society to present.[316]

276. The Society was conscious that in order to persuade government, it would need to put forward cost effective arguments. Minutes of the Society's Executive Committee meeting on 10 October 1974 record that the Society attended a meeting of Centre Directors where home treatment was discussed[317] and consideration was given as to *"how the Society could provide pressure on the appropriate authorities within the Ministry in support of finance for material for home treatment, and considered the difficulties in conveying the relevant arguments to the Ministry concerning the saving that home treatment programme would provide overall and in the long term. This led on to a discussion of the general shortage of cryoprecipitate in certain areas and the great variation in supply."* One of the attendees at the meeting *"felt it was important to meet the civil servant ultimately responsible for these decisions within the Ministry. The effect of the cash crisis may make our case more difficult, therefore it was of prime importance to be able to put the cost effective arguments to the relevant personnel under the Minister. The answer to the problem must inevitably be political rather than medical."*[318]

277. The Society's February 1975 issue of its 'News Bulletin' reported to members on important issues with respect to the challenges regarding Factor VIII concentrate supply in the UK, and highlighted efforts made by the Society with respect to lobbying Government to improve circumstances, including: successfully encouraging a number

[314] HSOC0029671_031/2
[315] HSOC0029671_033/2
[316] HSOC0029671_033/3
[317] HSOC0029671_033/4-5
[318] HSOC0029671_033/5

of members to write to their MPs; and questions being asked in the House of Commons. The Society's publication noted, however, that, *"Unfortunately, it appears from the answers given by the Minister responsible that it will prove extremely difficult for us to convince the Department of Health that apart from the moral right that haemophiliacs have to the most effective treatment available that it must be an economic advantage to provide such treatment… We fully realise that there are economic problems in the National Health Service but it must be obvious that now is the time to provide the necessary money for the production or purchase of Factor VIII concentrates. The extension of home treatment programmes, at present restricted by the lack of funds, will surely prevent demands, both now and in the future, upon the health and social services."*[319]

278. In due course, the Society wrote to the Minister for Health, Dr David Owen requesting a meeting and was pleased when he agreed. On 11 December 1975, there was a meeting between Dr Owen and a deputation from the Society, which included Rev Alan Tanner and Mr Ken Polton. During this meeting, the Society expressed its anxiety *"that the volume target set by the Department for self-sufficiency might not be sufficient in practice… the Society wondered if greater use of plasmaphoresis [sic] was a viable solution."*[320] The relevant part of the meeting was reported in the Society's 11 December 1975 Executive Committee's meeting minutes as follows, "*Dr Owen stated that in 1977 we would be fully self-sufficient in concentrates. The whole question of commercial concentrates, plasmapheresis, the regional structure of the BTS and other matters were fully discussed. Regular contact was to be maintained in the future and annual meetings held to discuss haemophiliacs' problems."*[321]

279. Later the Society had a meeting with Dr Gerard Vaughan seeking clarity over whether self-sufficiency was still Departmental Policy; and asking questions about this.[322] An internal departmental briefing paper prepared for Dr Vaughan dated 21 October 1981 sets out the Society's position on self-sufficiency at the time being that, *"The Supply of Factor VIII to Meet Projected Demands Over the Next Few Years and the Achievement*

[319] HSOC0022693/1
[320] DHSC0100006_093/1
[321] HSOC0029671_045/3
[322] DHSC0002211_062/2

of Self-Sufficiency in Blood Products, Including the Position As it Affects Commercial Products."[323] The Society's David Watters (who attended the meeting) recalled that when the Society arrived, Dr Vaughan was *"effusive and assured us that the door he knew we had come to knock on was already open and need not be pushed too hard. We were informed that decisions had already been made to upgrade the facilities at BPL, and this came as a major shock to us at the time. We went in prepared to go all guns blazing, I believe this was potentially around 1982, and we were astounded. Of course, it became clear as history unfolded that the Department of Health were already aware, at that time, that there was a potential for a major crisis with blood products, therefore, they put their foot on the accelerator to achieve self-sufficiency at as early a date as was possible. However, there was nothing said during that meeting about the potential risks of imported blood products or what was later called HIV."*[324]

280. Minutes of this meeting with Dr Gerard Vaughan and representatives of the Society also record and evidence the concerns raised by the Society at the meeting:

1. The Haemophilia Society's representatives were concerned that the NHS was so reliant upon expensive imported blood products and feared that cuts in NHS expenditure might result in health authorities refusing to supply Factor VIII to haemophiliacs. MS(H) assured the Society of the Government's support for the principle of self-sufficiency in blood products though he stressed that this had to be a long-term aim as the present Blood Products Laboratory at Elstree was not able to manufacture sufficient factor VIII to obviate the need to import blood products. MS(H) reported that the Laboratory's current upgrading programme would double Factor VIII production to 30 million international units by the end of 1982. Planning of the new Laboratory had begun. It was too early at this stage to say what its capacity would be or when it would be fully commissioned.

2. The Haemophilia Society accepted that self-sufficiency should only be aimed for if it is could be shown to be economic to do so."[325]

[323] HSOC0022693
[324] WITN3429001/28-29, paragraph 59
[325] HSOC0022693

281. Lord Norman Fowler was asked in evidence to this Inquiry about his opinion on the meaning of point 2, as set out in the above-mentioned document. He said, *"the best interpretation on it is self-sufficiency should only be aimed for if the national economy could afford it… I assume that is the Haemophilia Society or the person who has actually written this leaning over backwards to say that the Society agreed with the Government's policy."* Lord Fowler agreed that he did not attend the meeting nor did he see this document at the time.[326]

282. The Society agrees with Lord Fowler that the best interpretation of point 2 is that "*self-sufficiency should only be aimed for if the national economy could afford it*". It disagrees that the minutes should be interpreted as the Society bending over backwards to agree with Government's policy. That speculation about what the minute means in terms of how the Society conducted itself in the meeting does not fit with either the Society's position on self-sufficiency or its actions in the preceding decade. All of these were directed at persuading different Governments of, amongst others, the economic case for self-sufficiency.

283. The suggestion that the Government should only be aiming at self-sufficiency if it was economical to do so was not new in October 1981. In his witness statement, Lord Owen referred to the article that he wrote in the New Statesman more than a decade earlier, on 22 January 1971.[327] There he referred to the moral case and the health case for self-sufficiency, and then addressed the financial case:

> "*The commercial blood market also fails in terms of economic efficiency, for the cost alone in the US is 5 to 15 times greater than in Britain. In terms of administrative efficiency, failure is revealed by serious shortages and marked wastage. So far from giving greater consumer freedom, the marketplace in blood actually involves considerable consumer exploitation.*"[328]

[326] Transcript of evidence of Lord Norman Fowler to the Infected Blood Inquiry, 21 September 2021, T82: 4:14
[327] WITN0663001/2-3, paragraphs 5 to 7
[328] LDOW0000343

284. Throughout the 1970s and into the 1980s the Society took the following positions: that the UK should make greater use of plasmapheresis because not doing so was wasteful of blood which is a scarce resource, that the UK should adopt a rational blood policy so that each unit of whole blood was used intelligently to benefit the greatest number of patients, that it made no economic sense to import US Factor VIIII at disproportionate cost when Factor VIII could be manufactured more cheaply in the UK, and that self-sufficiency was a sound investment because people with haemophilia treated with domestically produced replacement treatment derived from voluntarily donated blood would be net contributors to the economy, not a drain upon it. It is doubtful that Lord Fowler was aware, when he gave evidence to the Inquiry, of Professor Ingrams' DHSS-funded study completed two years before the Society's meeting with Dr Vaughan in October 1981. That study into the health economics of home treatment proved that not only was home treatment slightly cheaper for the NHS than hospital treatment, but also that some of the greatest benefits were "*savings in time lost from school and work.*"[329]

285. After the Society's meeting with Dr Vaughan, he wrote a letter to the Society, which was published in 'The Bulletin'.[330] Dr Vaughan's letter, dated 30 October 1981,[331] acknowledged the Society's concern about the extent to which the NHS relied upon commercial blood products and set out the government's plans for the upgrading programme being carried out at BPL in Elstree and plans to replace BPL *in the next few years"*. He wrote that, *"...the upgrading programme being carried out at the Blood Products Laboratory will, at present yields, enable the Laboratory to double its output of Factor VIII to 30 million international units by the end of 1982. While this will not eliminate the need for commercial products, it represents a major step forward in NHS production of the vital material."*[332]Dr Vaughan stressed that although he endorsed the principle of self-sufficiency in blood products, *"it is only realistic to recognise that demand for Factor VIII is constantly increasing, and that self-sufficiency is not a goal we can achieve in the immediate future"*.[333]

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[329] PRSE0003848
[330] BART0002327_001/6
[331] RLIT0001226
[332] BART0002327_001/6
[333] BART0002327_001/6

286. In its second edition of The Bulletin in 1983, the Society published a talk titled 'Home Therapy – Myth or Reality' given by Professor Bloom.[334] Professor Bloom, as a member and the Chair of the Society's Medical Advisory Panel and Chair of the UKHCDO, he was seen by the Society as carrying *"a lot of sway"*.[335] In this article, Professor Bloom informed the Society's members, *"... American concentrates have been used in this country for many years and the AID syndrome is not overtly prevalent here. Indeed evidence from the incidence of hepatitis does not lead one to believe that concentrates prepared from British blood are necessarily safer, in this latter respect at least. Although it is prudent to keep an open mind, the use of factor concentrates has revolutionised the lives of many sufferers from haemophilia A and B and it does not seem reasonable to curtail treatment at the present time."*[336]

287. Similarly, in the same edition of The Bulletin, in an article about 'The Acquired Immune Deficiency Syndrome (AIDS)', Dr Anthony Pinching, Senior Lecturer and Consultant Immunologist at St Mary's Hospital Medical School informed the Society's members, *"... As in any other medical setting, the risk of treatment has to be balanced against the dangers of the disease itself. Factor VIII concentrate from the USA may be the most likely to contain the AIDS agent; however, the risk is probably small and no source can be regarded as completely free from risk. Furthermore, the USA is the only country capable of providing the quantity of Factor VIII currently needed by UK haemophiliacs. US producers of Factor VIII concentrates have already acted to reduce the risk of transmitting such an agent. The present balance of opinion among haemophilia centre directors in the UK therefore is that imported Factor VIII concentrate should continue to be used for those selected patients already receiving it; i.e. severely affected haemophiliacs with frequent bleeds, and excluding children and those with mild disease."*[337]

288. As addressed earlier in these submissions, at the request of the Society,[338] Professor Bloom, wrote a letter which was circulated by the Society to its members on 4 May

[334] PRSE0000411/2
[335] WITN3429001/18, paragraph 44
[336] PRSE0000411/3
[337] PRSE0000411/12
[338] CBLA0000060_158

1983.[339] The Society's position on self-sufficiency and imported blood products aligned with the advice given in that letter by Professor Bloom, which included that:

a. *"haemophiliacs, their parents and doctors have always balanced the quality of life and the dangers from bleeding against the risks of treatment"*;
b. *"Recent evidence suggests that, in this respect at any rate, concentrates prepared from British blood are not necessarily safer than those prepared in the United States. Even so, we welcome the fact that the Government is investing over GBP 20 million in the Blood Products Laboratory at Elstree so that this country shall become self-sufficient in blood products"*;
c. *"The cause of AIDS is quite unknown, and it has not been proven to result from transmission of a specific infective agent in blood products"*;
d. *"The number of cases reported in American haemophiliacs is small, and in spite of inaccurate statements in the press, we are unaware of any proven case in our own haemophiliac population."*[340]

289. A letter from the Society's Chair, Reverend Alan Tanner to Professor Bloom on 26 July 1983 shows the extent of the Society's reliance on Professor Bloom's advice, *"We were very grateful indeed for your preparing a statement for us so quickly [that's the 4 May 1983 document] because that gave us a definite Society policy regarding AIDS and helped to allay a good deal of anxiety among our members."*[341] As acknowledged by Counsel to the Inquiry in the Inquiry Presentation on Professor Bloom and the Cardiff Haemophilia Centre, this letter illustrates *"the role of Professor Bloom's statement in shaping The Haemophilia Society policy and its wider impact upon members."*[342]

290. On 12 May 1983, there was a further communication between Professor Bloom and the Society. In this letter, Professor Bloom referred to an upcoming meeting with Minister Geoffrey Finsberg in connection with AIDS publicity at the time and that various matters were going to be raised including, *"(b) An assurance that there will be no immediate ban on the importation of US blood products."*[343] As acknowledged by Counsel to the Inquiry in the Presentation on Professor Bloom and the Cardiff

[339] DHSC0001228
[340] DHSC0001228
[341] DHSC0001246
[342] Transcript of Presentation to the Inquiry on Professor Bloom and the Cardiff Haemophilia Centre, 30 September 2020, T95: 2-18
[343] CBLA0000060_044/2

Haemophilia Centre, Professor Bloom effectively endorsed the Society's view that the Government should be asked to give an assurance that there be no immediate ban on the importation of US blood products. [344]

291. Against this background, on 17 May 1983, the Society wrote to an official at the DHSS expressing their wish to meet a minister as soon as possible after the election, with one of their concerns being *"No ban on the importation of American concentrates"*.[345] A meeting with Lord Glenarthur, Joint Parliamentary Under Secretary of State at the DHSS, was arranged to take place on 8 September 1983. On 15 August 1983, the co-ordinator of the Society, David Watters, wrote to a civil servant regarding the meeting that was to take place with Lord Glenarthur. [346] The Society sought an assurance *"that there will be no attempt to suspend the importation of US commercial Products [until there is] definite evidence that this would be necessary.*" The same letter also noted that the Society pressed for *"an assurance from HMG that self-sufficiency in blood products is achieved within two years, will remain a priority with every effort being made to reduce this period."*[347] Lord Glenarthur was asked by this Inquiry whether he agreed with the policy of continuing to allow importation of blood products manufactured from pooled plasma from the United States. He said he did. Lord Glenarthur's reasons for supporting this policy aligned with those of the Society, "*There seemed no practical alternative, other than to suddenly imperil the lives of haemophiliac patients. These were complex clinical, medical and scientific matters. Ministers did not have the qualifications to gainsay the experts, and were wholly reliant on expert advice, although they might challenges expert views in discussion.*"[348] He understood the dangers to haemophiliac patients to be, *"bleeding intracranially and joints, the damage, and that sort of thing were the issues that arose. Untreated haemophiliacs also, as far as I'm aware, and I'm not a doctor, were in peril of dying, you know, if things went badly wrong and that was what I was advised. This was not just basically my information, my knowledge; it was knowledge that I was given by the experts in that particular field."*[349]

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[344] Transcript of Presentation to the Inquiry on Professor Bloom and the Cardiff Haemophilia Centre, 30 September 2020, T70: 19-23
[345] DHSC0003824_170
[346] HSOC0020344
[347] HSOC0020344
[348] PRSE0002095, paragraph 36.1(v)
[349] Transcript of evidence of Lord Simon Glenarthur to the Infected Blood Inquiry, 22 July 2021, T176: 14-22

292. On 18 May 1983, The Sun newspaper reported in an article, 'U.S. Gay Blood Plague Kills Three in Britain' that three Britons had died from AIDS, *"British doctors have blamed the U.S. blood transfusion system which "exports" blood here. Because it pays donors, they say it has encouraged gays, junkies and other "less than ..." people to give blood for money. Despite the doctors' fears the British Haemophilia Society has appealed to the Government not to ban American blood supplies. The Society says that without U.S. imports – which accounts for two-fifths of all Britain's blood needs – there would be a sharp rise in deaths* among haemophiliacs".[350] This is consistent with evidence given by Dr Christine Lee to this Inquiry that *"it's a balance between risk and the necessity of treating... if you don't give the treatment, there's the possibility of dying. And I would take you back to the fact that in 1937 the life expectancy was 20 years. Towards, I would say, the beginning of the '90s, it was approaching 70. And this was at the cost of having hepatitis and sadly, for many people, HIV. But the other side of it was people lived a life."*[351]

293. The Society's position at the time was in line with that of Professor Bloom, as illustrated in a letter dated 23 May 1983 from Professor Bloom to Dr F Bolton, Deputy Director of the Regional Blood Transfusion Service, in which he said, *"I do not think that anyone is complacent about the situation but I think that we all agree that it would be counter-productive to ban the importation of blood products at this moment. We are however taking steps to recommend that imported products from the U.S.A. at least meet with the new F.D.A. regulations."*[352]

294. A letter from Lord Glenarthur, Department of Health and Social Security, to Clive Jenkins, Association of Scientific Technical and Managerial Staffs dated 26 August 1983 confirmed that the Society had made known to him its opposition to any move to ban American Factor VIII. He wrote, *"We have to balance the risk of AIDS against the severe risks to haemophiliacs of withdrawing a major source of supply of Factor VIII which cannot be made good from elsewhere in sufficient volume. In view of this I am*

[350] PRSE0000589
[351] Transcript of evidence of Dr Christine Lee to the Infected Blood Inquiry, 21 October 2020, T156: 19 – T157: 5
[352] HSOC0001272

satisfied that the decision to carry on using the current stock of F. VIII is justified, but it is also worth bearing in mind that some of the American manufacturers had, well in advance of the FDA, instituted their own precautions which were at best as demanding as those later contained in the new regulations. Haemophilia Society is aware of the situation and has in fact made known to me its opposition to any move to ban American F. VIII."[353]

295. At the beginning of 1984, the Society maintained the position that there was no reliable evidence that AIDS was transmitted by blood products. In 1984, the Society published an article in 'The Bulletin' by K.E. Milne (who became Vice Chair of the Society's Executive Committee later that year and held this position until June 1993) which stated, "*We have no evidence as yet [as] to whether AIDS may be acquired more readily from commercial Factor VIII than from the NHS product but, of course, if AIDS becomes established in the UK then NHS blood and plasma supplies are just as likely to transmit AIDS as commercial concentrates. All things considered, haemophiliacs have no reason to be worried about using commercial concentrates*."[354]

296. In 1984, the Society continued to press for the supply of imported heat-treated products based on information it was receiving from the medical community. For example, Dr Brian Colvin, Senior Lecturer in Haematology wrote to David Watters on 22 February 1984, "*I agree that we know little about AIDS at present. In my opinion there is no reason to spurn commercial concentrate and we have to keep an open mind on the risk associated with NHS material*."[355] Dr Colvin explained that what he meant here was that he believed, "*we know little about AIDS at present, and that seems a statement. The question is whether we spurn commercial concentrate and the advice from UKHCDO and from our discussions is that it is not appropriate at the moment not to use commercial concentrate. I'm also pointing out that we're not entirely clear, and it's going to be very difficult to know, whether there's a risk associated with NHS material or not. So I think it is what it is and the word "spurn" I suppose implies that I am not,*

[353] DHSC0002231_036/1
[354] PRSE0002925/2
[355] BART0002310

on the evidence presented to me, recommending that we don't buy commercial concentrate at all. That's what it means."[356]

297. In a letter to the Society dated 29 February 1984, Professor Bloom set out his response to a discussion paper authored by Professor Milne[357] and continued to encourage the Society to press for self-sufficiency while acknowledging that imported blood products would still need to be used, *"We must bear in mind that we may not have had the AIDS problem in the UK, had we been self-sufficient in blood products. At least, we certainly wouldn't have this niggling worry about the importation of a hypothetical AIDS virus, or other unknown viruses from the New World in the future. Thus, although we must still use imported materials, I would not be happy about accepting this situation forever, and I think it would be nice if the Society could continue to press for an increase in facilities for producing all the necessary Factor VIII concentrates within the UK."*[358]

298. At around this time, information received by the Society from medical professionals reinforced the message that the incidence of AIDS within haemophiliacs was low. Following a request to provide information about AIDS, Dr Christine Lee wrote in the Society's publication, 'Haemofact. AIDS. Release number 3' dated 11 May 1984 that, *"In Great Britain, the number of haemophiliacs who have been reported with AIDS remain at two. Thus, the incidence is less than 1 in 1,000 patients at risk."*[359] In evidence to the Inquiry, Dr Lee confirmed that when she was requested to provide information, she was not *"given any kind of brief from the Haemophilia Society as to the kind of message they wanted to convey"*. She said the Society wanted information[360] and that, *"it was written to convey what the knowledge was at that time. And the number of cases of AIDS in people with haemophilia in the UK at that date, at that time, was two, and this had come from the Oxford records... And when I write in here that the number at risk was 2,000, this was the number of people in the UK who had been treated with clotting factor concentrate at that time. So the incidence was 1 in 1,000."*[361]

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[356] Transcript of evidence of Dr Brian Colvin to the Infected Blood Inquiry, 7 October 2020, T29: 19 – T30: 7
[357] BPLL0001351_093
[358] BPLL0001351_094/2
[359] WITN1003018/2
[360] Transcript of evidence of Dr Christine Lee to the Infected Blood Inquiry, 29 October 2020, T32: 18 – T33: 12
[361] Transcript of evidence of Dr Christine Lee to the Infected Blood Inquiry, 29 October 2020, T35: 12-22

299. Minutes of the Meeting of the Council of the Society on 24 November 1984 list issues which would be raised by the Society at a forthcoming meeting with Minister Norman Fowler, which included:

"1. That since the DHSS have recognised heat-treated product as important enough to bring into production from April 1985 (in small quantities), immediate steps should be taken to import supplies to treat everyone now. The Government will be asked to do this irrespective of cost.

2. The Government will be asked to introduce national plasmapheresis programmes to ensure self-sufficiency by 1986. It was noted that while Blood Products Laboratory will have the capacity to achieve self-sufficiency by 1986, the strong evidence was that adequate supplies of plasma could not be obtained otherwise than by plasmapheresis."[362]

300. On 28 November 1984, the Society wrote to Lord Glenarthur, noting concern at the time gap while the supply of a UK heat-treated Factor VIII product caught up with product demand and urged that heat-treated commercial concentrates be introduced forthwith.[363]

301. A letter from Lord Glenarthur to the Chairman of the Society dated 12 December 1984 refers to their meeting on 7 December 1984 and the Society's concerns around the introduction of commercial heat-treated Factor VIII. Lord Glenarthur wrote that "*The decision has been taken at BPL to heat treat their product commencing in April next and existing commercial product licence-holders have been asked to make early application for variations in their license to allow introduction of heat-treated products."*[364] Lord Glenarthur also acknowledged that during the meeting that the Society asked him to confirm the government's commitment to attaining self-sufficiency in blood products. He wrote, *"The new production unit at the Blood Products Laboratory Elstree, is still on target for completion in January 1986. The*

[362] HSOC0019923_011/6
[363] DHSC0002251_016/1
[364] PRSE0002095/1

Department is aware of projected shortfalls in plasma procurement in certain Regions, and is discussing the matter with the Regional Health Authorities concerned."[365]

302. A letter from Professor Bloom to David Watters dated 2 January 1985 states that, *"in the past my committee has always been under pressure from patients and from the Society to seek increased funding for the purchase of Factor VIII"*[366] David Watters gave evidence that he is *"uncertain"* about what Professor Bloom meant by his committee being "under pressure" at this time but that he assumes Professor Bloom was *"under pressure to make sure that patients could be treated at all, because without American product at this stage there would have been little or no treatment available because of the systemic failure of successive governments to fulfil the David Owen pledge of self-sufficiency. At that point in time, the only reason we had been pressuring doctors to get the extra funding necessary for heat treated product, for commercial Factor VIII from the United States, was that people could be treated at all. The UK was not self-sufficient at that time and the alternative was no treatment at all. We were seeking funding for more expensive, safer products that had been heat treated."*[367]

303. In the December 1985 edition of The Bulletin, the Society published an article, 'As construction at Elstree keeps to schedule: UK self-sufficiency confirmed for 1986'. The author is quoted as saying, *"And although the press has been dramatizing the AIDS problem and the risk of imported blood coming into this country, I think it is very important not to forget that without the imported product the quality of those who need Factor VIII and Factor IX would have been much poorer."*[368] David Watters gave evidence that in relation to the comment of "dramatizing the AIDS problem" he had *"reached the conclusion that the press and the media were dramatizing the reality based on the number of calls I have received from anxious parents whose child had haemophilia, possibly not even HIV positive, and the fact that they were being stopped from going to school because of protests from other parents. Fears were also expressed by teachers, clergy and it felt like everybody else in the country as well as large numbers of abusive telephone calls. The overreaction of teachers, parents and the*

[365] PRSE0002095/1
[366] DHSC0001260/1
[367] WITN3429001/61-62 , paragraph 133
[368] PRSE0001088/1

public generally to the potential risk of HIV infection, was exaggerated by the media. I did not intend this comment to be in the context of dramatizing the AIDS problem for those with haemophilia, I meant it in the context of the wider population and the media reaction, which detracted greatly from our work in serving the needs of people with haemophilia so tragically coping with life changing and life limiting situations."[369] This is a coherent explanation, which is not at all inconsistent with the actual wording of the article, and it is submitted that it should be accepted.

304. Minutes of a meeting of the Haemophilia Centre Directors in September 1990[370] record Professor Bloom accounting for the historic situation: *"Professor Bloom pointed out that in 1979-85, when he was Chairman, all the Haemophilia Centre Directors and The Haemophilia Society were pushing the Department of Health to purchase imported products. Everyone knew the result of that."*[371] As Counsel to the Inquiry acknowledged in the Presentation on Professor Bloom and the Cardiff Haemophilia Centre, *"This appears to be a recognition that a push for imported products came from Haemophilia Centre Directors themselves"*.[372] And as Sir Brian Langstaff acknowledged, *"It's also a recognition that, at least in his view at this stage, imported products were the principal cause of the problems that followed."*[373] This is consistent with what Professor Bloom is recorded as saying in the same minutes – that he was not convinced that there were good reasons to use imported concentrates rather than British products.[374] As illustrated in this section, this was inconsistent with what Professor Bloom was communicating to the Society and its members at the time. It was also at odds with the limited availability of British products at the relevant time.

305. From the mid-1980's onwards, the Society continued to campaign for self-sufficiency and to consider what more it could do to help its members. The statement of Kate Burt, lists a number of documents which record some of the Society's work for achievement

[369] WITN3429001/47-48, paragraph 106
[370] HCDO0000015_021
[371] HCDO0000015_021/03
[372] Transcript of Presentation to the Inquiry on Professor Bloom and the Cardiff Haemophilia Centre, 30 September 2020, T167: 9 – 14
[373] Transcript of Presentation to the Inquiry on Professor Bloom and the Cardiff Haemophilia Centre, 30 September 2020, T167: 15 – 18
[374] HCDO0000015_021/3

of self-sufficiency in blood products.[375] A number of steps taken with respect to making representations to government include:

a. On 1 March 1986, the Society held a lecture delivered by Dr Richard Lane, Director of BPL at Elstree ("BPL") regarding self-sufficient manufacture of Blood Products in England and Wales.[376]
b. In March 1986, David Watters wrote to Dr G E Whittaker of the Northern Regional Health Authority expressing concern at the Northern Region's performance in respect of the amount of plasma sent to Elstree.[377]
c. On 6 July 1988, David Watters wrote to Dr John Cash of the Scottish National Blood Service confirming had sent letters to a variety of political and medical people in Scotland confirming the shortfall in home produced Factor VIII and expressed his desire to *"do whatever we can to help Scotland retain its UK lead position on self-sufficiency"*[378]
d. On 2 December 1988, representatives from the Society met with Mrs Edwina Currie, the Junior Minister, to discuss UK self-sufficiency in Factor VIII, voicing their disappointment that self-sufficiency had not been achieved and that it would not be possible within the time-scale previously envisaged.[379]
e. In August 1990, the Society wrote to the Chief Medical Officer of the Department of Health about the UK view of European self-sufficiency.[380]

306. One of the actions outlined in Kate Burt's statement is a note prepared by Ken Milne dated 11 October 1987 which records him *"wonder[ing] if we should not have pester[ed] BPL and the DHSS more about the continuing delay in achieving self-sufficiency – this would not, of course, advance self-sufficiency by any significant period, but might give us a tactical advantage in any future demands we might make. It seems possible, for example, that we will be asking for monoclonally—purified products before long, a request which will not be terribly popular. As this is to a large extent a P & E R matter, I think it would be helpful if we could establish a more formal*

[375] WITN6392001/126, paragraph 294
[376] LOTH0000010_006
[377] HSOC0020340
[378] HSOC0015347
[379] HSOC0013041_003
[380] DHSC0030028

liaison between me and the P & E R working party."[381] This note demonstrates that the Society's trustees were constantly questioning how and what they could do more in relation to self-sufficiency. All the while, the Society was trying to help people who had been affected by infected blood products; it was being pulled in different directions also trying to help those with bleeding disorders who were not infected.

307. David Watters gave evidence that the Society's position regarding self-sufficiency would have been communicated to Government "*even before Dr David Owen made his commitment for self-sufficiency, because that came about very much as a result [of] pressure from the Haemophilia Society... There was continual lobbying of the Government towards self-sufficiency from the mid-1970s onwards by the Society... the Society had no effective administrative back-up to support them in that lobbying. There was no great campaign other than the occasional newspaper article and suchlike, because life was not that sophisticated in those days.*"[382] The Society did not cease to make representations about the Government's actions in relation to self-sufficiency right up to 2006 when it criticised the report of an internal review by the Department of Health which looked at actions relation to self-sufficiency in the period between 1973 and 1991. The Society criticised the report as *"an attempt to gloss over the details of a medical disaster that left a generation of people with haemophilia infected with life-threatening viruses."*[383]

308. In evidence before this Inquiry, Lord Kenneth Clarke said, *"I don't think the Department did anything wrong. I've never heard anybody suggest anything that in the real world a minister or a civil servant might have done that would have prevented it. I've already said, had we taken the step we now know would have saved lives, we'd have been treated with outrage by the Haemophilia Society and most haemophiliacs by denying them their Factor VIII. There just wasn't the evidence to suggest that."*[384]

309. Lord Clarke went on to say in his evidence:

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[381] WITN6392001/126, paragraph 194(e); the note prepared by Ken Milne dated 11 October 1987 has been previously disclosed to the Inquiry but it does not appear on Relativity; it has been re-submitted to the Inquiry at the time of submitting this closing submission
[382] WITN3429001/67, paragraphs 146 to 147
[383] PMOS0000106/1
[384] Transcript of evidence of Lord Kenneth Clarke to the Infected Blood Inquiry, 27 July 2021, T210: 1 – 10.

"Factor VIII made such a difference to the quality of life and the life expectancy of haemophiliacs, I can't -- and they would have, you know, the consequences of stopping taking Factor VIII were very serious for them. I find it difficult to imagine anybody did -- when the suggestion came up the Haemophilia Society was ferociously against any idea that you stopped people taking imported Factor VIII, and had we banned taking imported Factor VIII, we'd have been faced with campaigns as vehement as the ones we do now but on the other side saying what were we doing destroying the life expectancy and the quality of life of haemophiliacs? Because, at that stage, there were very, very few cases of anybody actually dying."[385]

310. The Society has addressed elsewhere in these submissions the reasons why it continued to support importation of US Factor VIII from 1983 onwards. It has reflected deeply on where it went wrong and the harm that has resulted from its actions. That reflection should not be taken as the Society "marking its own homework": the independent scrutiny of its actions that this Inquiry brings to bear is a necessary part of the Society's reckoning with and atonement for its past.

311. It is disappointing that Government appears to have engaged in less reflection. The Society agrees with Lord Clarke that there was no or very little enthusiasm within its membership for action by Government that would reduce access to self-injected Factor VIII concentrate for all those who had come to depend on it, those people being largely patients with severe haemophilia. But that lack of enthusiasm hardly absolves Government from responsibility.

312. It is unfortunate that even now, those with the power to have changed the course of history still seek to use the invidious position in which people with haemophilia, the Society's membership specifically, and the Society itself were placed as some manner of "human shield". The commitment that Government made, through David Owen, to become self-sufficient in blood products was never properly resourced and the demand for Factor VIII concentrate was always underestimated. Government allowed England's

[385] Evidence of Lord Kenneth Clarke to the Infected Blood Inquiry, 27 July 2021, T187: 15 – T188: 4

Factor VIII manufacturing infrastructure to become so run down that it was not fit for purpose. Government was unsighted of the problem and the decision making around and speed at which the vital modernisation work was undertaken was woeful. And it wasted money that could have been used to increase domestic production of safer products more quickly on buying in riskier US product.

313. From at least the early 1970s, Government was aware that use of US blood products derived from US commercial blood banks in the UK and exposed NHS patients to greater risk than did treatment with UK products derived from voluntary blood. It was aware of the additional risk of serious disease to which it was exposing NHS patients at the time when US products were licensed and when central funds were used to pay for imports. It knew, or ought to have known, that NHS patients prescribed US product would be exposed not only to additional risk of known hepatitis viruses but also the increased risk of viruses not yet detected. Having done so, it had no preparedness or contingency plan for how to respond to the foreseeable public health emergency of a new US imported blood borne virus in the UK population.

314. In licensing, funding, and prescribing imports of increased risk bearing US product for use by UK haemophiliacs, the healthcare system, for which Government was responsible, allowed a very vulnerable section of the population, whose history was one of generational disability, poverty, and lost opportunity, to become physically, psychologically, and emotionally dependent on treatment that revolutionised their today whilst taking away their tomorrow.

315. The opportunity to choose an immediately improved quality of life at the price of a fatal illness later on is not one that any person with haemophilia would have been offered had the UK produced enough domestic Factor VIII to meet the needs of severe A patients. As it happened, however, many were not even given that choice. Some were treated with US imported product without their knowledge, others were treated with knowledge of where their Factor VIII came from but without information about what that meant in terms of risk. Few were given the opportunity to choose their treatment from the range of options available in the UK.

316. Once dependent, it is unsurprising and understandable that people with haemophilia did not want to give up the freedom, safety from the fear of a fatal bleed on the brain and improved mobility that access to home treatment provided. This was a Government made, Government licensed, and funded public health emergency. It was not appropriate for the Government to ask the Society or people with haemophilia to take responsibility for saving themselves. It was the job and the responsibility of Government to protect the lives of people with haemophilia particularly if they were resistant to being protected by reason of dependency. Covid-19 has demonstrated the extent to which the public is prepared to accept restrictions on its freedoms in order to save lives. And in the 1980s, the Government demonstrated, with the Tombstone campaign, how effective was its ability to create the environment of fear necessary to persuade people to change their sexual practices in order to protect themselves from life-threatening disease.

317. By March 1983, Dr Craske, the CDC, and the UKHCDO were aware of mounting numbers of cases of AIDS. This was also apparent from the letter from Dr. Evatt to Professor Bloom dated 7 March 1982 and which the Society was not shown at the time (see paragraph 126 of these submissions). Dr Galbraith's view is a matter of record. This information was not shared with the Society.

318. In a properly run healthcare system, the evolution of an epidemic, which was unfolding at a frightening pace, and which was causing deaths to a specific section of the US population, possibly though a injected treatment, which treatment was imported from the US to the UK, and prescribed to the same section of the UK population by NHS doctors, was a matter which the responsible Minister, Lord Clarke, could and should have been informed of immediately.

319. The information about AIDS, and the information about Factor VIII transmission of Non-A Non-B Hepatitis provided at the January 1983 meeting at Heathrow,[386] could have formed the basis of an effective and persuasive information campaign directed at people with haemophilia. People with haemophilia did not have a death wish. Had Dr Evatt's letter to Professor Bloom been shared with the Society, for example, and had

[386] DHSC0001800

Government invited the Society into its tent and explained why it was planning to stop the importation of US imports until an AIDS free Factor VIII treatment was available, there is no reason to think that the Society's response would have responded with outrage and a vehement campaign for continued importation. It is much more likely that such a discussion would have led to agreement and implementation of the sort of imaginative measures that could have made life more bearable for severe haemophiliacs during the period of treatment suspension that were never contemplated, much less put in place.

320. It is distressing, and unedifying, to see the Minister of State responsible, still appearing to hold the Society in some way accountable for Government failure to act, particularly when there was so much that Government and the healthcare system knew that was hidden and misrepresented to the Society and its members.

SECTION A7: STATEMENTS ON FACTOR TREATMENTS

321. This section relates to paragraph 366 in the Inquiry's Amended List of Issues, which is, *"Why did the Haemophilia Society continue to issue statements reassuring its members that the factor treatments were safe and to continue using them?"* and paragraph 367, which is, "*What should they have advised their members to do?"*

322. The witness statement of Kate Burt summarises the position of the Society as follows:

"*Historically, the Society relied heavily on its Medical Advisory Panel and the Inquiry has heard significant evidence in respect of how the Society sought the Medical Advisory Panel's advice and relayed such advice and information to its members. Due to the limited number of haemophilia clinicians in the UK, the Society's options in respect of obtaining assistance was limited. Also, most members of the Society's Medical Advisory Panel were members of the UKHCDO. We are aware that some of our members are angry and disappointed by actions taken by the Society in the past. During the early 1980s, the Society issued statements reassuring patients that the new factor treatments were safe and to continue using them. The information we gave our*

members was based on guidance from the UKHCDO and from the government. On 27 March 2017, the Board of Trustees issued a statement on behalf of the Society in which the Society accepted that its actions and statements at the time, while well intentioned and based on expert advice, had been shown to be damaging to the community and incorrect. For this, we apologised unreservedly".[387]

323. The underlined text in the quote above continues to reflect the Society's position, and, we would submit, has been borne out by the evidence received by the Inquiry.

The Society's Statements on Factor Treatments

324. The Society's publications addressing AIDS and Factor VIII concentrates started with what later became Haemofact No 1, the letter to its members written by Professor Bloom.[388] Kate Burt acknowledged in her second witness statement:

"*The Society knows that its letter to members of 4 May 1983 (Exhibit WITN6392278) was a mistake which certainly caused a loss of trust and which may have caused harm. The Society knows that this Inquiry's report will have some hard things to say about its shortcomings. Those will make for reading that is uncomfortable but necessary*".[389]

325. The Society has reflected and acknowledges that it was not just the letter of 4 May 1983, but also the later publications which contained the same messages, that ill-served its members. They repeatedly suggested that Factor VIII concentrate might not transmit AIDS, minimised the risk of getting AIDS, and strongly asserted that the risks of untreated haemophilia greatly outweighed the risk of getting AIDS.

326. The Society respectfully refers the Inquiry to the full text of Dr Evatt's letter to Professor Bloom of 7 March 1983[390] and its letter to members of 4 May 1983[391]

[387] WITN6392001/69, paragraphs 162 to 164
[388] WITN6392278
[389] WITN6392268/18, paragraph 42
[390] BPLL0001351_021
[391] DHSC0001228

containing the information and advice Professor Bloom wrote for the Society's members. The Society could have laid the responsibility for its errors squarely at Professor Bloom's door. It has not done so. Nevertheless, the full scale of the information available to Professor Bloom which he withheld from the Society is devastating. The members of the Executive Committee who died of AIDS did so believing, and perhaps drawing comfort from the belief, that Professor Bloom had given them the best possible advice. Professor Bloom could and should have given the Society a copy of Dr Evatt's letter: it was not confidential and Professor Bloom must have known that Dr Evatt was doing everything he could to warn the people with haemophilia of the risks as he saw them. Professor Bloom should have given The Society the letter. When the Society wrote to him on 19 January 1983[392] it sought clarification on current thinking in the UK and guidance, but it is clear that it also wanted information because the aim of the early-date article the Society was saying it might ask him for, was "*so that we can keep our members in touch with the situation*".[393] This is exactly what Dr Evattt's letter would have done. His withholding of it from the Society was a gross breach of trust.

327. We will never know whether the Executive Committee would have made different decisions had it had this letter in March 1983: the fact is that both the NHF in January 1983[394] and the WFH in July 1983 had the benefit of Evatt's views when those organisations finalised their advice to people with severe haemophilia to continue to use US Factor VIII. However, it is submitted that it is likely that the Society would have published Evatt's letter in the first or second edition of the 1983 Bulletin. At a minimum, members would have been significantly better informed and better placed to make their own decisions about treatment, and UK patients and parents of patients attending Stockholm would have been better equipped to hear the warning bells that, it appears, Dr Foster alone of all the UK clinicians, scientists and other healthcare professionals, was able or willing to hear.

[392] BPLL0001351_071
[393] BPLL0001351_071
[394] ARMO0000250_002

The Society's relationship with the Medical Advisory Panel

328. To put the Inquiry's question in a proper context it is important to have regard to the explanations provided in evidence about how the Society received and assessed advice and vies, and in particular its relationship with and reliance on the Medical Advisory Panel. Although this issue is also covered in section A4 of these submissions, it may be helpful to remind the Inquiry that in his statement dated 22 April 2021,[395] , Simon Taylor (an Executive Committee Member / Trustee of the Society from 1998 to 2002) gave the following evidence about the context in which the Society relied on advice from the Medical Advisory Panel:

"I would like to bring to the Inquiry's attention a range of matters that provide a deeper context to how the Haemophilia Society acted over the period I was involved with its work.

BART0002365

The Society was always a very small charity, with limited income and resources. It was not until the appointment of David Watters in about 1980, that the Society had any full time staff.

The level of funding was severely limited, and was mostly in the form of community fundraising, such as raffles, indeed I believe that for a time the Christmas Raffle was the largest single source of income, local events, individual fundraising efforts etc. This changed somewhat as the impact of the HIV epidemic amongst the haemophilia community grew and government grants, grants from charitable trusts and commercial donations became available.

At no time was the Society in a position to pay for its own scientific and medical expertise, and so at all times it had to take on trust, the advice given to it by clinicians

BART0002365

[395] WITN4500001

and scientists within the haemophilia community. The Trustees were all lay individuals in this connection.

The Society had to make policy, and take decisions, based on the medical and scientific advice available to it as a group of lay individuals. As is frequently the case with emerging threats, this advice was frequently confusing, conflicting, incomplete and with hindsight, some of it was incorrect."[396]

329. It is respectfully submitted that this evidence is a fair and accurate description of the constraints and context within which the Society operated (and continues to operate). There is no evidence before the Inquiry that the Society had, or could have had, access to greater financial or academic/specialist resource, and – as far as we are aware – no reasonable alternative model for the receipt of advice and support has been identified or proposed before the Inquiry.

330. In his statement to the Inquiry, Peter Wetherell (who was the Local Chairman of the Cambridge branch of the Society in 1981 and an Executive Committee Member of the Society from 1983 to 1990) confirmed his belief that the "*judgement of the Executive Committee was informed by the advice of the Medical Advisory Panel at all times.*"[397] Similarly, David Watters in his statement comments:

"[52] ... I cannot recall any instances where the Society relied on its own judgement when deciding whether or not to formulate a policy on the basis of the Medical Advisory Panel's advice; or when the Society did not follow the Medical Advisory Panel's advice; or when members of the Medical Advisory Panel disagreed with the advice of the Chair of the Panel; or when the Society did not follow the advice of the Chair of the Medical Advisory Panel. As far as I recall, the situations simply did not happen. As stated at paragraph 35 above, the opinion of the Executive Committee in 1982 was that the Society would ignore the advice of the Medical Advisory Panel "at [its] peril".[398]

[396] WITN4500001/67-68, paragraphs 335 to 339
[397] WITN3912001/6, paragraph 18
[398] WITN3429001/23, Paragraph 52. Ibid, paragraph [211]

331. This is echoed in the evidence of Simon Taylor who said this in his written statement:

"None of the members of the Executive Committee or any members of staff were clinicians or scientists expert in haemophilia. Accordingly, we were highly reliant on the MAP for such opinions.

The Society did not have the expertise or resources to conduct its own scientific research or to review of scientific journals and papers. The MAP consisted of clinicians who were national, and in some cases world, experts in all aspects of haemophilia care. It is my understanding that the nature of haemophilia as a condition made it a complex interaction with other conditions such as hepatitis and orthopaedics, and thus a pure specialist in another discipline might not have the experience or expertise to advise on its presentation in haemophilia. Accordingly the MAP as experts in haemophilia were the most appropriate expert advisors that the Society could call on for advice."[399]

332. The Society would like to make clear that, notwithstanding the financial and operational constraints under which it has to act by virtue of its charitable status, that it can and should aspire to continual improvement in the quality of the flow and nature of information it receives for dissemination to its membership. In a direct response to the concern expressed regarding the information and reassurance given to patients, the Society now has a Clinical Advisory Group ("CAG"), established in 2015,[400] whose purpose is set out below:

"*The Society shall establish a Clinical Advisory Group (CAG) which shall be asked to advise on all aspects of treatment relevant to bleeding disorders. The Society shall ensure that all of its statements and publications on clinical issues are approved by an appropriate member of the CAG. Any advice received should be in a written (e-mail) form to ensure accuracy. For the avoidance of doubt, the Society shall be responsible*

[399] WITN4500001/11, Paragraph 60 to 61
[400] The Terms of Reference

for its own statements and publications. It is recognised that the United Kingdom Haemophilia Centres Doctors' Organisation (UKHCDO) is a key source for identifying and defining clinical best practice, and that the CAG should often be able to rely on published statements of the UKHCDO. The UKHCDO is invited to nominate a senior member to act as a liaison between it and the CAG."[401]

333. The following comments made by David Watters go a long way in illustrating the representative view of the Society on the wider premise of this question raised by the Inquiry:

"I have often reflected on the events that happened over 30 years ago, and it is very easy to stand back and think, "oh, you got that one wrong!". Maybe we did, but we could only act on the information that we were being provided with at the time."

SECTION A8: HIV LITIGATION

334. This section addresses paragraph 368 in the Inquiry's Amended List of Issues, which is, *"What representations were made to the Government by the Haemophilia Society in relation to the HIV litigation?"*

335. The Society was not a party to the group HIV haemophilia civil litigation which commenced in 1989, having itself made a decision to try to achieve some level of swift financial relief for those in dire and urgent need by exerting moral pressure, rather than by litigating. The evidence demonstrates that it maintained this position throughout the relevant period.

336. The reason that the Society did not litigate was that it considered that the best chance of achieving a swift and positive outcome for those infected and affected was to force the Government to accept that it had an immediate moral duty to compensate. It told the Government that it had received negative advice on the prospects of success of

[401] WITN6392001/71, paragraph 170

litigation and would therefore not be litigating, to force the Government's hand in relation to making a payment on moral grounds. The Society persisted in this approach that it was not going to sue as a result of the merits advice, but that it was still going to campaign for recompense because it regarded the Government as having a moral responsibility to meet financial need now whilst people were ill and dying. It was only by convincing Government that it was not going to go down the litigation route that the Society was able effectively and successfully to achieve recompense through the moral duty route.

337. A significant part of the impetus and urgency which informed the Society's approach to seeking compensation on moral rather than legal grounds was the immediate need for support on the part of those infected and affected. It is a self-evident truth that litigation, as well as being uncertain, takes significant time. Those suffering had a real and present need. The Rt Honourable Jeremy Hunt MP acknowledged this obvious fact in his evidence to the Inquiry.[402]

338. For context, in the early 1980's the Society, along with the newly developed Terrence Higgins Trust (founded in 1982) were one of the few sources of information, support and guidance to those infected with HIV. Little was being done by Government in this regard; whose focus was instead on public health campaigns such as the 'Tombstone' campaign, launched in 1986 by the Department of Health and Social Services. The Society continued to provide this information, support and guidance during the course of the litigation, without itself having a direct involvement in proceedings. This did enable the Society to lobby for those bringing claims, with the intended aim of increasing the available damages resource from Government.

339. The Society was aware that not all infected members qualified for Legal Aid and it focussed its efforts on campaigning for swift financial relief for the greatest possible number, in the context of many being infected or affected by a rapidly fatal illness for which there was no cure. It did so by exerting public pressure on the Government to provide recompense for people infected with HIV, rather than by litigating. To this end,

[402] Transcript of evidence of Jeremy Hunt to the Infected Blood Inquiry, 27 July 2022, T148: 9–10

number of key representations made to Government by the Society are set out in this section.

340. The Society did not intend to dissuade its membership from pursuing litigation; it did however, make public statements that the prospect of the majority of the claims succeeding was remote, with the reasons being: the difficulty of proving negligence and the difficulty of identifying the proper body or person from whom compensation might be sought.

341. David Watters provides context about the Society's relationship to the HIV litigation in his statement to this Inquiry:

[164] As I recall it, the Society's role in the HIV litigation was minimal. We provided a list of potential solicitors to those members who wanted to follow such action. We attempted to identify solicitors spread around the country.

...

[168] Throughout the entire litigation we had been at pains to show people that their relationship in relation to this was with their solicitors, and not with the Haemophilia Society (as referred to above). We were without function in relation to the litigation, as such, when people were offered settlement that had been negotiated by their lawyers, they were told that they should follow the advice of lawyers, and we could not become involved in that. On recollection, the work that had been undertaken by the Society to guide people towards accepting the settlement was simply to obtain the correct legal advice. The Society could not hold a view as to whether a settlement was fair and reasonable. It was up to individuals to hold that view.

342. In 1986, the Society sought advice from counsel about whether the Society, could bring a legal claim and the advice it received was that it would be unlikely to be able to do so.[403] The Society's position in relation to pursuing litigation on behalf of its members was set out in its 1986 Annual Report as follows:

[403] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T75: 19 – 24

"Compensation

We have taken legal advice about the position of people with haemophilia who are known to be 'HIV antibody positive', an indication that they have been in contact with the virus. Many of those in this category experience serious disadvantages regarding employment, life insurance and mortgages, as well as in their general social relationships.

It is clear from the advice we have received from Counsel that there is no case that the Society can pursue on behalf of our members, either corporately or individually. As each individual's circumstances are different it would be necessary for them to discuss their particular position with a solicitor before it can be established whether it is worth pursuing such an action through the Courts. While we sought this advice generally, and not based on any particular set of personal circumstances, we have to say that, on present known facts and upon our judgment of the advice we have received, the prospect of the majority of the claims succeeding is remote. There are two important reasons for this: the difficulty of proving negligence and the difficulty of identifying the proper body or person from whom compensation might be sought.

Meanwhile, we are continuing to present to the Government the very special needs of people with haemophilia with regard to such matters as life insurance and mortgages. We shall press for some special recompense for the benefit of our members who have been diagnosed as 'HIV positive".[404]

343. An edition of the Society's publication, 'Haemofact' dated 13 May 1987 sets out the Society's position regarding compensation for people with haemophilia who have become HIV positive as a result of receiving contaminated blood products.[405] The Society's position was:

[404] HCDO0000276_033/7–8
[405] HCDO0000279_025/2

a. that people with haemophilia who are HIV positive deserve special financial support from the Government
b. the Government has a "clear moral duty to provide recompense"
c. the extent of the problem would have been considerably reduced if successive Governments had honoured their pledges to make the UK self-sufficient and if steps had been taken sooner to screen blood donations and heat-treat products.[406]

344. The same document sets out the various steps the Society would take to persuade Government to pay a special financial benefit to those people with haemophilia who have been affected by HIV.[407] David Watters confirmed that this document accurately described the decision and steps the Society had decided to undertake to try and secure compensation from Government, noting that "we were immediately discouraged from using the word "compensation" and instead using the word "recompense" because compensation would imply liability".[408]

345. A paper dated October 1987 titled 'AIDS, Haemophilia and the Government, A submission from the Haemophilia Society calling for financial provision for people with haemophilia infected with the AIDS virus'[409] summarised the steps being taken in relation to AIDS, haemophilia and representations made to Government:

"We are asking the Government to help restore the quality of life of people with haemophilia and HIV infection.

At Government's suggestion the Society has already explored the question of redress through the legal system and has been advised that claims for compensation as such are most unlikely to succeed because of the difficulty of proving negligence. In any case, the Society is advised that any solution which may be provided by the courts will not be available in the short term. However, the needs of families are immediate.

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[406] HCDO0000279_025/2
[407] HCDO0000279_025/2 – 3
[408] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T76: 7 – T78: 7
[409] HSOC0003459

The Society is therefore looking to Government as the only available source of support, recognition and recompense."[410]

346. David Watters was asked by Counsel to the Inquiry why the Society shared the outcome of its advice with the Government that claims are most unlikely to succeed. Mr Watters responded, *"I think we did -- this is, you know, my thought today looking at it, it wasn't necessarily the fact on the day itself. I think we did it to increase the urgency of the situation for some kind of settlement to help with the predicament that we were finding individuals and families in. I mean, elsewhere, you'll see that the Society had expended £23,000 of its own money prior to anything else becoming available and that, in those days, was absolutely unsustainable as an ongoing process to help people with their immediate financial problems."*[411]

347. A Society publication dated June 1989 records that the Society would be launching a new campaign designed to achieve an out-of-court settlement of compensation from the Government.[412] It refers to the Society's investigation of the legal position of claims for compensation and advice received *"that cases should proceed on an individual basis. Some 250 individuals have started actions during the last two years. The Society has now reviewed the situation, and it's our belief that the Government must recognise the need for compensation now, rather than in five to ten years' time."* At this point in time, the Society had led a compensation campaign which resulted in a £10 million fund provided by the Government to the Society, which led to the initial establishment of the Macfarlane Trust.[413] David Watters confirmed that by 1989, the Society had formed the view that this was not enough, and were voicing support for the individual litigation that has been brough by a number of patients. His recall was that, *"the pursuit of litigation was somehow orchestrated by us. It was certainly aided and facilitated by us through knowing experienced lawyers in similar cases around the country and things like that."*[414]

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[410] HSOC0003459/1
[411] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T79: 22 – T80: 7
[412] HCDO0000276_047
[413] HCDO0000276_047/1
[414] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February, T82: 8 – T84: 11

348. A briefing paper on Haemophilia and AIDS prepared by the Society dated October 1989[415] explains that a reason why the Society did not pursue litigation was that Legal Aid was only available to some infected members – others would have to pay legal fees privately and could not afford it. The Society therefore focussed its efforts on campaigning for speedy financial relief for the greatest possible number, in the context of many being infected or affected by a rapidly fatal illness for which there was no cure.

349. In its 1989 Annual report,[416] the Society reported on its campaign to lobby Government to settle claims out of court as follows:

The greatest concerns facing the Society for the past seven years have been associated with HIV infection acquired through the use of contaminated factor VIII. Despite the creation of the Macfarlane Trust in 1988 to meet the immediate needs of people with haemophilia and HIV, the Society has always been of the view that those who had been so tragically infected should have a measure of control over their own financial affairs.

It was with this in mind that a campaign was launched during 1989 to persuade the Government to settle, out of Court, the many claims for compensation which had started in the High Court. This disaster – the greatest tragedy in the history of the National Health Service – demands the utmost compassion by Government. While their immediate response with a grant of £24m, to enable each infected person with haemophilia to receive £20,000, was welcome, it did not meet the main thrust of the campaign.

The Society was fortunate in having the services of GJW Government Relations, who made an invaluable contribution of free advice and manpower. Many MPs from both sides of the House gave their support and thanks are most especially due to Robert Key, Frank Field, Patrick Cormack, Jack Ashley, Alf Morris, Geoffrey Johnson-Smith, Emma Nicholson, John Hannam, Sir Michael McNair-Wilson, Sir Bernard Baine, Sir

[415] LDOW0000295
[416] WITN6392033

Russell Johnson and John Marshall for their encouragement. The help of The Sunday Times was also important and greatly valued.

350. On 24 October 1990, David Watters wrote an urgent letter to all Society members.[417] It referred to media speculation about the possibility of an out-of-court settlement:

"It is being implied that negotiations are taking place between lawyers representing both sides – i.e. YOUR lawyers and the Government lawyers – to establish an acceptable out-of-court settlement. The Haemophilia Society is not and cannot be involved in those negotiations. If they are taking place, they are being held between the lawyers and any level of settlement will be determined by them and the court. It is therefore important that you get in touch with your lawyer in that connection… The role of the Society throughout has been to make it politically expedient for the Government to settle our case out of court now rather than in three or four years' time. The other point, of course, is that money paid out now is guaranteed, whereas there is certainly no guarantees associated with the final outcome of the legal case."[418]

351. David Watters commented that the purpose of writing this letter, *"I remember the letter and political expediency was always something that we had on our map because it's political expediency that makes Governments move in things, and settling out of court, I may as well have said now rather than in 34 years' time, because that's where we are today and there has still been no real settlement, no meaningful settlement, by Government."*[419] It is submitted that this evidence should be accepted.

352. On 9 November 1989, David Watters and Rev. Alan Tanner met with Strachan Heppell from the Department of Health. The Society's position was set out in Mr Heppell's record of the meeting:

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[417] RFLT0000004
[418] RFLT0000004
[419] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T91: 21 – T92:7

2. The Society is interested in promoting an out of Court settlement as the Court action is likely to drag on over a number of years and any compensation awarded would come too late for many of their members.

3. The Society would commend a settlement to its members but only if the amount were sufficient to win the support of the plaintiffs solicitors. The Society has been criticised by some for accepting an inadequate £10 million for the Macfarlane Trust and they do not want to be put in the same position again. Their aim is to obtain compensation but they would be happy not to call it that as they recognise the difficulties for Government in making any payment which implied acceptance of any liability on its part, on the part of the NHS or on the part of Committee of Safety on Medicines

...

5. The plaintiffs have seen press reports of payments in other countries, usually the generous end of the scale, and this has raised expectations. The Society's present view, having consulted lawyers, is that a sum of GBP 120 million - on average around GBP 100,000 a case - would be required to bring legal action to an end...[420]

353. David Watters accepted that this record of the meeting was *"broadly accurate"* with the caveat that, *"The plaintiffs have seen press reports of payments in other countries, usually the generous end of the scale, and this has raised expectations. The Society's present view, having consulted lawyers, is that a sum of GBP 120 million - on average around GBP 100,000 a case - would be required to bring legal action to an end."*[421] He confirmed in evidence that the Society was not making a formal offer to settle litigation but was suggesting a ballpark figure that it thought the Government should consider that the Society might feel able to recommend to its members. He elaborated in relation to consultation with lawyers that, *"The lawyers representing litigants with haemophilia came from across the country and they formed a steering group, and that steering group would communicate with us and we would communicate with the steering group, and this would have been a figure that emerged from a conversation with the steering group of lawyers."*[422]

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[420] DHSC0004415_155/1-2
[421] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T4: 12 – T17
[422] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T5: 23 – T6: 6

354. David Watters agreed with Counsel to the Inquiry that during the above-mentioned meeting, what was being conveyed in point 7 of the document about the Government's position, *"was aimed at discouraging the Society from expecting too much by way of an offer from the Government"*. He said, *"That was indeed the impression of the meeting, yes. It was going to be the minimum possible buy-off, as indeed the initial 10 million had been."*[423] He commented further that, "*I would say that the Society at this point were between a very hard rock and a hard place because we were getting phone calls from people saying: My husband's died, I can't feed the children. How am I going to get shoes? I need to visit my husband in hospital. There's no public transport. I need a car. And requests -- heart-breaking requests like that -- that we couldn't possibly meet from our own extremely limited funds, which is why we were so keen to see something additional that would help people with haemophilia take charge of their own lives rather than have to go with a begging bowl to a charitable trust every time they needed something and justify themselves and fill in forms and so on.*"[424]

355. David Watters did not have any recollection of a phone call which is referred to in a document dated 16 November 1989 that says the Society had *"consulted its lawyers and the sum of £86 million – on average around £71,000 a case – would be required to bring legal action to an end"*.[425] Mr Watters said, *"It's the sort of thing one wouldn't do in a phone call."*[426] The same sum is referred to in a briefing for a meeting between the Prime Minister, and Robert Key and Society representatives regarding Haemophiliacs with HIV infection, dated 22 November 1989:

'Out of Court Settlement

8. We know the Haemophilia Society were advised around March 1987 against pursuing legal action. They are however pressing for compensation out of court, and have suggested that a settlement of £86m would be appropriate; this would average

[423] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T7: 17-24
[424] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T8: 3-17
[425] Transcript of evidence of David Watters to the Infected Blood Inquiry, 12 February 2021, T6: 7–14; DHSC0002536_061
[426] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T92: 8 – T93: 9

about £71,000 per case. Any out of court settlement of the litigation would carry with it a tacit admission of negligence and could set an unacceptable precedent by implying NHS liability for treatment which reflects the best available medical information at the time but turns out later to be wrong. The implication of liability could also undermine the medicines licensing system. The Licensing Authority (i.e. UK Health Ministers) and the Advisory Committees have been involved in a number of court actions. They have consistently denied liability and resisted any moves towards any out of court settlement. Any such move could encourage further litigation and expectations of similar settlements. Constant litigation would be damaging to the integrity of the licensing system, could lead to over defensive licensing decisions and could lead to problems in attracting members to sit on advisory committees. For these reasons Health Ministers are not considering an out of court settlement. Legal advice is that it would be inappropriate to comment on whether the Government is prepared to consider compromising the court proceedings by offering an out of court settlement."[427]

356. The citing of figures being put forward by the Society to Government is at odds with information set out in letter dated 3 November 1990, written by Andy Cowe to the then Secretary of State, The Rt. Hon. William Waldegrave MP setting out the Society's position with respect to the HIV litigation:

"...I also want to take this opportunity to correct some false impressions which appear to be present within the thinking of the Department in relation to people with haemophilia and HIV who are seeking compensation. The most serious of those relates to the fact that it has been alleged from within the Department that 'The Haemophilia Society' has named an acceptable sum for an out of court settlement. This is not the case: our position is very simply this - we have not, nor do we intend to, put forward a settlement figure. Proposals of this nature are entirely for the lawyers acting for those plaintiffs who are pursuing a claim for legal compensation. It must also be pointed out that those who are pursuing this course are doing so at the behest of the Government who have, again and again, insisted that this was the only course available to those

[427] WITN6392101/4-5

seeking compensation: those who have chosen this route have done so because of Government policy.

It has been open to the Government since 1986 to settle this matter in an open-handed manner without the need for litigation: the matter only became one of public and political interest because of the piece meal fashion in which the Government has chosen to deal with it. Contrary to the view which has been expressed by the Department in recent weeks I would want to quietly remind you that the payments which have so far been made to the Macfarlane Trust have only been made as a result of very hard campaigning by ourselves. This, in turn, generated widespread political and public support. It is also surprising that, in recent weeks, those 'ex-gratia' payments have suddenly become payments made from a sense of moral responsibility.

We believe that there is a great deal to be gained on both sides by an out of court settlement - not least for people with haemophilia themselves: they are currently dying at the rate of at least one a week and that, of itself, is a telling factor about the overall urgency of our unique situation. However, more importantly for you, and for the Department, it would mean that a settlement could be made without any admission of liability for negligence.

It is also, in our view, most unfair that the Department should continue to make direct comparisons between people with cancers, heart conditions, renal failures, etc; and people with haemophilia and HIV. None of those people acquired -their condition as a result of treatment prescribed by the NHS. It is this fact which makes the position of our affected members so tragically unique.

We are deeply concerned that there now appears to be little or no negotiating taking place between yourselves and the plaintiff's lawyers. We are giving active consideration to the possible role of an intermediary to look at a constructive way out of the impasse which exists between the two sides. We would welcome your early response to this suggestion so that the matter might be progressed if you feel that it would be helpful."[428]

[428] WITN6392102/2-3

357. David Watters gave evidence consistent with the abovementioned document; it was his understanding that it was not the Society's role to participate in the settlement negotiations or to put forward settlement sums.[429] Mr Watters gave evidence that the Society's frustrations and concerns about the Government's stance at the time were that, *"we were deeply frustrated because the grant of £10 million, which was a reasonable sum of money -- I think in those days it would have bought a 737 airliner or something -- it was really a cynical attempt by the Government to dismiss us and put us off the scent for all time, and I'm very proud of the fact that that was not the case. We did not accept a £10 million one-off payment as being something that would meet the needs for all time of people who were so sadly impacted upon by this dreadful disease."*[430]

358. Although there is conflicting evidence before the Inquiry about whether figures were put forward by the Society in relation to settlement of the HIV litigation, it is submitted that the purpose of the discussion of any sum between the Society and Government was for not for the purpose of making a formal offer to settle litigation but to suggest a ballpark figure that it thought the Government should consider that the Society might feel able to recommend to its members.

359. A press notice was issued by the Society on 11 November 1990 reacting to the Government's announcement by the Government that £42m is to be made available to people with Haemophilia and HIV:

"We welcome the fact that the Government have finally recognised a greater responsibility to people with haemophilia and regret that by deferring that decision for so long a great deal of [personal] anguish and suffering has been caused to so many of our members… It is a triumph for a caring prime Minister and Secretary of State for Health. John Major and William Waldegrave are to be applauded for addressing this problem so promptly - it is unfortunate the settlement has been so low… We are naturally very disappointed with the level of the proposed settlement. It means that each

[429] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T96: 1 – 10
[430] Transcript of evidence of David Watters to the Infected Blood Inquiry, 11 February 2021, T96: 20 – T97: 4

of the 217 claimants will receive an average payment of £35,000'. This is a settlement which has been agreed between both the claimants and the Government's lawyers and is naturally one which we have to accept."[431]

360. Lord Waldegrave gave evidence to the Inquiry that he was aware of the Society's view that the settlement was too low.[432] When asked whether this caused any pause for reflection, he said, *"Well, I think what dominated my mind at the time was first of all obviously that the proposal had come from the victims' lawyers, and secondly, some benchmarking against what was happening in other countries, and that I think led me and others to think that this was a fair settlement, though clearly, as I say in the letter, not compensation, but a fair and settlement which stood reasonably well in comparison to other countries and to what the lawyers themselves had suggested."*[433] The Society disagrees with Lord Waldegrave's characterisation and maintains that the sum was too low.

SECTION A9: ADVICE OR INFORMATION PROVIDED ABOUT HEPATITIS

361. This section relates to paragraph 370 in the Inquiry's Amended List of Issues, which is *"What advice or information was provided by the Haemophilia Society to members about the risks of or seriousness of hepatitis and was it appropriate?"*

362. The Society submits that the evidence before the Inquiry demonstrates that it did engage regularly with and publicly reported to its members on issues related to Hepatitis.

363. The Society passed on information and views informed by the sway of medical opinion as it was at the time; importantly, it has not and will not provide any medical, diagnosis or treatment advice.[434] The Society's knowledge grew and opinion changed over time as to the risk associated to hepatitis, and this is reflected in communications issued to the membership over the period.

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[431] HSOC0012313/1
[432] Transcript of evidence of Lord William Waldegrave to the Infected Blood Inquiry, 6 July 2022, T52: 2–5
[433] Transcript of evidence of Lord William Waldegrave to the Infected Blood Inquiry, 6 July 2022, T52: 8–16
[434] https://haemophilia.org.uk/resources/

364. The Society acknowledges that with hindsight a limited number of its early publications did appear to downplay the risks associated to Non-A Non-B Hepatitis, but that reflected wider medical views at the time rather than a misinterpretation of these by the Society. This is illustrated by Mr David Watters' evidence to the Inquiry on 9 February 2021; Jenni Richards KC addressed what Mr Watters agreed was most likely the first reference to Non-A Non-B hepatitis in a Society Bulletin in 1982, that being the reproduction in The Bulletin of an article published by Andrew Veitch in the Guardian on 5 August 1981.[435] It was Mr Watters' position that Non-A, Non-B Hepatitis was not at the forefront of the Society's mind at this time because of the Society's understanding that it was a mild condition.[436] As reflected in communications to the membership, at the time, the focus was on disability support and the introduction of home therapy.

365. As set out in the second written statement of Kate Burt, between 1983 and 2003, the Society prepared and circulated various publications to its members with advice and information concerning Hepatitis C:

"The long list of publications referred to above, coupled with the extensive (but certainly not exhaustive) actions described above, indicate to me that the Society has for the past 30 years, been continually engaged with the issue of people with bleeding disorders being infected with HIV and Hepatitis C."[437]

366. The dissemination of information about Hepatitis by the Society is demonstrated in documents dating back to the early 1980s. For example, a Society publication dated February 1983 titled "Group Seminar Proceedings" records that a group seminar was held from 12-14 March 1982.[438] This document reports on highlights from the workshops at the seminar and includes articles written by some of the speakers. At page 2, there is an article by Dr Brian Colvin titled "Haemophilia the State of Play 1982". In a section headed "Hepatitis", Dr Colvin sets out his understanding of the "state of play"

[435] BART0002327_001/6
[436] Transcript of evidence of David Watters to the Infected Blood Inquiry, 9 February 2021, T83: 5-20
[437] WITN6392268/54-56, Paragraphs 117-118
[438] BART0002325

regarding Hepatitis C at the time. He states that hepatitis is caused by concentrate, discusses the Non-A Non-B variety of hepatitis, says that, "*there is growing evidence that mild inflammation of the liver can continue after clinical recovery and the long term consequences of this are not yet clear", and notes that research is taking place to produce "a low hepatitis risk commercial factor IX concentrate".*

367. The Society's May 1991 Edition of The Bulletin[439] contains an article entitled "Haemophilia and Liver Disease" by Dr C.R.M Hay, Director of the Mersey Region Haemophilia Centre. Through this document, the Society provides its members with a detailed analysis of transfusion transmitted viruses, including information about Acute Non-A and Non-B Hepatitis; haemophilic liver disease; prevention and treatment.

368. The Treasurer's Statement in the Society's 1992 "Annual Report and Accounts"[440] states, "*As we reported in our Review of 1991 the large numbers of hepatitis infections in the past was a source of major concern. There have been no new infections since 1986/7 but it remains important to ensure that blood products in the UK are safe from hepatitis in all its forms. Important work is being carried out on treatment with Interferon and the future could be brighter for some of those infected, although unfortunately some have already died. Our role continues to be keeping everyone up to date with developments surrounding hepatitis."*

369. Notes of a meeting of the Hepatitis Task Group on 16 September 1993 record that it was agreed *"that the most valuable roles which could be provided by the Society lay in the provision of accurate and up to the minute advice and information and an ongoing lobby to ensure the very best levels of treatment and care of people with haemophilia and hepatitis in any/all its forms along with support for those who are and become ill*."[441] The Society placed importance on the publication of a hepatitis booklet and planned meetings around the UK related to publication of the booklet which was

[439] WITN4500004/2-3
[440] HCDO0000279_033/5
[441] HSOC0003289/1

discussed at Executive Committee Meetings which took place on 29 to 31 October 1993.[442]

370. The Society published articles on various topics related to Hepatitis C. By way of example, in The Society's November 1993 Edition of The Bulletin,[443] there is an article dealing with the transmission of Hepatitis C and HIV to family members titled *"Viral Transmission of Hepatitis C and HIV in partners of people with haemophilia"*. The article provides an update on research by Dr Telfer at the Royal Free Hospital which concluded that heterosexual partners of haemophilia patients do not carry an exaggerated risk of Hepatitis C infection. At page 12 of the same edition of The Bulletin, there is an update on "Haemophilia and Hepatitis C" from the British Society for Haematology annual scientific meeting.

371. On the front page of the Society's April 1994 edition of The Bulletin[444] there is an article titled *"Hepatitis C – A cause for concern?"* written by Simon Taylor. In the opening paragraph, Mr Taylor comments that, *"It is now clear, with the advent of the [Hepatitis C] test, that virtually everyone who has been treated with clotting factor concentrates, prior to the introduction of processes such as heat treatment to destroy viruses in the mid-1980s will have come into contact with the hepatitis C virus"*.

372. The article goes on to describe some of the Society's work at the time with regard to hepatitis, *"The Haemophilia Society is following developments in hepatitis closely, liaising with our medical advisers and encouraging the provision of more information and research. On Saturday 12 March, the Society held the first of what may be a series of meetings devoted to hepatitis. Dr Christine Lee from the Royal Free Hospital, gave a talk and answered questions on the issue. In addition the Society has published a booklet on hepatitis which is freely available by contacting the Society's office.*"

373. During an Executive Committee meeting of the Society held on 7 May 1994, an update was provided that following this announcement in the Bulletin (which generated a good

[442] HSOC0023737/3
[443] HSOC0022994/4
[444] HSOC0022991/1

response with members contacting their local Centres), a second Hepatitis meeting was arranged for Saturday 21 May in Leeds attended by guest speakers.[445]

374. In the editorial section of the Society's October 1994 edition of The Bulletin,[446] Andy Cowe, editor of The Bulletin at the time, commented on the limited medical knowledge of Hepatitis C and its effects:

"Medical knowledge of the hepatitis C virus (HCV) and its effects is still at an early stage and much work remains to be done in identifying the progression of liver damage caused by the HCV and in developing treatments. The Society is actively seeking to spread the knowledge which does exist."[447]

375. This statement acknowledges that the role of the Society was to accumulate and pass on existing knowledge and information.

376. In the same section, Mr Cowe goes on to introduce the article at page 8 of the publication – which is a whole page dedicated to a Q&A about Hepatitis C by Dr Mike Makris. Again, he refers to the Society's dedication to keeping its members updated about the latest information in this area:

"*Dr Mike Makris' article on page 8 and 9 provides a valuable set of answers to some of the most important questions in this area. The Society is pledged to keep our members and readers of the Bulletin up-to-date with the latest additions to knowledge in this field.*"[448]

[445] HSOC0000447/3
[446] HSOC0023000/2
[447] HSOC0023000/2
[448] HSOC0023000/7

377. Dr Makris' article notes that the *"Hepatitis Days held up and down the country to inform people with haemophilia about hepatitis C were very well received by those attending"*.[449]

378. A minute of the meeting of the Society's Services Committee on 10 November 1994[450] records differing opinions given by Executive Committee members about a proposal from the Hepatitis Task Group for a Hepatitis C publicity campaign. During these discussions, Mark Winter raised the issue of the complexity of Hepatitis C and stated that there is not sufficient knowledge about it. His view was that increasing public awareness creates a risk of causing panic and discrimination. It was his view that the Society should discuss the issue with the Department of Health, and its priority should be to seek the best medical advice for its members, which should include funding research and making sure that members are counselled on diagnosis.

379. The discussions during this meeting and the publication of the abovementioned documents demonstrate the time and effort committed by those at the Society to ensure members were provided with timely and proper advice with regards to Hepatitis C, but also serves to illustrate the difficulties experienced in providing information to its members in a balanced and proportionate way.

380. In response to a question from Counsel to the Inquiry, Jenni Richards KC, Professor Gordon Lowe (Glasgow Haemophilia Centre Co-Director from 1990 to 2009) spoke of "*a very active Scottish branch of The Haemophilia Society"* where a talk was given to patients on the topic of hepatitis in around March 1980, by Dr Alistair Parker.[451] In his evidence to the Inquiry on 11 December 2020, Professor Lowe confirmed that patients (at Glasgow Royal Infirmary) were always encouraged to take away information leaflets which gave patients the current information on the different types of hepatitis and the tests available.[452] The Society submits that this is evidence that demonstrates it

[449] HSOC0023000/7
[450] HSOC00233531-3
[451] Transcript of evidence of Professor Gordon Lowe to the Infected Blood Inquiry, 9 December 2020, T111: 5-21
[452] Transcript of evidence of Professor Gordon Low to the Infected Blood Inquiry, 11 December 2020, T11: 6-14

was regarded by clinicians in the field to be a credible and reliable source of information on hepatitis.

381. During Dr Mark Winter's evidence to the Inquiry on 1 October 2020, in response to a question concerning his understanding of the reasons for patients expressing a preference for British concentrate, Dr Winter described the close knit community of haemophilia patients who are all encouraged to interact with the Haemophilia Society. He said, *"The Haemophilia Society used to produce lots of written information for them and we used to have these residential seminars. Once or twice a year, there would be a national seminar and we very much encouraged our patients to go. The weekends were free and they were of great benefit to the patients. They could be given lectures by doctors or nurses about matters of interest. There would be little workshops they could go and attend."* He spoke of the strong feeling amongst the British Haemophilia Society population of American Factor VIII being bad and considered that a lot of that came from publications from the Society, or it came from these residential weekends and meeting other patients.[453] Later, he went on to clarify that the perception that British Factor VIII was less likely to transmit viruses was in respect of hepatitis. He said there was *"nothing known about AIDS"* at that time.[454]

382. During the Inquiry's presentation of the Cardiff Haemophilia Centre on 8 October 2020, Jenni Richards KC, took Sir Brian to relevant excerpts of Professor Bloom's litigation report.[455] In this report, Professor Bloom says, *"Representatives of The Haemophilia Society were regularly present at HCD meetings at which hepatitis was always discussed. Reference to hepatitis was included in the book 'Living with Haemophilia' by Dr Peter Jones, a book intended for patients and relatives and published in 1974."*[456]

383. As expressed in Kate Burt's statement of 25 August 2022 to the Inquiry, the Society submits that, *"The Society has for the past 30 years, been continually engaged with the issue of people with bleeding disorders being infected with HIV and Hepatitis C. It is*

[453] Transcript of evidence of Dr Mark Winter to the Infected Blood Inquiry, 1 October 2020, T28: 4 – T29: 3
[454] Transcript of evidence of Dr Mark Winter to the Infected Blood Inquiry, 1 October 2020, T29: 17-22
[455] DHSC0001297
[456] DHSC0001297/74

clear from the selection of references and documents set out above that The Society has been determined to campaign, advocate and fight to enable the voices of people with Hepatitis C or AIDS/HIV to be heard by Government decisions makers, the courts and the wider community."[457]

[457] WITN6392268/56, paragraph 118

SECTION B: SUBMISSIONS AS TO FACTUAL FINDINGS IN RELATION TO OTHER TOPICS

384. This section addresses some of topics that the Chair has noted he would find most useful for core participants and recognised legal representatives to focus on in their final written submissions. The suggested topics are listed at paragraphs 8 to 13 of the "Further Note" dated 30 May 2022 ("the Chair's "Further Note" on Closing Submissions"), attached to the Inquiry's Statement of Approach – Submissions at the end of oral evidence.[458]

385. This Society's submissions in this section have been informed by the responses of 64 of the Society's members to a survey asking for the membership's views on the topics listed in the Chair's "Further Note" on Closing Submissions ("the Society's survey on closing submissions"). A number of the responses are quoted in this section so as to reflect the views of the membership base. All of the responses were carefully considered and the Society has drawn on these responses to identify areas where there is a particular strength of feeling across the membership, and/or where a point raised can be supported by evidence that the Inquiry has heard. In preparing this submission, it has been a key consideration for the Society that it understands the priorities of its membership. With this in mind, Section B will address the following topics, these appearing to have the highest priority assessed through the survey responses:

a. Response of Governments;
b. Consent, communication, candour and transparency;
c. Viral Inactivation;
d. Treatment, care and support;
e. Self-sufficiency; and
f. Decision-making of the Committee on the Safety of Medicines and its Biologicals Sub-Committee.

[458] See 2022-05-30 Statement of Approach - Submissions at the end of the oral evidence (infectedbloodinquiry.org.uk)

SECTION B1: RESPONSE OF GOVERNMENTS

386. In this Section, the Society makes a number of observations on the issue of the nature, the adequacy and the timeliness of the Government response. Before doing so, it wishes to highlight the views of two respondents to the Society's survey on closing submissions.

387. In response to the question posed, *"Do you have any comments about the topic of the response of governments",* one member said:

"The delay and obfuscation of successive governments need to be highlighted. Ongoing publicity, rather than apologies, is the best antidote to future similar problems."

388. In response to the same question, another member said:

"Whilst individual ministers have been sympathetic and actively supportive of the plight of those infected and affected by contaminated blood products, I feel the response of governments generally has been poor at best and negligent at worst. It has felt to me that haemophiliacs in particular have presented as an expensive burden to the health and care system and at a time when a relatively small (but one would be too many) section of society has been desperate for recognition, acknowledgement and support, ministers have been caught like rabbits in the headlights. The collateral for offering adequate and appropriate support for fear of implication of blame, escalating expense and scandal has been prioritised over a very real and desperate human need."

389. The Society echoes the above views of its membership, and also makes the following observations about the nature, adequacy and timeliness of the Government response:

a. There was a deep-rooted stance by Government to only look for scientific proof of the HIV crisis rather than to appreciate the unfolding risk and to make an assessment of potential harm to those impacted. There was no real questioning as to whether this was the right decision.

b. There was a slow response to provide support, for all categories of infected people notwithstanding years of campaigning, and this is still true today. There is also a lack of regard for the infected community that still continues.
c. There was a lack of investment in research into the long term effects of HIV despite calls from the medical community for support.
d. There was a slowness to approve provision to buy safer blood products for all as they became available. There were delays in access to products to treat infections.
e. Devolution had an impact on equality across the nations.

390. Flowing from these observations, the Society submits that:
a. Government should have responded earlier for the calls for a statutory public inquiry;
b. Government should not have required individuals with haemophilia to sign a waiver in 1991 intended to block legal redress in the event of infection with Hepatitis C from NHS blood products after a Hepatitis C test was completed;
c. the Government was reluctant to settle the HIV haemophilia litigation; it was too concerned about accepting blame for negligence and did not accept its clear moral duty to provide recompense;
d. Government failed in its duty of care to citizens; and
e. Government ignored pleas from the community for support and did not respond in providing adequate treatment and funds for research into HIV and AIDS.

391. In the balance of this section, the Society draws the Inquiry's attention evidence to support the abovementioned submissions.

UK Government should have responded earlier for the calls for a statutory public inquiry

392. The Society submits that Government should have responded sooner to calls for a statutory public inquiry. Instead, issues of concern to the infected and affected community have been overlooked by successive Governments of different political persuasions. The eventual establishment of a public inquiry came decades too late, when many of those affected are no longer with us.

393. These are not new criticisms; the Society raised the issues in its oral opening submission to this Inquiry:

"...more than 30 years ago the Haemophilia Society called upon Government to launch a public inquiry into the infection of those thousands of its members with contaminated blood and blood products, and what has been correctly termed during the course of the past two days "the worst treatment disaster in the history of the NHS.

The Society demanded an immediate humanitarian response by government. After decades, and what I can only term an unconscionable delay, at least 2,400 people have died and many thousands more, who were needlessly exposed to Hepatitis C and HIV, continue to suffer with life changing consequences. Those persons, as I have indicated, have lived quiet lives of desperation, endured decimated futures and indeed suffered destruction of life itself. Eventually, government has finally begun to listen and has established this Inquiry.

It should be remembered the first duty of any government, in any jurisdiction, is to protect its citizens. If government fails in that duty, its secondary duty must be to do all in its power to redress the initial wrong. Yet, in the circumstances of person infected and affected by receipt of contaminated blood and blood products, government has consistently looked the other way and, indeed, refused to acknowledge the true scale of the personal and humanitarian disaster.

It has been complicit in the covering up of this immense human tragedy. For over 30 years various governments in this country have refused, neglected and omitted to put right its wrong. For that time the haemophiliac community and the whole blood community have had to fight unnecessary battles whilst suffering the devastating effects of terminal illnesses. It should be remembered those illnesses have connotations of stigmatisation and ostracisation..."[459]

[459] Transcript of Preliminary Hearing of the Infected Blood Inquiry, 26 September 2018, T89: 4 – T90: 14

394. These submissions have been borne out by the evidence the Inquiry has heard. The Society draws to the Inquiry's attention, the evidence of Bruce Norval,[460] whose experience as an infected and affected campaigner illustrates the individual tragedy of the infected blood disaster and also encapsulates the value of this public inquiry:

"I regard myself now as an expert patient and think it is reasonable to regard myself in this way. I can narrate the history of this disaster, not because I wrote it, but because I lived it and I have worked to understand it. I was there at the beginning of this campaign and I am one of the few fortunate ones to still be alive at the end of it. There are few of us that fulfil that criteria. I think it is important that the voices and questions of campaigners are heard within this Inquiry, that the reasonable questions that we have all asked for decades are finally addressed and that this Inquiry is willing to hear from people like me who will challenge it, who will ask questions of it, and who will push it. Also, my campaigning has meant that I have been in contact with many people, many friends who are no longer with us. I feel that I can tell their stories as well as mine and that their stories also need to be heard."[461]

395. The Society also draws to the Inquiry's attention references in the first statement of Kate Burt illustrating its tireless campaigning efforts in calling for a public inquiry, which were ignored for many years by government.[462]

396. It also draws to the Inquiry's attention the summary of efforts in relation to campaigning for a public inquiry, as set out in in its first submission to the independent public inquiry set up in March 2007, chaired by Rt Hon Lord Peter Archer of Sandwell QC ("the Archer Inquiry").[463]

[460] WITN2235001; WITN2235003: Transcript of evidence to the Infected Blood Inquiry of Bruce Norval, 9 June 2021
[461] WITN2235001/42, paragraph 123; Transcript of evidence to the Infected Blood Inquiry of Bruce Norval, 9 June 2021, T3: 8-25
[462] WITN6392001/49-50, paragraphs 107 to 112
[463] ARCH0001232/31–35

UK Government should not have required individuals with haemophilia to sign a waiver in 1991

397. In 1991, on settlement of the HIV haemophilia litigation, plaintiffs involved in the litigation were required to sign a Deed of Undertaking (often referred to as a "waiver") not to pursue any further legal action against the Department of Health or other defendants with respect to infection with any other viruses contracted through contaminated blood products.

398. On 4 May 2006, Caroline Flint (who was at the time serving as Secretary of State for Health) was asked, "*whether her Department (a) asked and (b) required individuals with haemophilia to sign a waiver in 1991 intended to block legal redress in the event of infection with hepatitis C from NHS blood products after a hepatitis C test was completed; and if she will make a statement*".[464] Ms Flint responded, *"In 1988, a special payments scheme was introduced for haemophiliacs infected with HIV through blood products. This scheme is administered by the Macfarlane Trust. In 1991, as part of a settlement of court proceedings a further lump sum payment was made under the scheme for haemophilia patients infected with HIV. From that time, all beneficiaries of the Trust have been required to sign a waiver undertaking not to take legal action against the Department or any other public body in respect of infection from HIV, or hepatitis viruses. It is usual in litigation that when a settlement is reached, claimants cannot then reopen proceedings"*. [465]

399. The Society repeats the submission made in its first submission to the Archer Inquiry, that, *"[t]his waiver is controversial because many people with haemophilia believe that the Government knew at the time that non-A, non-B hepatitis was widespread in the haemophilia community. Many patients say they were tested in secret in the 1980s but not told of the results for up to a decade."*[466]

400. The Society submits that the waiver was a cynical attempt by the Government to shut down further support or recompense in an area that little was known about, especially

[464] CBCA0000045/8
[465] CBCA0000045/8
[466] ARCH0001232/38

for those who were directly infected (and not aware) at the time. Karin Pappenheim summarised the position well in her letter to Lord Morris in June 1999:

"The Government at that time did not explain its reasons for not including Hepatitis C in the original financial assistance scheme established for the haemophilia community. One reason for not including HCV could have been that the virus was not formally identified as Hepatitis C until 1989, previously being referred to as 'non-A, non-B' hepatitis, and a test for it was only introduced in 1991. However, this had changed by 1991 when Government made a further ex gratia payment of £42million to avoid litigation and then required individuals to sign a waiver covering both HIV and hepatitis C. That waiver is surely evidence that the last Government saw the potential for an equally strong case being argued for recompense for people with haemophilia who had been infected with Hepatitis C, in the same way as those infected with HIV via contaminated blood products.

As you know the feelings of injustice and anger in the haemophilia community are very strong on this issue. To our members this waiver suggests the Government at that time appreciated the seriousness of Hepatitis C, but was more concerned to deny liability and distance itself from responsibility than to ensure a fair and humane response to patients who had suffered a devastating infection via their NHS treatment. The effect of the waiver is to seek to deny people with haemophilia and Hepatitis C the chance of recompense for that virus. Perhaps the greatest disappointment is to find the current Labour Government seeking to justify today the unjust stance adopted by its predecessor with regard to Hepatitis C."[467]

401. The Society echoes the proposals made following the Penrose Inquiry in the report by the Scottish Financial Support Review Group, 'Contaminated Blood: Financial Support Conclusions and Recommendations', that none of the proposals for financial support for people infected and affected by contaminated blood should *"require recipients to sign any sort of waiver to prevent individual legal action for damages*

[467] HSOC0002040/11

etc".[468] Indeed, the Society reinforces that that the Government should not have required individuals with haemophilia to sign a waiver in 1991.

UK Government was reluctant to settle the HIV haemophilia litigation; it was too concerned about accepting blame for negligence and did not accept its clear moral duty to provide recompense

402. The Society submits that the Government was reluctant to settle the HIV haemophilia litigation. Their reasons for doing so are summarised in a briefing for a meeting between the Prime Minister, and Robert Key and Society representatives regarding Haemophiliacs with HIV infection, dated 22 November 1989, which is extracted in Section A, paragraph 355 of these submissions.[469] This document illustrates that government was too concerned about accepting blame for negligence and did not accept its clear moral duty to provide recompense and support for those that needed it.

403. The Society repeats and adopts the points made about this in its oral opening submissions:

"... Government, in terms of doing the right thing, have maintained their policy of deleteriousness. I am going to bring you back through a little history.

A legal action was launched in 1990. When matters were due to proceed to court Government was encouraged yet again to do the right thing by vulnerable members of this nation. Somewhat uniquely, a very learned judge, who was due to hear the case, Mr Justice Argyle, wrote directly to Government as is referenced in his own memoirs. Also, privately, he wrote to the then Secretary of State for Health. He set out what might be described as the moral dimension in this case. He said:

"A Government which takes upon itself the role of public provider of medical advice and clinical service is in a very different position to any commercial organisation. It is clearly arguable that their duty to innocent citizens who suffer injury under the aegis of such treatment has a moral dimension which should distinguish the

[468] HSOC0014638/5
[469] WITN6392101

assessment of their position from the criteria to be adopted by the defendants of a corporate character."

So, he went on to say:

"Government owes a duty wider than to its shareholders and its insurers. It should also mean that the public may be entitled to expect from a Government an appraisal of their position which is not confined solely to legal principles to be found in the laws of negligence or indeed proof."...

The response to that plea by the UK Government of that time is nothing short of shameful.

On 2 November, the then Prime Minister, Margaret Thatcher, responded to a similar type of request to be delivered by Mr Justice Argyle. I'm going to refer to an excerpt from the Prime Minister's letter.

She said: "I am sorry if this is a disappointing reply, but the Government is showing its great concern for haemophiliacs with HIV, by the ex gratia payments it is making. The question of compensation has been made a matter for the court to decide."

So, in essence, you take it as a community, you accept what you are given and we, the Government on behalf of the people, will fight on against you in the courts, was the response".[470]

UK Government failed in its duty of care to citizens

404. The Society submits that the Government did not act in protecting its citizens and as a provider of medical advice and clinical care.

[470] Transcript of Preliminary Hearing of the Infected Blood Inquiry, 26 September 2018, T91: 2 – T92: 22

405. The Society repeats the submissions it made to the Archer Inquiry in section two, titled 'A Duty of Care?',[471] which illustrate that, *"A full exploration of the Government's policy on blood products from the 1970s onwards reveals a litany of delays, missed opportunities and careless assumptions."*[472] The Society submits this included:

- *Failure to work towards self sufficiency in the 1970s condemned the UK to a continuing reliance on imported commercial blood products. The Government was well aware that these products were made from plasma collected from paid donors, including prisoners and other people with high-risk lifestyles.*
- *Heat treatment of blood products could have been introduced in 1983. This was delayed for two years. Similarly, it became possible to test batches of clotting factor by the summer of 1983. Again, no testing was introduced until late 1985.*
- *Considerable delays in informing patients of test results contributed to the infection of 63 inmate relations, despite the risk of sexual transmission being known about in 1983. Without knowledge of their illnesses, those infected with HIV and hepatitis C could not take action to safeguard their own health and that of others.*
- *There are many apparent cases of failure to observe the guidelines, which recommended that patients with mild or moderate haemophilia and infants should not be treated with clotting factor.*
- *The UK was one of the last countries in the developed world to introduce hepatitis C screening and testing.*
- *The introduction of heat treatment to eradicate hepatitis C from Scottish blood products was inexplicably delayed by eighteen months.* [473]

UK Government refused to listen to the pleas of the infected community for treatment

406. In May 1996, the Prime Minister at the time, Sir John Major wrote:

"The Government has given the question of compensation very careful consideration, including the Irish scheme. I have great sympathy but I really do think it is better to

[471] ARCH0001232/21-30
[472] ARCH0001232/30
[473] ARCH0001232/30

spend money provided for health care, from whatever source, on treating patients than on payments to people who received the best possible treatment available at the time. I am convinced that the best way we can provide practical help is to encourage research, and best treatment for those infected, as well as supporting voluntary groups directly concerned with their care. We shall continue to support these effects and explore other ways in which we can provide help.

I am unable to comment on the possibility of any commercial company accepting liability through funding a settlement and I do not think it would be appropriate for us to explore that.

It is therefore possible that haemophiliacs and those suffering from Hepatitis C might be able to benefit from lottery grants, but this would be a matter for the board to decide in response to any applications received."[474]

407. The Society re-iterates points made in its oral submissions to this Inquiry, *"In short, the assistance contemplated or considered to be appropriate by UK Government was the prospect of seeking lottery grant funding. That was their response to the worst treatment disaster in the history of the NHS. Also, government, I would submit, laboured under the misapprehension that they had provided the best possible treatment at the time"*.[475]

408. The Society draws to the Inquiry's attention to evidence given by the Rt. Hon. Jeremy Hunt MP in relation to whether it is ultimately the position that the Government announced an inquiry that could and should have been established years or decades before, *"I think it is, yes. I think it's undeniable that this should have happened, you know, decades earlier, and I think the question is how it is that it could have become a kind of -- established by the establishment, if I can put it that way, that nothing wrong was done, and that line then religiously stuck to by government after government. And the further away that we got from those incidents, the harder it became for a succession of ministers to challenge them because it just became established as sort of received*

[474] HSOC0014325/1-2
[475] Transcript of Preliminary Hearing of the Infected Blood Inquiry, 26 September 2018, T97: 10 – 17

wisdom, as you could see from the documents that you showed me earlier."[476] The Society says more in section C about its recommendations for public inquiry reform to prevent history repeating itself.

409. The Society submits that for many years, people who were infected struggled to get access to the best possible treatments. This is illustrated by the case of recombinant factor treatments.

410. In 1996, UKHCDO guidelines on products to treat haemophilia listed the order of priority in which people should receive recombinant Factor VIII products and Dr Chris Ludlam, Chair of the UKHCDO commented on the reasons for the recommendation of the use of recombinant Factor VIII, *"This is to reduce the risk of virus transmission"*. He said, *'This is particularly true for non-enveloped viruses which continue to be transmitted despite attempts to develop new virucidal techniques. For these reasons recombinant factor VIII is now recommended treatment instead of plasma derived concentrates"*.[477] In the same edition of The Bulletin, Dr David Evans explained the situation at the time, *"Recombinant clotting factors do not carry the risk of transmitting viruses from blood donors. The Haemophilia Society would like to see everyone with haemophilia treated by recombinant products. This is the Society's official recommendation, and it is also the opinion of the Haemophilia Centre Directors. Unfortunately, recombinant clotting factors are more expensive than plasma derived products, and there is a problem with funding in the NHS. We must all keep up the pressure on the media, MPs, and society at large to make funds available."*[478]

411. A 1997 issue of The Bulletin reported on a meeting with Frank Dobson that, *"On the issue of recombinant factor VIII, the delegation highlighted the current unfairness in availability of the product across the UK and how funding decisions varied from health authority to health authority"*[479] Had Government taken steps to make recombinant Factor VIII treatments available for everyone sooner, there would have been no need

[476] Transcript of evidence of Jeremy Hunt to the Infected Blood Inquiry, 27 July 2022, T135: 21 – T136: 6
[477] HSOC0023016/1
[478] HSOC0023016/4
[479] HSOC0023019/1

for the Society's "Recombinant for All" campaign, which called for widespread introduction of recombinant Factor VIII.

412. The Society's "Recombinant for All" campaign was very active in advocating for safe therapies – and it still is to this day, with NHS England announcing in 2020 that the first recombinant treatment for adults living with von Willebrand disease would be made available. Kate Burt sets out details relating to the Society's campaign in her statement.[480]

413. To this day, the Government fails to offer the treatment they need, such as counselling and psychological treatment. The Society reminds the Inquiry of the evidence of Sarah Bowman to this Inquiry:

"I understand from colleagues nationally in Haemophilia Services that, in the past, the Haemophilia Society workers were predominantly in post to assist and support those people who were infected and affected by the Infected Blood situation, this was the main remit. This is especially pertinent when these infected and affected people require additional services as they are ageing, living with the viruses long term and having increasing psychological and physical needs…

Separate to Psychology provided by some Centres, my view is people infected or affected currently or in the past 10 years did not have access to consistent, dedicated and specialist counselling in regard to the issue of Infected Blood. I am aware that funding could be accessed via the Skipton Fund or Macfarlane Trust to access counselling services.

In Sheffield, those infected with HIV have had access to the general HIV Psychologist (ie not particular to contaminated blood issue). Family members do not have access. We have a Haematology Psychologist available for some hours weekly covering all Haematology services and we very have [sic] limited access to this service.

As far as I am aware, Haemophilia Nurses, particularly those working at the height of the diagnosis of people who had received infected blood undertook the bulk of the

[480] WITN6392001/119-120, paragraphs 282 to 284

counselling in addition to their duties, for example the Haemophilia Nurse in Sheffield was sent on a counselling course to help her manage the counselling requirements."[481]

414. Further, the Society submits that Government did not respond in providing suitable funds for research into HIV and AIDS. At times, research was funded by the Society as no other funding avenues were open. This is illustrated, for example, by the funds provided by the Society to Public Health Laboratory Service in 1985 so they could monitor antibody status of people with haemophilia as no other funding available.[482]

SECTION B2: CONSENT, COMMUNICATION, CANDOUR AND TRANSPARENCY

415. In this Section, the Society makes a number of observations on the issue of consent, communication, candour and transparency. Before doing so, it wishes to highlight the views of two respondents to the Society's survey on closing submissions.

416. In response to the question posed, *"Do you have any comments about the topic of candour, openness and cover-up?"* one member said:

> *"I feel this is paramount to understanding what went wrong, what could have been done differently and about the basic human decency of admitting failings that have had such a catastrophic effect on the lives of innocent and vulnerable people. Has there been an attempt to cover up a scandal, to save face and expense? This topic, I fear, is one which has the potential to cause the greatest anguish and anger – but one which nevertheless has to be appraised if there is to be accountability and a very genuine attempt at reparation of any small degree, given how it is impossible to repair so many ruined lives."*

417. In response to the same question, another member said:

[481] WITN0636001/6-7, paragraphs 29 to 33
[482] PRSE0002619/2

"In my opinion, this is what I want from the enquiry. I want to know how and why this happened to my Dad and who was responsible for letting it happen."

418. The Society supports and adopts the views of its membership and will address the following topics in its submissions on the issue of consent, communication, candour and transparency:

a. Individuals, if not institutions deliberately removed medical records of patients, impacting their ability to have the evidence to access the support they were entitled to;
b. there were attempts to cover up actions in government and civil service;
c. testing without knowledge and consent was widespread;
d. outcome of blood tests were not always shared with individuals; at other times, outcomes were shared inappropriately;
e. there was a lack of information available or provided to families to understand the risks of HIV/AIDS to family members and close friends; and
f. Previously Untreated Patients were treated with trial heated treated products without consent.

Individuals, if not institutions deliberately removed medical records of patients, impacting their ability to have the evidence to access the support they were entitled to

419. The Society submits that the evidence before the Inquiry demonstrates that individuals, if not institutions, deliberately removed patients' medical records. Quite apart from the general impropriety of this, a direct consequence was that infected and affected individuals no longer had the evidence to be able to access the support they were entitled to in the future. The Inquiry presentation on Destruction and Retention of Medical Records[483] illustrates the issue well and includes data and information about inconsistency between oral information and what is recorded in medical records; inaccuracy of records; missing records (including instances where there was no explanation for missing records; missing information for a specific procedure or

[483] INQY0000378

appointment; or specific years missing); and significant interference in medical records.

420. Evidence before this Inquiry shows countless examples of individual records going missing. Just a few examples include those of:

a. Margaret Madden, who made a witness statement on behalf of her son, Daniel, who was infected with HIV and Hepatitis C and whose medical records are missing from 1984 to early 1985. She recalls that there were blood tests results from this period.[484]

b. Karen Elizabeth Millard, who prepared her statement "without the benefit of access to her sons, Douglas', Russell's or Robert's, full medical records. I can confirm there are a large proportion of medical records which have gone *"missing"*.[485] Ms Millard also refers to medical staff redacting *"copious amount[s] of information in the records"*.[486] In relation to the impact of this she states, *"Initially Russell did not receive a penny from the Skipton Fund and following his passing I was also let down by them. It was not until last year after so much fighting that I finally received the £20,000 Stage 1 payment for Russell's infection with Hepatitis C. Russell and I had been denied this payment for years as we had no proof of him being infected with Hepatitis C due to the "missing medical records". I had to move in with my mother and father because I was struggling financially. The Skipton Fund, when assessing whether I was eligible for support, took into account my mother and father's pensions and therefore denied me any financial assistance. I am therefore of the view that the Skipton Fund was not fit for purpose"*.[487]

c. Cornelius Tersteeg, who applied to the Skipton Fund and was refused; appealed and again, was refused due to his medical records not showing the information they required.[488]

d. Colette Wintle, who was unable to access the medical records she needs to take legal action. In June 2003, Channel 4 reported on Ms Wintle's circumstances and noted that, *"Around the country, victims are finding that the medical notes*

[484] WITN1364001/5, paragraph 22
[485] WITN1396001/1, paragraph 3
[486] WITN1396001/3, paragraph 11
[487] WITN1396001/9, paragraphs 53 to 54
[488] COLL0000014

they need to join a class action in the American courts have either gone missing or have been destroyed."[489]

e. An anonymous witness who stated, *"Portsmouth Hospitals NHS Trust have denied that there is any record of me being a patient within their Trust which is surprising given that I was treated there fore 12 years and my GP medical records contain correspondence from them."*[490]

f. Fiona Elizabeth McTeare, who stated, *"I was extremely disappointed that the NRVI would not let me have Jonathan's medical records even though they saw fit to aid the Skipton Fund payments, they just ignored my requests. Eversheds Sutherland have now been able to gain access to Jonathan's records but I feel they are not complete, it would appear information is missing"*.[491]

g. Paul Thomas Bullen, who stated, "*I think it was only because of this complaint about the cleanliness that I was able to obtain my complete medical records from the MRI. I recall another patient I knew told me that he had asked Dr Hay for his medical records and Dr Hay refused on the basis that they had been destroyed. It was only after that patient threatened to take the matter further that Dr Hay suddenly changed his position and provided the medical records; they were in the drawer of his desk"*.[492]

h. Susan Violet Maggs, who stated, *"I have a letter from my father's solicitors, which he instructed later as part of his involvement in the litigation in 1990, dated 14 May 1990, which states 'I am afraid that the medical records disclosed to date are in any event very skimpy, because the BRI have not kept blood samples which can be tested retrospectively, and even the records which were carried out have been poorly maintained"*.[493]

i. An anonymous witness, who stated, *"I do want to address my medical records. I applied for and received my medical records from my GP practice and after reviewing them, there is no evidence that I had Hepatitis C – not one mention of it which I find very strange and I feel it necessary to bring this to the Inquiry's attention"*.[494]

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[489] HSOC0011855_013
[490] WITN0115001/2, paragraph 4
[491] WITN3114001/9, paragraph 43
[492] WITN3114001/10, paragraph 41
[493] WITN3137001/3, paragraph 12
[494] WITN3184001/8, paragraph 37

j. Another anonymous witness, who stated, *"As referred to previously in this statement, it has been very frustrating for me and my family to hear that the hospital does not hold my father's medical file. This is particularly so given that we have received small amounts of information regarding my father's health at different times over the years. As referred to above, despite being told by the hospital that they only seemed to have an envelope containing some of my father's medical details, Dr Benson later referred to re-checking my father's file.*

I feel that the information I have received over the years has been cherry-picked. As described above, I am surprised that information showing my father's AST and ALT levels is unavailable.

A further concern regarding my father's medical records arose when I attended the Haemophilia Centre in or around 2013. I was informed that they had my father's DNA and had compared it with my son, [GRO-B's] DNA. They said they could see same kink in the DNA of my father and [GRO-B] on the screen. I remember that Orla McNulty, was excited by this and that she also wanted to see my DNA so that it could be compared too. I was frustrated by all of this because despite being told that the hospital did not hold my father's medical records, his DNA was available to be examined nearly 18 years after his death.

Finally, in relation to my father's UKHDOC records, I am surprised that there is no result recorded for the HIV test for which a sample was taken on 10 November 1987. There is also no reference to the test for Hepatitis C which, as referred to above, Dr Benson confirmed was performed on 1 January 1992. These omissions, together with the fact that there is no reference to the period from 1971 to 1976 within the Patient Annual Treatment Records, give me concern about whether information was correctly sent to the UKHCDO".[495]

421. As already noted, the impact of missing or inaccessible records was that people no longer had the evidence to be able to access the support they were or are entitled to. In all cases, this only added to their already heavy mental burden, and the feeling that

[495] WITN3209001/13, paragraphs 46 to 49

they are trying to get access to support they are not entitled to. This inevitability discourages some from further pursuit of benefit.

422. The Society reminds the Inquiry of its report of the investigation into the decision making of the Skipton Fund, which notes the numbers of claims declined (with no appeal) and the reasons, which were: 22% lack of evidence and 24% medical records destroyed. Of those who went to appeal 43% were declined. Again, some of these were due to clinical implausibility or lack of evidence.[496]

423. The Society submits that compensation schemes, should include (more) generous assumptions in favour of applicants in circumstances where they are unable to provide medical evidence which could have been or has been destroyed.

There were attempts to cover up actions in government and civil service

424. The Society submits that there is evidence that there were attempts to cover up actions in government and civil service. One well documented example is that of Sir David Owen trying to get access to his own files and them being destroyed. In a letter from Lord Owen to Ann Abraham, Parliamentary Ombudsman for England, he wrote:

> *"Essentially, the issue which concerns me is that when I tried to get hold of my Private Office files as they related to the decision to become self-sufficient in blood products – which I took in 1975 – my office were told that none of my records had been kept and that there was a Departmental rule that Ministerial papers were pulped after 10 years. Given that I have to operate under the 30 years rule it seems very strange that papers of this kind are pulped with no reference first to the Minister concerned. That rule certainly does not apply to my Foreign Office papers, all of which have been kept and which I am regularly able to consult".*[497]

425. Former Conservative Social Services Minister Lord Jenkin of Roding, was reported as giving evidence to the Archer Inquiry that, *"he was horrified to discover, after leaving*

[496] INQY0000247/5-6
[497] LDOW00000116/1-2

the Department of Health, how widespread the contaminated blood disaster was and how files had been destroyed by civil servants as a conscious decision".[498]

426. It is apparent that for decades successive Governments have dismissed the infected and affected community. Up until today, there have been repeated promises broken. For example, as recently as November 2022, the Government would not reveal its plans for full compensation for those infected and affected by the contaminated blood scandal, despite promising to do so. On 24 November 2022, Junior Cabinet Office minister Alex Burghart told a parliamentary debate on the Infected Blood Inquiry and compensation framework that the government would wait until the final report of the inquiry before setting out its plans. The Society reported that, *"This leaves those infected and affected by the scandal in the dark about what full compensation is likely to be paid and how it will be administered. Although interim compensation of £100,000 was paid to all those registered with a UK support scheme in October 2022, many have been left out, including bereaved parents and children. They were hoping for some clarity on their situation from the government…"*[499] Dame Diana Johnson MP told Mr Burghart she was 'speechless' that the Cabinet Office had broken its promise to publish its response to Sir Robert Francis KC's crucial report which set out a potential framework for compensation. She warned him that the issue would be 'relentlessly pursued'.[500]

Testing without knowledge and consent was widespread

427. The Society submits that testing without knowledge and consent was widespread and should not have been allowed to happen. Historically, people with bleeding disorders (mainly haemophilia) freely gave blood at appointments to check factor levels. They were then tested for infection without being told. For many, this broke the trusting relationship between doctor and patient; that is, the Society asserts, an unsurprising outcome. As a result, some people living with a chronic (potentially fatal) condition did not access the care they needed in the future.

[498] LDOW0000014
[499] Government breaks pledge on compensation plans | The Haemophilia Society
[500] Government breaks pledge on compensation plans | The Haemophilia Society

428. In a follow-up submission by the Scottish National Blood Transfusion Service ("SNBTS") in response to a request from the Health and Community Care Committee of the Scottish Parliament following a meeting in 2001, the SNBTS commented on documents submitted to the Committee by the Society, on the decisions taken at the time and whether these were driven by clinical or resource considerations and also on the use of imported US blood. The SNBTS commented in relation to approaches to tracing, testing and counselling patients:

"The Society's evidence is that approaches to tracing, testing, and counselling patients varied widely between haemophilia treatment centres; in many cases patients were tested without consent and/or not informed of the results. This meant that infected patients could not take appropriate precautions to prevent infected those close to them or to make lifestyle changes to safeguard their own health (e.g. reducing alcohol in the case of HCV). Nor were steps taken to ensure all those infected were provided with the best treatment for the viruses. The Society has examples of patients denied necessary treatment (i.e. interferon for HCV) on grounds of cost".[501]

429. The approach to testing and providing results was ad hoc; and while counselling was provided to some, this was not consistently offered or provided throughout the UK. The Society submits that there should have been a structured approach to testing and giving results, which included:

a. an explanation to the patient as to what was happening;
b. the patient giving active consent to be tested; and
c. the offer of counselling support, before testing and at the time of sharing results.

430. The Society supports and draws the Inquiry's attention to a 1991 article from the British Medical Journal by Robert Bor, Riva Miller, Margaret Johnson titled 'A testing time for doctor: counselling patients before an HIV test'. This article sets out matters for consideration by medical professionals in relation to HIV testing.[502] The Society

[501] ARCH0002981/23
[502] RHAL0000333

also draws to the Inquiry's attention the book titled 'AIDS: A Guide to Clinical Counselling' by Riva Miller and Robert Bor, published in 1988.[503]

The outcome of blood tests were not always shared with individuals; at other times, outcomes were shared inappropriately

431. The outcome of blood tests were not always shared with individuals. Sometimes, this occurred because a parent did not want their child to know.[504] At other times, this was due to the practice in a particular medical institution. Withholding results from people, in some cases for many years, was incredibly harmful. Without having knowledge of their infection, some people could have easily gone on to infect others and put other lives in danger.

432. A letter from Dr Frank Hill to Dr Mitchell dated 18 October 1985 illustrates that the practice of withholding results from patients changed over time:

> *"As far as his HTLV-III antibody status is concerned, my attitude certainly is changing towards informing the patients. One of the problems we face at this Centre was many of the parents indicated they did not wish to know the results, but I am now firmly of the opinion that they have to face up to this reality and their children have to be also involved in discussions and certainly most of the teenagers have now been told, but I had not had the opportunity recently with Martin to do so. When he returns to Birmingham and prior to his transfer to the Centre at Stoke-on-Trent which is geographically nearer to his home, I intend to discuss the thing fully and openly with Martin and with his mother…".*[505]

433. There was a shocking variation in the ways people came to be given the news of their life-altering blood test results. The Society submits that at times, the information was shared in an inappropriate manner. Just a few examples in evidence before this Inquiry include:

[503] RLIT0000009
[504] WITN0012002
[505] WITN0012015

a. that of Martin Beard who gave evidence that, *"My first appointment at Staffordshire North Infirmary was on Monday 1 September 1986. I went to the appointment with my mother. We sat in the waiting room and were called into Dr Robert Ibbottson's office. The door remained open allowing people behind me to hear the conversation. The doctor said, 'Good morning, I see you are HIV positive'. Just like that. I looked at him, looked back at my mum and said 'well that's life'. Dr Ibbottson said 'that is your life for the next two years'. He said I have two years left to live. That is when it hit me and I went into a state of disbelief after which I cannot remember a single word he said to me".*[506]

b. that of Derek Frank Martindale, who gave evidence that, *"In August 1985 I went to York District Hospital and asked to be tested for HIV. No-one from the hospital had previously contacted me about this. On Friday the 13th September 1985 I took a long lunch break from work and went to the hospital to see Dr Wylie and find out the results of the test. Dr Wylie informed me, in a matter of fact way, that the test results had come back and that I was HIV positive. I was told that I would be dead within 12 months, I was 23 years old. Dr Wylie was very upset when he told me; he had been treating me and my brother since we were very small. Also, I was told not to tell anyone, including my parents, as the stigma associated with this infection would mean I would become a social pariah if anyone knew. I did not tell anyone and the 'secret' of being HIV positive became a crippling burden".*[507]

c. that of Luke O'Shea Phillips, who said, *"My mother received a letter on 06.01.1997 that read 'you will remember that Luke has acquired Hepatitis C Infection at some time in the past'. This was the first time she was made aware of my infection". "According to my records I tested positive for Hepatitis C antibodies on 29.04.93".*[508]

d. that of Amanda Patton who gave a statement about her late brother, Simon Cummings and said, *"It was while he was having physiotherapy sessions at Treloars that he was told he had been infected with HIV in around 1985 or 1985. Simon was having regular treatment there for his legs and one day, he and a group of other patients also receiving physiotherapy were called into a*

[506] WITN0012001/3, paragraphs 21 to 22
[507] WITN1688001/3, paragraphs 12 to 14
[508] WITN1696001/3, paragraph 15

meeting. They were told en masse that blood tests had been undertaken and they showed that all of the group had been infected with HIV".[509]

e. Dr David Tibbutt, who said about his wife, Jane Tibbutt, *"Jane received a letter from Dr Giogrande at the OHC [Oxford Haemophilia Centre] in August 1995 arranging an appointment. Jane was informed during that appointment that she had Hepatitis C. Jane recalled that Dr Giogrande seemed puzzled whilst he was talking to her and said something like 'oh, didn't you know you had Hepatitis C?'".*[510]

f. that of Mavis Rimmer, who gave evidence about her late husband, David Rimmer, *"On 31 July 1997 David received a letter from the Blood Transfusion Service informing that he had contracted Hepatitis C (WITN0820003). This letter states that David had attended for blood tests on 27 June 1997 by Dr Muddu. I understand that the test was suggested by Dr Bullimore due to unexplained liver abnormalities. We did not know what Hepatitis C was and the letter told us to arrange to visit the GP for further information. As far as I can recall David did go to see the GP but he gave us no answers so David decided to continue as he was, without seeking further consultations".*[511]

g. that of Gary Kenneth Sheriff, who said, *"I was surprised to be diagnosed with Hepatitis C in 1996, as I had not been experiencing any symptoms. I was given the diagnosis during a routine clinic appointment and I found it quite a difficult way to be told. It was almost as I was leaving the appointment that Dr Wilde mentioned that I had been exposed to Hepatitis C, and that I had tested positive for the virus".*[512]

h. Bruce Edward Norsworthy, who made a statement about his late son Richard, *"I do not know if he became infected then, or whether he had already been infected, but it was after Richard had that operation when we were notified that he was HIV positive. We were not even aware that a test was being carried out. We were living in Shropshire and Richard was living at home and going to work daily. One evening when Mavis was preparing the evening meal, we received a telephone call from Dr Michael O'Shea at the Haematology Department at Shrewsbury Hospital. He informed us over the phone that Richard was HIV*

[509] WITN0042001/6, paragraph 20
[510] WITN0555001/3, paragraph 10
[511] WITN0820001/4, paragraphs 16 to 17
[512] WITN1014001/5, paragraph 24

positive which was a pretty awful blow. There was no face to face consultation and no request to attend the hospital to discuss it".[513]

i. that of Christopher Reeve, who stated, *"My treatment continued unchanged until the mid-1980's, when I was around 16 years old. At one of my regular review appointments at Margate, Dr [GRO-D] informed me that soe of the blood product I had been treated with had been contaminated, and that I had been infected with Hepatitis C as a result. The way in which I was told this was rather blasé, and I was not given any further information about the implications or treatment of this infection. I had no idea it was something serious as it was presented to me in such a casual way".*[514]

434. Lessons were not learnt from the HIV crisis and people continued to be told or not told about their Hepatitis C infection in a similarly ad hoc manner. Some people were accused of being alcoholics or drug abusers whilst having no understanding why. This is illustrated in the evidence of an anonymous witness who said, *"I remember that Dr Neil asked me whether I was a drinker. When I said that I wasn't she asked me whether I was 'sure'. I told her again that I didn't rely on drink but that I did have a drink here and there. She responded by asking me if I was a secret drinker and I had to convince her that I wasn't an alcoholic".*[515]

There was a lack of information available or provided to families to understand the risks of HIV/AIDS to family members and close friends

435. Evidence before this Inquiry illustrates that there was a woeful lack of information available or provided to families of people with HIV/AIDS or Hepatitis to help them understand the risks. In many cases, people were left to figure things out on their own. Just a few examples of the evidence before the Inquiry in this regard include:

a. The evidence of an anonymous witness who said, *"I would also have liked to be told about the stigma around HBV so that I could be prepared for that, and given advice on how to avoid infecting others. The lack of information available meant that my parents grew very concerned about becoming infected and made*

[513] WITN3143001/3, paragraph 11
[514] WITN3147001/3, paragraph 9
[515] WITN0379001/2, paragraph 7

me use separate cutlery around them when I saw them, which was distressing an could have been avoided with proper education".[516]

b. The evidence of another anonymous witness who said, *"Personally, when I got the letter in 1985 telling me of his HIV infection it was the scariest time of my life, which was made worse by the lack of information available and the amount of stigma and hysteria attached to HIV. It was not easy for us to keep it a secret ... At one point I read an article saying that those who have HIV should be locked away in institutions so that they could not pass on the disease".*[517]

c. The evidence of another anonymous witness who said, *"I understand that because of the stigma and lack of information available at the time, medical professionals were hot on HIV and Hepatitis; however, it is extremely frustrating that even to this day I have to take extra blood tests despite them always coming back negative, and I feel as though 'One a leper always a leper'".*[518]

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437. Evidence before this Inquiry illustrates that there was a woeful lack of information available or provided to families of people with HIV/AIDS or Hepatitis to help them

[516] WITN1951001/3, paragraph 12
[517] WITN1134001/[This document appears to have been removed from Relativity; the quote has been retained for relevance to this section.]
[518] WITN0140001/10, paragraph 52
[519] WITN0379001/2, paragraph 7

understand the risks. In many cases, people were left to figure things out on their own. Just a few examples of the evidence before the Inquiry in this regard include:

a. The evidence of an anonymous witness who said, *"I would also have liked to be told about the stigma around HBV so that I could be prepared for that, and given advice on how to avoid infecting others. The lack of information available meant that my parents grew very concerned about becoming infected and made me use separate cutlery around them when I saw them, which was distressing an could have been avoided with proper education"*.[520]

b. The evidence of another anonymous witness who said, *"Personally, when I got the letter in 1985 telling me of his HIV infection it was the scariest time of my life, which was made worse by the lack of information available and the amount of stigma and hysteria attached to HIV. It was not easy for us to keep it a secret ... At one point I read an article saying that those who have HIV should be locked away in institutions so that they could not pass on the disease"*.[521]

c. The evidence of another anonymous witness who said, *"I understand that because of the stigma and lack of information available at the time, medical professionals were hot on HIV and Hepatitis; however, it is extremely frustrating that even to this day I have to take extra blood tests despite them always coming back negative, and I feel as though 'One a leper always a leper'"*.[522]

438. There was no UK-wide coordinated approach to information sharing, even after the risks had been established. There should have been a coordinated approach. Infected and affected people should have been far better supported at the time.

Previously Untreated Patients were treated with trial heat-treated products without consent

439. A lack of consent was not only limited to testing; it also extended to treatment. Evidence before this Inquiry shows that Previously Untreated Patients were treated

[520] WITN1951001/3, paragraph 12
[521] WITN1134001/[This document appears to have been removed from Relativity; the quote has been retained for relevance to this section.]
[522] WITN0140001/10, paragraph 52

with trial heat-treated products without consent. This should never have happened. Examples from evidence before this Inquiry include:

a. that of Mark Stewart, who explained, *"I researched matters further and located some published academic papers on blood products and blood borne viruses. I found a paper that had been published in the British Journal of Haematology in 1985 titled 'High risk of non A non B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates: effects of prophylactic immune serum globulin'. The papers authors include Professor Peter Kernoff, Dr Howard Thomas and Professor Christine Lee and it was based upon research carried out at the Haemophilia Centre and Haemostasis Unit at the Royal Free Hospital between April 1978 and March 1983. I was shocked to read the reasoning and methodology behind the research which stated that: 'Since 1978, both because of increasing awareness of the probability underdiagnosis of acute post-infusion hepatitis, and because we wished to obtain plasma samples which might be used as sources of antigen/antibody in assays for serological markers of NANB infection (Luo et al, 1983), we have prospectively monitored biochemical liver function tests in patients receiving first exposures to clotting factor concentrates and cryoprecipitate whether or not they had previously received other blood products. The very high incidence of acute NANB hepatitis observed following concentrate therapy prompted a pilot clinical study of prophylactic immune serum globulin (ISG)… Blood samples were taken, and patients clinically assessed, immediately before their first exposure infusions, at 1-2 weekly intervals for the next 3 months, and at 1-2 monthly intervals for a further 6 months. Biochemical liver function tests were carried out on all blood samples, and were normal in all patients before first exposure infusions. Sera were stored frozen and selected samples from all patients retrospectively analysed for serological evidence of acute or previous viral infection…. The occurrence of acute post-infusion hepatitis was the primary endpoint of the study'. I could not believe what I was reading. I was infected with HCV on 12 May 1981, which was during the second half of this study. Professor Kernoff, who was the Consultant in charge of my care when I was infected, had led the research and was clearly acutely aware of the probability of infection. Despite this, I was given factor VIII in circumstance where I never had the chance to reject it and avoid HCV infection. I believe that I was deliberately infected so*

that they could use me as a guinea pig in this study and other research on PUPs that was being carried out at the Haemophilia Centre and Haemostasis Unit at the Royal Free Hospital".[523]

b. An article by Tainted Blood entitled 'Children Used Instead of Chimpanzees', which stated, *"In January 1982, four commercial companies were poised to release heat-treated Factor VIII. The infectivity of initial batches had been tested by injecting the product into chimpanzees but it was stated in a letter from Dr C R Rizza and Dr A L Bloom, that it was unlikely that commercial manufacturers would be able to ensure this form of quality control in all future batches and that it was therefore very important to find out in studies of HUMAN BEINGS the extent to which infectivity had been reduced. The Oxford letter went on to recommend that the most 'clear cut' way of doing this was by administering those concentrates to patients requiring treatment who had NOT been previously exposed to large-pool concentrates."*[524] This article attached the relevant letter from Professors Bloom and Rizza on letterhead from the Oxford Haemophilia Centre, dated 11 January 1982.[525]

SECTION B3: VIRAL INACTIVATION

440. In this section, the Society makes a number of observations on the issue of viral inactivation. Before doing so, it wishes to highlight the views of one respondent to the Society's survey on closing submissions.

441. In response to the question posed in the Society's survey, "Do you have any comments about the topic of viral inactivation?", one member said:

"One would hope, that learning the lessons from the past, viral inactivation processes are routinely and comprehensively carried out on all blood products before administration."

[523] WITN1000001/10-11, paragraphs 41 to 44
[524] WITN1196017/2
[525] WITN1196017/4-5

442. The Society supports and adopts the views of this member, and also submits that too little was done too late in relation to viral inactivation. To this end, the Society submits that:

a. there was not enough investment and research into viral inactivation;
b. research developments in viral inactivation were not shared; this hampered progress;
c. there was little urgency to access earlier safer heat-treated products; and
d. only a few healthcare practitioners sought to gain early access to heat-treated products.

There was not enough investment and research into viral inactivation

443. The Society submits that there was not enough investment by Government into the process of fractionation, in which different types of proteins found in blood plasma are separated, purified and concentrated into therapeutic doses. There should have been greater investment in the fractionators in the UK, including BPL, the Protein Fractionation Centres and Plasma Fractionation Laboratories to develop heat-treated products or the means to achieve viral inactivation. In particular, there was little research into the structure and functionality of Factor VIII or Factor IX. Acknowledging the limitations of modern techniques for computer modelling of proteins available in later years, the Society submits that there should have been research into finding a stabilising molecule for Factor VIII and Factor IX much earlier.

444. The Society draws the Inquiry's attention to an excerpt from 'HIV and the Blood Supply: An Analysis of Crisis Decision making' published by the Committee to Study HIV Transmission Through Blood and Blood Products, Institute of Medicine 1995, which describes the development and implementation of treatment methods used to inactivate viruses in AHF concentrate:

"The Committee developed two hypotheses to explain the actions that were taking during the period from 1970 to 1983:

- *Plasma fractionators and other organizations responsible for the safety of blood products did not begin research on viral inactivation of AHF [antihemophilic factor] concentrates until the onset of the AIDS epidemic.*
- *Hepatitis was viewed as an acceptable risk by the government regulatory agencies responsible for the safety of blood and blood products, the plasma fractionation industry, the physicians who treated the individuals with haemophilia. As a result, little incentive was available to improve AHF product safety through the expeditious development and implementation of viral inactivation technologies.*

Testing these hypotheses against the evidence gathered through documents and fact-finding interviews, the Committee concluded they were able to reject the first hypothesis but unable to reject the second.[526]

445. The Society agrees with the Committee's finding and draws to the Inquiry's attention Lauren B. Leveton et al's study published in 1995, ''HIV and the Blood Supply: An Analysis of Crisis Decision Making':

"In the interval between the decisions of early 1983 and the availability of a blood test for HIV in 1985, public health and blood industry officials became more certain that AIDS was a blood borne disease as the number of reported cases of AIDS among haemophiliacs and transfused patients grew. As their knowledge grew, these officials had to decide about recall of contaminated blood products and possible implementation of a surrogate test for HIV. Meetings of the FDA's Blood Product Advisory Committee in January, February , July and December 1983 offered major opportunities to discuss, consider, and reconsider the limited tenor of the policies.

Despite these opportunities and others to review new evidence and to reconsider earlier decisions, blood safety policies changed very little during 1983. Many officials of the blood banks, the plasma fractionation industry, and the FDA [U.S. Food and Drug Administration] accepted with little question estimates that the risk of AIDS was low ('one in a million transfusions') and they accepted advice that control strategies (such

[526] CGRA0000660/37

as automatic withdrawal of AHF concentrate lots containing blood from donors suspected of having AIDS, or a switch from AHF concentrate to cryoprecipitate in mild or moderate haemophiliacs) would be ineffective, too costly, or too risky. During this period, there were missed opportunities to learn from local attempts to screen potentially infected donors or implement other control strategies that had been rejected as national policy… In the early 1980s the CDC's [Centre for Disease Control and Prevention] surveillance program identified AIDS patients an rapidly characterized the disease. Scientists at NIH [National Institute of Health] isolated and characterized HIV in 1984. Viral inactivation methods for AHF concentrate were developed in laboratories of the plasma fractionators and the FDA licensed the new processes quickly. Although the pace of viral inactivation research had been slow, it accelerated in the 1980s largely in response to hepatitis, and had identified effective strategies by 1984. However, research into other potential ways to safeguard the blood supply such as the use of surrogate tests was not pursued vigorously and there was relatively little research on blood safety issues per se".[527]

446. The Society echoes this observation and submits that in the pace of research into viral inactivation in the UK was also slow. As a former CEO of the Society, Karin Pappenheim, stated before the Select Committee on Health on 24 June 1999, even when viral inactivation procedures were put in place in 1985 and 1986, they did not result in blood product being 100 per cent safe, "*It is important to state that in 1985 and 1986 viral inactivation procedures were put in place to prevent future transmission of HIV and hepatitis through blood products, but we still know that there are viruses such as TTV, which is a recently identified one, and hepatitis A, which actually escaped that inactivation process. We cannot be entirely confident to this day that blood products are 100 per cent safe, because we already know that some viruses are escaping the inactivation processes".*[528]

447. The Society draws the Inquiry's attention to the evidence of Professor Willem van Aken to the Penrose Inquiry about denaturisation of a protein:

[527] BPLL0010935_002/9
[528] HSOC0003545/1

"...The fluid component, the plasma proteins and the other ingredients like fats and sugars, can be heated, perhaps they are not so sensitive to heat as blood cells are but still, if you heat all these proteins, you get the denaturisation, they fall apart in smaller parts in fact, and these smaller parts react with each other. So you get again a big clump which is not further to process and therefore heating as – it looks very simple, when you talk about it from the kitchen for instance, from boiling an egg, but it is not as simply when you apply it to blood, which is a very complicated substance and therefore you have to take into account which substance of blood you want to inactivate and you have to take into account the characteristics of each of these components, how they will react to increase in temperature. You can modify that. You can influence it, by adding certain substances like, for instance, amino acids or certain carbohydrates or even citrate to make the effects of heating on the protein structure less, but it always remains a risk that you introduce changes in the protein, which affect the function of it when you infuse it in patients.

Q Right. So any idea of taking the donation of blood in the transfusion centre and subjecting it to pasteurisation is a non-starter?

A. Yes, absolutely impossible".[529]

448. The Society submits that infection with HIV and Hepatitis C might have been avoided if a protein stabiliser could have been developed to protect from denaturisation of the protein and heat treatment had been available from the late 1970's. Then, even with potentially lower yields, plasma collection could have been increased and with more cautious use (for example, through restriction of home treatment due to increased demand).

449. It is evident from the expert report on Fractionation to this Inquiry, that research was being conducted during the 1970s into viral inactivation as licences had been applied for by fractionators for heat-treated Factor VIII concentrates to the US Food and Drug Administration in December 1982, meaning at least some Phase II trials had taken place before that time.[530]

[529] PRSE0006047/4-5
[530] EXPG0000044/86

450. Further, Haemate P (Behringwerke's product patent, 1979) was licenced in Germany in 1981. The expert report on Fractionation, explains that:

"In 1981, Heimburger et al described a method to heat a Factor VIII preparation (Haemate P) in the presence of sucrose and glycine for 10h at 60oC. The FVIII preparation is then separated by precipitation. The efficacy of HBV inactivation was assessed in a study in chimpanzees. The yield is low, at about 8% of the initial plasma. The loss of yield due to the application of heat resulted in the need to obtain larger volumes of plasma.

The pasteurised Factor VII was licensed in 1981 under the name of Haemate HS in Germany (also called Haemate P), followed by the publication of two early clinical studies. One hundred and fifty-five eligible patients with haemophilia A or von Willebrand's disease attending 11 haemophilia centres in the Federal Republic of Germany, were selected. Between February 1979 and December 1986, they received a total of 15,916,260 IU of pasteurised Factor VIII (60oC-10h) (Haemate HS, Behringwerke). By September 1988, the patients were tested for HIV-1 (all) and HIV-2 (66 patients). All were found negative. Neither hepatitis nor post-transfusion seroconversion for hepatitis in 26 patients treated for one year with 32 batches of pasteurised-Factor VIII were found".[531]

451. Although there were concerns about development of inhibitors and yields, the Society submits that with development (and financial investment), viral inactivation could have been accomplished quicker. To this end, the Society reminds the Inquiry of the Presentation by Counsel to the Inquiry relating to pharmaceutical companies involved in blood products: Speywood, Alpha, Abbott and Grifols:

"In 1975, Speywood registered the trade name 'Hyate', the reference for that is IPSN0000089_001. There's evidence from various documents that show some financial support, albeit at a limited level, from both The Haemophilia Society and the

[531] EXPG0000044/83-84

Department of Industry during the 1970s for the development of that product. Professor Bloom wrote an article in 1978 in the British Journal of Haematology, volume 40, pages 21 to 27, which referred, among other matters, to the use of porcine products in patients with Factor VIII inhibitors. He said, and I quote: ' This material, however, causes thrombocytopenia. It is also expensive and may increase the immunological logical response. It is rarely if ever needed'.

You may recall, sir, that on Friday Ms Middleton referred to the traditional view of porcine Factor VIII as having a very bad reputation because of all of these complications with it, and she mentioned thrombocytopenia, which is the below platelet count, that was particularly connected with it and the risk of a response creating inhibitors, rendering a patient who was already difficult to treat even more difficult to treat".[532]

Developments in viral inactivation were not shared; this hampered progress

452. The Inquiry's expert report into Fractionation shows that research developments in viral inactivation were not shared through the normal academic means, such in scientific journals and publications. The Society submits that the absence of knowledge-sharing hampered progress in this area, or at the very least, failed to enhance it:

"Mostly, virus inactivation treatments were developed within the laboratories of plasma fractionators or by individuals closely associated with these industries. These developments were not usually published in scientific journals so that information can only be found in product package inserts."[533]

[532] Transcript of Presentation by Counsel to the Infected Blood Inquiry relating to pharmaceutical companies involved in blood products: Speywood, Alpha, Abbott and Grifols, 5 October 2021, T4: 24 – T6: 5
[533] EXPG0000044/89

There was little urgency to access earlier safer heat-treated products

453. The Society submits there was little urgency to access earlier safer heat-treated products in the UK. As early as 1983, there were products being licenced in the US such as Baxter Healthcare's 'dry heat' process. As reported in the study, 'HIV and the Blood Supply: An Analysis of Crisis Decision making' published by the Committee to Study HIV Transmission Through Blood and Blood Products, Institute of Medicine 1995: *"There were basically three methods utilizing heat for viral inactivation used by U.S. manufacturers in the early 1980s: (1) in 1979, the Baxter Healthcare company initiated studies on heat inactivation of AHF concentrate using a 'dry heat' process. The dry heat process involved the application of heat at a specified temperature and time to the concentrate in the lyophilized (freeze dried) state (Persky pers. Com. 1995); ..."*.[534]

Only a few healthcare practitioners sought to gain early access to heat-treated products

454. The Society submits that only a few healthcare practitioners sought to gain early access to heat-treated products. Evidence before this Inquiry illustrates this point including:

a. The Presentation on Cardiff and Professor Bloom,[535] during which Counsel to the Inquiry referred to a document which said, *"With regard to Health Authorities' Defence to the Re-amended Statement of Claim, Dr Savidge said that he had been using heat-treated Factor VIII as early as 1983 and he was trying to get the Defence's Statement amended as it said heat-treated Factor VIII was not used until the end of 1984"*.[536] Counsel to the Inquiry noted that the Inquiry had seen that "it may even have been late 1982 in terms of early trials."[537]

b. Dr Mark Winter, who gave evidence that:

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[534] JREE0000019/102
[535] Transcript of Presentation by Counsel to the Infected Blood Inquiry relating to Professor Bloom and Cardiff Haemophilia Centre continued, 8 October 2020, T150: 18 – T152: 2
[536] HCDO0000271_014/4
[537] Transcript of Presentation by Counsel to the Infected Blood Inquiry relating to Professor Bloom and Cardiff Haemophilia Centre continued, 8 October 2020, T151: 23-24

"*There was intense discussion and disagreement at UKHCDO about which treatment to use at this very sensitive time. Many clinicians did not believe that British donor plasma carried any significant viral risk. No British patients had been reported as having AIDS who had been treated exclusively with BPL concentrate. There were very significant and understandable concerns that the heating inactivation process might alter the Factor VIII molecule so that it might lead to the development of inhibitor formation in the patient, a particularly serious event as it makes future treatment with concentrate very much less effective. There was no proof at that time that heating inactivation worked because neither HIV or HCV had been isolated. For these reasons many centres opted to continue with non heat-treated BPL concentrate until July 1985, by which time all haemophilia centres in the country did convert to the exclusive use of heat-treated product. Heat treated concentrate was in any case in short supply til 1985. By May 1984 I had managed to obtain funding for heat treated factor VIII and factor IX and therefore made the decision to switch all of my patients with both factor VIII and factor IX deficiency to the heat-treated product. I had obtained consent from my trust, and had completed the necessary paperwork to allow me to use a named patient product for each of my patients.*

All patients on home therapy were summoned to the centre and asked to bring with them any residual supplies of unheated concentrate. The situation was explained to them in (sic) and they were given the choice as to whether they would like to remain on unheated concentrate or move to the new heat-treated concentrate. They were instructed by the nursing staff as to how to administer the new product and were given supplies for home treatment".[538]

[538] WITN3437002/7, paragraphs 35.6 to 35.8

SECTION B4: TREATMENT, CARE AND SUPPORT

455. In this section, the Society will address the topic of treatment, care and support. In inviting views on this topic the Chair referred core participants to paragraph 8 of the terms of reference which requires the Inquiry to consider:

> *'8. ... the nature and the adequacy of the treatment, care and support (including financial assistance) provided to people who were infected and affected (including the bereaved), including:*
>
> a. *whether and to what extent they faced difficulties or obstacles in obtaining adequate treatment, care and support;*
> b. *the availability and adequacy of any counselling or psychological support for those infected or affected;*
> c. *the actions of the various Trusts and Funds set up to distribute payments;*
> d. *the differing criteria for eligibility for financial assistance applied by the various Trusts and Funds, the justification (if any) for such differences and whether such differences were or are equitable;*
> e. *the appropriateness of preconditions (including the waiver in the HIV Haemophilia Litigation) imposed on the grant of support from the Trusts and Funds;*
> f. *the extent of any differences in the arrangements made for financial assistance between England, Wales, Scotland and Northern Ireland;*
> g. *a broad consideration of the extent to which support is and has been comparable with support for those similarly infected and affected in other countries, for example, Canada and EU nations, such as France and Ireland.*'

456. The Society wishes to address the following sub-paragraphs of paragraph 8 a, b, c, d and f of the terms of reference in this submission and will do so in turn.

Whether and to what extent people infected and affected faced difficulties or obstacles in obtaining adequate treatment, care and support

457. This is an area in which the Society's membership feel very strongly that they were let down. In response to the question posed in the Society's survey, "Do you have any comments about the topic of treatment, care and support?", one member said:

"In our experience, there was too little, too late offered by way of treatment, care and support. In general I would say my late husband was well supported by his medical team in assessing which treatments could best meet his health needs however, on a wider scale it seems that treatment for patients at large was ill-considered for whatever reason, as it became clear that diseases such as HCV, CJD etc were still being spread after the risks were known. Care and support were shamefully lacking - until ministers were shamed into providing support through schemes such as EIBSS - which was far too late for a number of patients who had long since died and their families left in hardship. Although the Macfarlane Trust was responsive and helpful (and our experience of its staff was very positive), funds were too scant for meaningful support and people were left to plead and rely on whatever benefits they could claim. It really was a shameful way to treat a cohort of patients who had been so terribly let down."

458. In response to the same question, another member said:

"This section is very important. With my limited understanding of the situation, it did (at times) feel like Dad was being used as a guinea pig. I know research was vital to aid further develop[ment] of treatments and to understand the infections but I felt confused about what was happening. No support was offered to us (I have a sister) as children until my father died. Also, when he was dying, it felt as if he was kept away from us, as his decline was quite dramatic. This may not have been intentional but at no point were we asked how we felt or what we wanted to do. I know I am focussing on the situation as an affected child of an infected father, but I feel strongly that the impact of the situation on the children within families must be considered. The more we know about how traumatic, adverse childhood experiences affect the outcomes of children once they reach adulthood, the more apparent it becomes that the lack of any psychological support will have had a negative impact on the affected children."

459. Each of the above quotes eloquently articulates the wholly inadequate levels of service that was provided to those infected or affected, and which still remains one of their predominant memories all of these years later. This echoes a great bank of evidence already received and considered by the Inquiry.[539]

460. It is now clear that there should have been far greater consideration of the risks of treatment, of clinicians weighing up the risks, discussing those risks with patients and looking for alternatives. In fact, there was a push towards home therapy for those who could receive regular home treatment so they could get on with living their lives, but there should have been more opportunities for discussion and openness. It could be argued that an absence of this was part of the culture of the time, but there are lessons to be learnt from this. The Inquiry will recall this latter point being established through the evidence, particularly exemplified by the statement from Professor Geoffrey Francis Savidge in relation to aspects of haemophilia management in relation to contaminated products prior to 1979 and between 1979 and 1986, in which he said at paragraph 2:

"...there was a concerted effort from leading haemophilia physicians and from the Haemophilia Society to increase the individual patient consumption of factor VIII, in particular to initiate self-infusion home treatment policies and prophylactic treatment regimens particularly in children. These changes were considered to be of priority as the UK had been known for many years of all the developed countries in EU and in the US to offer remarkably low levels of factor replacement for the general management of patients. Such 'false economy' resulted in extensive long terms problems, with associated joint and muscle disease that was considered to be an excellent example of poor cost benefit. The funding of such projected increased expenditure on product would require central support, that was only forthcoming through the RHAs funding for the allocation to all DGHs to disperse to each and every discipline to fund ongoing service and proposed development. Consequently little money if any reached hospitals treating haemophilia patients with the proposed requirement for additional replacement therapy, and further reliance of any increased product supply was demanded of an inert Blood Transfusion Service and a terminally failing BPL fractionation facility. Thus extra money when found was spent on the purchase of

[539] See for example WITN0014001/8, paragraphs 6 to 6.10, WITN0015001/4, paragraphs 6 to 6.2

commercial imported factor VIII concentrate, usually from the US, in preference to the safe cryoprecipitate that as the recommend treatment of children and mild haemophilia patients (assuming failure with DDAVP) generally available (in some regions in excess). The US commercial concentrate was considered to be more user friendly, it could be stored at room temperature and was eminently more suitable for patients on home care programmes."[540]

461. Moreover, there were instances of centres not following UKHCDO guidelines from December 1984[541], with previously uninfected patients being treated and non-urgent surgery taking place where there should have been consideration of alternatives. Heat treated product was available as early as 1981 in Germany, and alternative treatment and wider use of Cryoprecipitate was a viable alternative. The evidence is clear that these options do not appear to have been canvassed or considered in consultations with patients.

462. Explanations around risk were either poor or non-existent, as confirmed by Dr Peter Jones in his witness statement:

"*What were PUPs told about the risks of receiving factor concentrates for the first time? From memory, the majority of PUPs were children in which case the parents were briefed on all available up-to-date information. This included the need to check on the safety of any product being used, including heat treated concentrate. Everyone, including PUPs or their parents, was aware that anonymous reporting of results occurred and no one ever to my knowledge raised any problem with that at any time. Of course, patients or their parents could decline any testing if they wished.*"[542]

463. Not only was initial treatment often inadequate, erratic, and contrary to guidance, but those infected were also often failed by poor or inadequate aftercare. There is ample evidence to this effect before the Inquiry from those affected by Hepatitis C:

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[540] ARCH0002508_002/2 – 3, but see also BART0000922_011, BART0002289, HSOC0000006
[541] WITN3289042
[542] WITN0841038/63, paragraph 92

"I remember him saying 'has no one ever mentioned Hepatitis C to you all before?' We said that no one had, we had never even heard of it being mentioned. Professor Evans looked shocked as dad had been an inpatient for 5 days with a Liver Specialist in a liver ward with people who had Hepatitis C back in 2005. During that time, there was no follow up blood tests to check for Hepatitis C".[543]

"Between initially seeing the consultant at [GRO-B] and the symptoms becoming worse in or around 2011, I did not receive any advice or treatment until I went to my GP. I therefore had no medical, financial or general support for approximately twenty years. There were no follow up appointments in the intervening period until I again pursued it myself when I felt really terrible".[544]

464. There are many other similar accounts in evidence before the Inquiry.[545]

465. Similar criticisms arise out of the treatment of those affected with HIV; some were asked to attend STD clinics and others had access to dedicated services which led to different outcomes. This is evidenced, for example, by Richard Smith, who says in his statement:

"When Linda then asked if it could ever be proved that I had not been infected in the past six weeks, since I had donated blood, the doctor simply shrugged. Linda and I were both devastated by his body language but even more so when we asked about our son, who was born after the blood transfusion. The doctor was more concerned about our daughter Faith who had been in the nursery whilst Linda was in theatre, and therefore, safe from infection. We again queried about Luke and were advised to take him to the STD clinic, a totally unsuitable place for an innocent teenager. Linda tearfully told him that Luke was under age and if she took him, she could lose her job if she was recognised".[546]

466. Unhappily the Inquiry has heard that this remains an ongoing problem in pockets:

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[543] WITN0206001/8, paragraph 47
[544] WITN0308001/9, paragraph 69
[545] By way of further examples WITN2006001 and WITN2254001
[546] WITN0460001/6, paragraph 25

"Only my close family know about what has happened to me and of course some people that I am compelled to tell such as health professionals and DWP but aside from that, I do not have the confidence to tell anyone else. Each time I have to tell someone, I worry that they will think it is my fault that I contracted these infections and I am terrified of the associated stigma. To this day, some doctors still make that assumption and inform me that I should attend the STD clinic for my care. There are still pockets of ignorance and my parents are also constantly afraid that people will find out."[547]

467. Relevant to the issue of wider support is the evidence that the Inquiry had heard about the difficulties encountered by those with a bleeding disorder in accessing other medical services usually regarded as routine treatments, such as dentistry and endoscopy. The following excerpts of evidence illustrate the issue:

"The dentists are afraid to do anything with you due to the bleeding disorder as well as the HIV status.

Even when they see you, they won't do a lot with you. They would wear two sets of surgical gloves as a precaution and you're always treated last in the day with a specific set of equipment for the HIV positive patients".[548]

"Whilst I had Hepatitis C, I was the last in the day for any operations, but now I don't have it, it is no longer an issue. When I go to doctor's and dental appointments, I no longer have to declare that I have Hepatitis C. When I had HCV, I had to tell everyone and they had to do things differently. For any examination they had to be extra careful, for example, wearing double gloves".[549]

468. This continuing failing, ultimately a form of discrimination, provides another illustration of the privations, lack of care, and lack of respect prevailing with regard to the medical treatment and support made available to them.

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[547] WITN1018001/7, paragraph 32
[548] WITN0008001/14, paragraphs 76 to 77
[549] WITN0071001/11, paragraph 61

The availability and adequacy of any counselling or psychological support for those infected or affected

469. The evidence demonstrates that the lack of provision of medical treatment and support of those infected or affected was and is repeated with regard to the support available for mental well-being. For example:

"I have never been offered any counselling or psychological support relating to the hepatitis C. I do believe that counselling and support should have been given. It may have stopped me turning to alcohol as a crutch if there had been someone to talk to about my illness".[550]

470. This is not an isolated example. Additionally, even those affected who were offered support often found this difficult to accept

"*I was offered one-to-one counselling on being diagnosed with HIV; however, I never went. Counselling is something that I might consider soon as I am finding it all hard to deal with at the moment.*

When I was first diagnosed with HIV I was required to meet regularly with a social worker from the hospital. The social worker also met with my first wife to explain chances of infection. The social worker even went as far to tell my wife to leave me. I feel they tried their best to separate us. I think medical professionals at the time felt under pressure from the CD to separate couples."[551]

471. The Inquiry is accordingly invited to reflect the evidence by making a finding that the supply of adequate psychological support has in a large number of cases either been absent or lacking. This failing has been repeated through from the provision of test results throughout the course of the lives of those affected, continuing with a lack of

[550] WITN0091001/8, paragraph 33
[551] WITN0054001/11, paragraph 53 to 54

support to those who have been bereaved. Still today there is no dedicated service in England to support people[552]; despite regular calls to rectify this even as the Inquiry began, only now has a report been commissioned.

472. The Inquiry will recall the evidence of Paul Sartain, who was infected by Hepatitis C, and who was ultimately driven to pay for his own psychological support to the sum of £12,000 as events took their toll on him.[553] It is shameful that the complete lack of support meant that Mr Sartain had to find this support of his own initiative, and then pay for it himself.

473. It is also right to record that the absence of any or adequate support provided by the state inevitably had an impact on the family lives of those infected. The Inquiry has heard that in many cases otherwise happy marriages could and did not survive:

"*The biggest impact of the treatment was on my relationship with Pauline. She did not cope very well with me undergoing treatment for Hepatitis C and she could not manage with the side effects. I had told her about the Hepatitis C diagnosis and we decided together that I should undergo the treatment. The reality was I could just about manage to go to work, but then every evening I would need to go straight to bed, to reserve energy for the next day. During the weekends I also needed to rest, trying to gain strength for the following week at work. This inability to function day to day as a result of the treatment, led to marital problems.*

Ultimately the treatment cost me my first marriage. Apart from the haemophilia and until I was diagnosed with Hepatitis C, I had led a normal life. But the impact of the treatment seemed to be that, to Pauline, I had become a disabled person, and it started affecting our marriage. Our relationship deteriorated and eventually fizzled out.

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[552] See INQY1000054/43; Transcript of Infected Blood Inquiry hearing - Witness Bleeding Disorders Experts, 28 February 2020: *"The Inquiry understands that (a) in October 2018 NHS England announced funding of up to £50 million for a new screening service to be put in place to provide long-term support and treatment for people with physical and mental health issues following the Grenfell Tower fire, and (b) a free and confidential NHS service, the Grenfell Health and Wellbeing Service, is available to children and adults affected by the Grenfell Tower fire. Please confirm whether there is any equivalent or similar service in England for people infected or affected in consequence of infected blood or blood products". The short answer to the question is that there isn't any such service in England".*

[553] WITN1013001/24-25, paragraphs 101 to 107

We got divorced in late 1999, following completion of my treatment. Following our divorce, Pauline sadly died from cancer."[554]

474. This was not an isolated example[555], and will be many other examples both from witnesses before the Inquiry, and experienced by those who have not, or could not provide evidence of the consequential damage arising from inadequate treatment, infection and the lack of support.

475. The continuing lack of a proper structure under which enduring psychological support can be made readily accessible has led and will continue to lead until resolved to long term mental health issues for a significant proportion of the infected and affected community. As the Inquiry will be painfully aware, people infected with contaminated blood products have complex and increasing care needs, and the Society submits that these have not been fully recognised, let alone met. The Society submits that it is vital that these undeserved consequences are acknowledged and addressed within the Inquiry's report and recommendations.

The actions of the various Trusts and Funds set up to distribute payments;

the differing criteria for eligibility for financial assistance applied by the various Trusts and Funds, the justification (if any) for such differences and whether such differences were or are equitable

476. It is convenient from the Society's perspective to deal with these two issues together. The Inquiry has heard evidence of dissatisfaction from those intended to benefit from the various Trusts and Funds both around inconsistencies in the amount distributed and the speed and quality of their response. Representative examples of this evidence follow:

"*The MacFarlane Trust seemed to cause issues with the various HIV groups, involving how they were distributing monies. The Groups felt this was being carried out unfairly. It appeared that they would give different amounts to different people, depending on*

[554] WITN1014001/9-10 , paragraphs 44 to 46
[555] See also WITN0072001/6, paragraph 28

the quality of their application, rather than its merits. This caused anger and despair about the MacFarlane Trust"[556]

"*I contacted the English Infected Blood Support Scheme (EIBSS) to tell them of my condition and forwarded them the hospital letter explaining I will be an inpatient for three days. I exhibit my requests and their replied. Exhibit WITN006107 details EIBSS' request for details of any travel and accommodation arrangements I might require, and my response. Exhibit WITN006108 details their response to the details I provided. I then phoned them and requested additional answers to my other requests for funding regarding the hospital stay, and I received an email in response (WITN006109). In summary, the email stated that EIBSS 'do not have any additional payments available during a time of recover'. The EIBSS is the worst scheme that has ever existed. How dare they say there will be no financial support during the recovery of any condition that was brought on by this outrageous cover up that the Department of Health is responsible for. They expect victims to look after themselves when they are at their most vulnerable. They expect their families to continue to be unpaid carers, saving the Department of Health billions of pounds in hospital fees over the years. Then, when the victims die, their way of saying thank you to the widows is putting them on an income top-op means tested annual payment. My biggest fear at this stage is not death from cancer, but the way EIBSS will treat my wife if I do die. We have to leave our spouses and family under the control of the very people who abused us physically, financially and psychologically. These are the people who have got away with murder and are now administering support for us. They have become judge and jury on what support we receive. I am now, as a victim, stood here with my begging bowl again, while dealing with the diagnosis of cancer*".[557]

477. There is ample evidence before the Inquiry that the availability of funding was poorly advertised, and that applications were not easy to negotiate:

"*We only found out through St Thomas's Hospital that we could make an application to the Macfarlane Trust which ran a relief fund but the paperwork was very*

[556] WITN0047001/7, paragraph 18
[557] WITN0061005/5, paragraph 11

bureaucratic and it felt like begging for charity or asking for benefits which neither of us had ever done. I don't remember the Macfarlane Trust giving us any more than approximately £500 in discretionary payments. The process was not made easy for someone so ill and no assistance was provided to facilitate the process. They did not take my needs into account, and it was 'one size fits all' payment. The procedure was comparable to apply for welfare state benefits, and for a proud Yorkshireman this was extremely difficult. There were numerous preconditions to receiving the money. The money offered was paltry. Additionally, we received the ex gratia payment of £30,000. The money was inadequate and too little too late".[558]

478. In many cases it was clearly more than just a fight to achieve an award. In some cases awards were declined for no apparent reason. An example of this is provided in the written statement of Allyson Adams, whose mother contracted HIV from an infected blood transfusion:

"*My mum prior to her death was refused payment from the Skipton fund as they said there was no record of her having a contaminated blood transfusion. Despite appealing this in 2012 it was turned down*". [559]

479. From evidence received by the Inquiry, it is clear that the failings in the way the Trusts and Funds operated arose because of their structure and operation, and not through any action on the part of those who used them:

"*The DWP carried out a review of cases of people with haemophilia, who were refused PIP. This was a result of representations and my supporting evidence from some of my challenges at Tribunal cases. This demonstrated that there were many poor quality assessments of the impact of haemophilia on people's functional ability. As a result, 62% of those reviewed were either awarded PIP or awarded higher rates of PIP, and £1 .2 million was paid out in arrears of PIP. 31. The private assessment companies were required by the DWP to issue new guidance to their staff about haemophilia. However, I still see examples of poor quality decisions, which I have had to challenge. In addition, for beneficiaries without haemophilia or who have mild haemophilia, the*

[558] WITN0664001/15-16, paragraph 54
[559] WITN2324001/6, paragraph 1

impact of hepatitis C, liver disease, post-treatment symptoms, and the psychological impact of acquired infections, can still result in poor quality decision making. Although, in fairness, the presentation of these conditions is variable so it makes assessments more difficult.[560]

... (paragraph 41) My understanding was that on occasion CF and MFT required people to have a benefits check before CF or MFT considered what additional financial support they might award. This is best practice as I have commented earlier in this statement. It was not my understanding that payment would be refused without me having had a referral, though I knew that if I obtained additional income for someone, that might obviate the need for additional financial support by a charity or enable the charity's payments to top up benefits, this being to the beneficiary's advantage as it further increased their disposable income".[561]

480. The Grants and Trusts schemes overall have been set up and changed as a result of pressure applied to the government at every stage, and it was only the community continuing to fight for the money to continue to exist that has led to them evolving. It is the Society's considered view that these organisations were never sufficiently funded, or given any reassurance of the long-term support needed for the community, or even considered the community and the impact of infection.

WITN0061007

481. The Society believes that both the weaknesses in the operation of the Trusts and Funds, and the repeated failing of the Government to address this when it was (persistently) raised, must be exposed by the Inquiry's findings, and that the impact this had on those infected and affected should be acknowledged.

WITN0061008

WITN0061009

482. In contrast to what the Society believed should have happened, the support schemes rarely involved real consultation with those infected and affected, and never took into account the longer-term financial impact on families. Those people and families who were entitled to make claims should never have been made to feel like they were charity cases (as the evidence shows that many did). Nor should claims have frequently

[560] WITN3487001/6-8, paragraphs 29-32
[561] WITN3487002/13, paragraph 41

been refused without any or any real reason resulting in many claims not being pursued.

The extent of any differences in the arrangements made for financial assistance between England, Wales, Scotland and Northern Ireland

483. The Society does not have extensive submissions to make on this issue, but it does wish to note that it will be clear to the Inquiry from the evidence that it has heard that the impact of the devolved governments was such as to offer varying levels of support (and, in fact, including treatment[562]). This is wrong as a matter of principle and creates what has been described in evidence as a 'postcode lottery':

"*The money I got from the fund has helped me, but I think it should be more as it is higher in other parts of the UK. It makes me angry to think that people are treated differently because they are 'just' a stage 1 category, and because of where they live. As Raymond Bradley QC said during the preliminary hearings, 'It's a postcode lottery'. If my accident had happened in Scotland or Ireland, I would have got more money. But because I happened to have it in England, I get less. The most ironic part is that my parents are Irish born and bred, they moved to Scotland which is where I was born, then they moved down to London when I was two or three months old. That is the irony*".[563]

484. Examples of discrepancies which the Inquiry will be aware of include the exclusion of a special category mechanism in Northern Ireland, and the exclusion of widows from eligibility outside of Scotland.

485. The Society submits that it is self-evident that the existence of differing levels and categories of award in different home nations is a source of great irritation to its membership. It leads to confusion and resentment. It is in the interests of good governance as well as fairness and consistency of operation that all of the devolved

[562] WITN0262001/10, paragraph 66 and WITN0215001/6, paragraph 19
[563] WITN0436001/10, paragraphs 7.8-7.9

nations align their offer to the community; the Society submits and expects that the right solution to this issue would be default to the most generous model. It trusts that this issue can and will be addressed in the Chair's ultimate report and recommendations.

SECTION B5: SELF SUFFICIENCY

486. In this Section, the Society will make a limited number of observations on the issue of self-sufficiency. The Inquiry has already set out its response to the question specifically addressed to it as to 'representations made to government by the Haemophilia Society on self-sufficiency and imported blood products' above in section A6. The Inquiry will note that the Society continued to lobby the Government to seek to achieve self-sufficiency throughout the relevant period, albeit recognising that in the meantime continued reliance on imported blood would be required to treat demand from those already receiving transfusion.

487. In response to the question posed, *"Do you have any comments about the topic of self-sufficiency?"* the Society received the following four responses, which it believes are illustrative of the views of its membership, and which it adopts unhesitatingly:

'Self-sufficiency would have saved many lives. they should have listened to Lord Owen. Lives should have been a top priority and not money.'

"It was the failure of successive governments to implement self-sufficiency that was the root cause of most of the HIV infections. It would have had less impact on HCV as this had been widely circulating in the population of the UK for many years before it was identified."

"I believe self-sufficiency was not a priority simply as a cost saving measure. There did not appear to be the infrastructure or capacity to become self-sufficient, and there appeared to be a lack of political will to become self-sufficient - to me it appears the

'easiest' route was taken – ie. 'just buy it in and let someone else do the hard work of donor collection"

"In achieving self-sufficiency we need to ensure that all product is fit for purpose. This includes regular screening of donors, definite checking the source and content of any blood purchased for stocks, definitive recognition of product used in patients, and properly maintained storage facilities for product (including unannounced inspectors to check the storage of product)."

488. The Society reminds the Inquiry that there was clear advice from the World Health Organisation in 1975 that countries should be aiming for self-sufficiency in blood and blood products. Lord Owen stated this would be pursued as a policy in the House of Lords in 1975, and investment was forthcoming, but for reasons that have never been clear the policy was not pursued at that time. The Society regards this as a complete failure by Government to invest in a safer and reliable blood supply. Many more lives would have been saved from HIV if this had been achieved, and if such a project had been linked to extra investment in the development of heat-treated products.

489. It was widely known that the imported products included blood that had been gathered from 'Skid Row' (cf. 'World in Action' TV 1975 "Blood Money" programme) and this should have served to prompted more urgent action to improve self-sufficiency, but in fact at the time there was actually an increase in the importation of Factor. Considering the evidence at the time and despite the economic outlook, it is obvious even without the benefit of hindsight that self-sufficiency should have had higher priority.

490. There was a serious under estimation of the requirements to become self-sufficient with ever moving goalposts, and an underestimation of future needs for home treatment and in the light of knowledge at the time whether expanding the use of home treatment at this time with significant unknown risks was a sensible cause of action.

491. Furthermore, the situation at BPL leading to the Medicines Inspectorate Report of 1979 where it was found BPL did not adhere to commercial standards was used to (seek to) improve standards rather than improve output, and this should not have been allowed

to happen. There were proposals at the time that could have included the development of BPL as well as improving supply; these should have been adopted.

SECTION B6: DECISION-MAKING OF THE COMMITTEE ON THE SAFETY OF MEDICINES AND ITS BIOLOGICALS SUB-COMMITTEE

492. In this section, the Society makes a number of observations about the decision-making of the Committee on the Safety of Medicines and its Biologicals Sub-Committee. Before doing so, it wishes to highlight the views of two respondents to the Society's survey on closing submissions.

493. In response to the question posed, *"Do you have any comments about the decision-making of the Committee on the Safety of Medicines and its Biologicals Sub-Committee?"*, one member said:

"While attention quite rightly focused on the efficacy of treatment available, the decision making of the committee should have addressed clearer communication to patients on risks of side-affects."

494. In response to the same question, another member said:

"By being more open to communicate with patients and haematology staff, making everyone aware verbally of any potential risks and supported with printed/online content as well as demonstrating a comparison between different drugs and potential risks with each alternative. This would help to empower the patient on making a more informed decision on which treatment they can have, when there is the option of alternative medications."

495. The Society supports and adopts the views of its membership and also submits the following in relation to the decision-making of the Committee on the Safety of Medicines ("CSM") and its Biologicals Sub-Committee:

a. there was not enough scrutiny of the source of blood donations; and

b. the risk of infection should have been clearly communicated to patients through safety information provided

There was not enough scrutiny of the source of blood donations

496. Professor Michael Rawlins gave evidence to this Inquiry that, *"Even before I joined the CSM, it would consider the source of donated blood used in blood products. Our interest and scrutiny of this issue grew as the terrible situation of infected blood emerged."*[564] The Society does not accept that this assertion is supported by the weight of evidence that the Inquiry has received.

497. The risk of transference of Hepatitis was well-known in the 1970's; and it was known that risks arose from using blood donated from intravenous drug users as well as prison populations; and the payment of members of this population in the collation of plasma. This point was made in the World in Action episode, 'Blood Money' which first aired on 1 and 8 December 1975. World in Action investigated the American blood business; their investigation took them to ten of the 24 Plasma Centres of the Hyland Division of Baxter Laboratories, a leading American drug company. The presenter said on the program, *"We found that Hyland's paid donors included many alcoholics and down and outs. Paid donors are from six to thirteen times more of a health hazard than British volunteer blood donors. Because of their lifestyle, many carry a high risk of passing on hepatitis, a serious liver disease"*.[565] Closer supervision or inspection of these facilities should have been carried out or investigated by the CSM.

The risk of infection should have been clearly communicated to patients through safety information provided

498. The Society submits that the risk of infection should have been clearly communicated to patients through safety information. Professor Michael Rawlins gave evidence to this Inquiry that in July 1983, *"the Biologicals Subcommittee and CSM were unsure*

[564] WITN6406001/26, paragraph 7.5
[565] WITN4032004/15

of the aetiology of AIDS but an infectious agent 'seems likely'"; they also acknowledged that *"Patients who repeatedly receive blood clotting-factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small."*[566] The Society submits that although the risk was small, this was not included on the patient information leaflet or for clinicians. It should have been.

499. The CSM should have taken greater responsibility in communicating the risks of blood products. The Society submits that too much responsibility fell to treating clinicians, who having direct contact with the patients, could see the life-altering and beneficial impact of new treatments on patients. Whilst that of itself is true, the Society submits that clinicians would not have had sufficient information available to them to objectively assess and advise on the risk of treatments. The Society regards this latter points as falling squarely within the remit of the CSM.

[566] WITN6406001/63, paragraph 16.18

SECTION C: SUBMISSIONS ON RECOMMENDATIONS

500. This section outlines recommendations that the Haemophilia Society submits that the Chair should make. It is divided into two sub-sections; in section C1, for convenience of access it repeats the submissions made in the Haemophilia Society's interim submission on non-financial recommendations submitted to the Inquiry on 20 June 2022;[567] and in section C2 it addresses submissions in relation to financial compensation.

SECTION C1: SUBMISSIONS ON NON-FINANCIAL RECOMMENDATIONS

501. This section of the submission relates to the non-financial recommendations the Society submits that the Chair should make. It is informed by the responses of 251 of the Society's members to a survey asking for the membership's views on non-financial recommendations, and considerable correspondence with its membership and former trustees over the past years.

502. The topics that this section addresses are:

a. Public Inquiry Reform;
b. Redress for Avoidable harm;
c. Consent;
d. Continuing scrutiny of recommendation implementation;
e. The Irish Experience;
f. Access to current treatment and up to date information;
g. Ongoing longer term assistance;
h. Research on future care and palliative care;
i. Training and education;
j. Education about the contaminated blood scandal; and
k. Apology / Memorial

[567] SUBS0000020

Public Inquiry Reform

503. Section 1 of the Inquiries Act 2005 contains the power to establish a Public Inquiry. The power is solely exercisable by a Minister. Save in the event of a successful judicial review resulting in an order requiring the Minister to establish an inquiry, the public, or affected sections of the public, are frequently denied justice or have justice delayed. This Inquiry is a paradigm example: decades of delay have resulted in many dying without answers or compensation, whilst evidence is lost or destroyed, memories fade and witnesses become unavailable.

504. Under current legislation, the public find themselves disenfranchised, and unable to bring matters of public concern to light. This (and previous) legislation, has therefore resulted in meritorious groupings repeatedly seeking the establishment of public inquiries on matters of public concern to no avail, with such concerns eventually leading to the establishment of a belated public inquiry – often after many decades of waiting. By then, it may be too late for those that have been affected by the concerns forming the basis of the original demand, and the public will have been wrongly deprived of recommendations by the eventual public inquiry which should have been available far earlier. There can surely be no better example of this than this Inquiry, where the scandalous issues of concern have been overlooked by successive Governments of different political persuasions, with the eventual establishment of a public inquiry decades too late, and when many of those affected are no longer with us.

505. The Society and its members feel strongly that reform of the Inquiries Act is the only way to ensure that others caused avoidable harm by the State, and who thereby find themselves in poverty and poor health, do not have to expend energy lobbying Ministers/Governments who may have an interest in refusing a statutory inquiry or non-statutory review.

506. The Chair is therefore asked to consider whether the circumstances leading to the establishment of this Inquiry are such as to justify a recommendation that steps be

taken to ensure that those affected by an issue of genuine public concern are provided with a clearer gateway to pursue the establishment of a public inquiry. Such a recommendation might commend an amendment to the Inquiries Act 2005, whereby a Minister (or Parliament) would be required to consider the establishment of a public inquiry if a certain percentage of Members of Parliament formally demanded it. Alternatively, a recommendation could be made to establish an independent body who would have the power either to convene a public inquiry (which would require an amendment to the Inquiries Act), or to recommend to the relevant Minister that a public inquiry be held. There is precedent for such an independent voice. Canadian Judge Cory was asked, as an independent figure, to consider whether various matters of concern in Northern Ireland merited the establishment of a public inquiry, and to make recommendations to government. The Chair could consider recommending that formalising such an ad hoc arrangement to an independently constituted body for such a purpose.

507. Such an independent body could be charged with applying transparent criteria to assess the circumstances in which statutory and non-statutory inquires/reviews must be held. Such a body could also collate inquiries and reviews (so that there is a central repository of recommendations), monitor recommendation implementation and, in appropriate circumstances, require inquiry Chairs to review implementation.

508. The Society draws to the Inquiry's attention other submissions to this Inquiry related to the topic of public inquiry reform.[568]

Redress for Avoidable harm

509. The Inquiry's work has laid bare the fact that the contaminated whole blood and blood products infected and affected community has suffered avoidable harm as a result of patient safety systems failures.

[568] SUBS0000003/39-40; SUBS0000015/12-13

510. Historically, the Government was reluctant to settle the HIV haemophilia litigation. These reasons are summarised in a briefing for a meeting between the Prime Minister, and Robert Key and Society representatives regarding Haemophiliacs with HIV infection, dated 22 November 1989, which is extracted in Section A of these submissions.[569]

511. Litigation takes years which, the Government knew, people with haemophilia infected with HIV/AIDS did not have. Almost 40 years on, people with haemophilia are still dying of infected Factor VIII and IX products without adequate recompense and, as Sir Robert Francis KC's Infected Blood Compensation Study highlights, without being able to put their affairs in order. This continues to impact the Society's members. On 7 June 2022, Sir Robert published his study, 'Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework', that looks at options for a framework for compensation for the victims of the infected blood tragedy.[570] This report is referred throughout this submission as "Sir Robert's Infected Blood Compensation Study report".

512. In the 1980s and 90s, the Society decided that fairness and equality for all its members, and the community as a whole, required that there be some level of immediate financial relief for all those infected and for families and the bereaved. The only means of securing that was to mount successive campaigns based on moral, not legal, rights. As Sir Robert observes in his Infected Blood Compensation Study report, those successive campaigns resulted in a *'"patchwork" of support"* which has been wholly inadequate for reasons explained by the APPG and which he sets out in the report[571].

513. The support monies made available are considered by the current Government to be *ex gratia* payments[572] but even here there is confusion: in March 1995, speaking about the Macfarlane Trust, Baroness Cumberlege told the House of Lords, *"the majority of*

[569] WITN6392101
[570] RLIT0001129
[571] RLIT0001129/43, paragraphs 4.10 to 4.12, in particular.
[572] Transcript of evidence of Matthew Hancock to the Infected Blood Inquiry, 21 May 2021, T148: 17-21 and also RLIT0001715/22, paragraph 3.2, Government's Response to the Cumberlege Review dated 26 July 2021, which described the Infected Blood Support Scheme as providing "ex-gratia support" .

the payments made were not ex gratia since an undertaking had to be made not to take the matter to the courts"[573].

514. As set out below, history appears to be repeating itself. Mr Hancock told the Infected Blood Inquiry that he accepted that the Government has a moral responsibility to address the impact of what has happened to those infected and affected[574]. But it is clear from the evidence received by the Inquiry (or indeed the absence of evidence) that this 'acceptance' has been arrived at without there being any clear or coherent approach to Government decision making about those sections of the public caused avoidable harm by patient safety systems failures where Government owes a moral responsibility, as opposed to those to whom it does not owe moral responsibility.

515. The Society seeks a recommendation that there be publicly available, clear and coherent criteria setting out the circumstances in which the State will pay financial redress to members, or a section of the public, who are suffering or who have suffered avoidable harm as a result of patient safety systems failures.

516. The Society seeks a further recommendation that this Inquiry endorses the Cumberlege Review's recommendation 3 that there be a new, independent Redress Agency (see below). This may be an appropriate body to determine when such criteria are met. References in this submission to "the Cumberlege Review" refer to the report of the Independent Medicines and Medical Devices Safety Review (titled 'First Do No Harm'), prepared by Baroness Cumberlege and published on 8 July 2020. The Cumberlege Review is addressed further later on in this submission.

517. In its response to the Cumberlege Review, dated 26 July 2021, when giving reasons for declining to accept the Redress Agency recommendation, the Government, through the Department of Health and Social Care ('DHSC'), prayed in aid its ability to set up

[573] BWCT0000017/8, which is a letter dated 3 May1995 from F.G.H Hill (Consultant Haematologist) to 'Maggie', enclosing a photocopy of the proceedings of a debate in the House of Lords dated 15 March 1995. One notes that this statement preceded Lord Clarke's views about the Government's thinking in 1989 highlighted by Sir Robert in his Infected Blood Compensation Study Report at page 44 paragraph 4.17, RLIT0001129

[574] Transcript of evidence of Matthew Hancock to the Infected Blood Inquiry, 21 May 2021, T126: 15-19

support schemes. It referred to the 'Infected Blood Support Scheme' (sic).[575] The only inference that can fairly be drawn from that reference is that the current Government believes that the EIBSS (one presumes) and various other infected blood support schemes (and possibly trusts) provided/provide an example of redress done well. The evidence does not support that construction.

518. The Government representation to other sections of the public who have suffered avoidable harm as a result of NHS patient safety systems failures, that the infected blood support schemes evidenced its ability to set up vehicles for providing financial support that were/are fit for purpose, is of concern for two main reasons.

519. First, that suggestion flies in the face of all the evidence heard in this Inquiry by those who utilise the schemes. This part of the Government's response to the Cumberlege Review suggests that it (and the authors of the DHSC response) were either ignorant of, or paid no heed to, the evidence of trust and scheme users to this Inquiry. They provided abundant evidence of the adverse effect on them of: the lack of any financial assessment of their losses or their needs; the psychological harm caused by different treatment of infected and affected in each of the devolved nations; divisive means testing; needless complexity and opacity; onerous requirements for evidence before even small sums would be paid out; unexplained exclusion of bereaved parents in financial need; the lack of any proper voice of the infected and affected within the trust and scheme administration; and the conflict between users in dire need and trust/scheme administrators who held back large reserves of monies intended by Government to be paid out to those infected. The end result for the large majority of infected people was that the trusts and schemes demeaned them because they were constantly required to hold out a begging bowl.

520. Second, the Government's July 2021 response failed to acknowledge, or even refer to, the oral evidence of Mr Hancock. Speaking to the Inquiry on 21 May 2021, the then Secretary of State for Health and Social Care accepted that the trusts and schemes had

[575] RLIT0001715/22, paragraph 3.2

been run without there being a *"proper process around coming to a fair and just way of ensuring that people are supported"*[576].

521. As the Government's July 2021 response to requests for financial support by other harmed sections of the public appears uninformed by its own former[577] Minister's acceptance, just two months earlier, that the infected blood support trusts and schemes were inadequate and unfair, it is hardly surprising that Sir Robert Francis records[578] that trust is so low on the part of some, that doubts were expressed about the authenticity of the Government's intention to pay compensation[579].

522. The Society was also astonished to see from the blog written by lawyers representing families harmed by sodium valproate[580], that the Government recommends, just as did the Governments of the 1980 and 1990s in relation to infected blood, that those families litigate. Nothing, it seems, has changed. When presented with an NHS tragedy that should never have happened, Government's knee jerk reaction is to deny financial support, pray in aid the need to protect the principle of no fault compensation, state that the priority must be improvement of health services, and invite those harmed to litigate.

523. The Society notes from the Cumberlege Review and the Select Committee's report on NHS Litigation, that there is now a significant body of authoritative work which has found that not only does the current adversarial clinical negligence system fail those who have suffered avoidable harm, but, importantly for the public at large, that the adversarial system is an obstacle to improving patient safety.

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[576] Transcript of evidence of Matthew Hancock to the Infected Blood Inquiry, 21 May 2021, T125: 10-16
[577] Mr Hancock resigned on 26 June 2021
[578] RLIT0001129/10, paragraph 1.11, Infected Blood Compensation Study Report.
[579] That commitment having been made expressly by Mr Hancock: "*...if the Inquiry points to compensation, as opposed to a support scheme, in the future then the Government will pay compensation*" (see transcript of evidence of Matthew Hancock to the Infected Blood Inquiry, 21 May 2021, T151: 17-19).
[580] Leigh Day blog, 'Lawyers look forward to the implementation of redress schemes recommended by Baroness Cumberlege', dated 27 May 2022, https://www.leighday.co.uk/latest-updates/blog/2022-blogs/lawyers-look-forward-to-the-implementation-of-redress-schemes-recommended-by-baroness-cumberlege/

Consent

524. Improvements have been made to the way healthcare professionals go about seeking patient agreement to treatment (ie. consent) in the decades since the NHS first started prescribing US Factor VIII, and the General Medical Council's guidance was revised recently[581]. However, the Cumberlege Review provides a significant body of evidence which demonstrates that there is still a great deal going wrong. Doctors remain too ready to make assumptions about what patients want, or to adopt the position that they know what is in their patients' best interests. They are still overselling possible benefits, underselling possible burdens, and not being clear enough about what is uncertain and unknown.

525. The Cumberlege Review records that women treated with pelvic mesh in the twenty first century faced not only an arrogant attitude, but also that the Review was told of *"missing or altered medical records"* and *"concerns about deliberate cover ups"*. Further that some hospital Trusts routinely destroy medical notes which is concerning for long latency adverse events where harm may not become apparent for many years[582]. In Annexe A to the Government's Response to the Cumberlege Review and in relation to pelvic mesh, it is said that *"Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators."*[583] And the response refers to the fact that the GMC is currently reviewing its guidance *Good Medical Practice* which came into effect in April 2013. But no conclusions are reached as to why this cultural issue of dismissive, defensive attitudes persisted into the twenty first century, and after April 2013.

526. It is difficult for those harmed by new medicines and by new medical products and devices to succeed in a claim for damages for personal injury based on the negligent failure to provide information. That may be for a variety of reasons including the fact

[581] General Medical Council, 'Decision making and consent: Guidance on professional standards and ethics for doctors'. published on 30 September 2020, https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf.
[582] The Independent Medicines and Medical Devices Safety Review (aka First Do No Harm, referred to herein as "the Cumberlege Review"), published on 8 July 2020, see paragraphs 5.43-5.44 at pages 152-153
[583] RLIT0001715/43 and 98 (item 50), Government Response to the Cumberlege Review dated 26 July 2021

that "consent" appointments are not audio or video recorded, and the difficulty for patients in proving that they would have acted differently if complete or differently presented information had been provided.

527. The Society invites the Chair to consider the "Informed Consent" section of the Government's Response to the Cumberlege Review[584], where it accepted the "Actions for Improvement", and consider whether those go far enough. Publication of this Inquiry's report may also provide an opportunity to monitor implementation of, for example, the National Institute for Health and Care Excellence's shared decision making guideline and the extent to which patients are routinely made aware that they have the right to record a discussion with a doctor if they wish to do so. The Chair may feel that the infected and affected would derive particular benefit from hearing evidence to assist with consideration of recommendations addressing cultural attitudes in the NHS, particularly to believing patients as well as listening to them.

Continuing scrutiny of recommendation implementation

528. The Society and its members are aware that this Inquiry's recommendations to Government are no guarantee of their ultimate implementation for the benefit of current and future people infected and affected by infected blood products. However, the Society asks the Chair to make recommendations to enhance the scrutiny and implementation of his recommendations. It is submitted that this might be achieved in a number of ways, including:

a. the adjourning of the Inquiry, post its report, with a recommendation that the Chair review implementation of recommendations within a given time period, with the possibility of a supplemental report commenting on the success or otherwise of the implementation of the final recommendations in the interim; and/ or

b. a recommendation that the implementation of the recommendations in the final report be reviewed by the cross-party Health and Social Care Committee on a regular basis, with consequent reports to Parliament.

[584] RLIT0001715/15-18, paragraphs 2.23-2.24, Government Response to the Cumberlege Review dated 26 July 2021

The Irish Experience

529. When Brian O'Mahony gave evidence to this Inquiry, he spoke of how non-compensation elements of the Irish Compensation Scheme for Hepatitis C and/or HIV, including the Health Amendment Act Card and liaison officers/case managers were implemented in Ireland. These changes have proved most valuable over time as infected people age and their needs change, and the important role played by knowledgeable and experienced case managers in ensuring that infected and affected people gain the maximum benefit from non-financial areas of redress.[585] This example clearly demonstrated the advantages for people of these roles and should be incorporated into any proposed system.

Access to current treatment and up to date information

530. The Chair is asked to make a recommendation that all those affected by bleeding disorders, contaminated blood products and all related infections are afforded the following due to current services not providing the necessary level of support and care, as is apparent from evidence provided to this Inquiry:

a. access to all knowledge of new treatments and information relating to their condition, to be provided through Haemophilia Centres;
b. guaranteed access for all with bleeding disorders to recombinant (non-plasma) products;
c. the choice of treatment to suit people's lifestyles and guaranteed access for all sufferers to new therapies, to include gene therapy;
d. guaranteed access to care that would include psychological services, pain management and physiotherapy for all of those identified with the current service specification;[586] and
e. equality of access to all care to include dental treatment and endoscopies.

[585] Transcript of evidence of Brian O'Mahony to the Infected Blood Inquiry, 8 November 2022, T49: 23 - T50: 25
[586] The current service specification is available online: https://www.england.nhs.uk/wp-content/uploads/2013/06/b05-haemophilia.pdf

531. The Society and its members are conscious that all patients will require prompt access to appropriate NHS treatments for a full range of ailments, and that such access for many will be problematic, particularly in the post Covid-19 era. A recommendation is not sought that by virtue of their condition, people with bleeding disorders/ infected with contaminated blood/ HIV/ Hepatitis B/C should be able to "queue jump" in relation to NHS waiting lists. A recommendation is however sought, given the extensive delays that such sufferers have endured, that in relation to their conditions and issues associated with such conditions only, they be afforded a facilitated and expedited means of access to NHS services to avoid future delays and to avail themselves of prompt treatment. This could be facilitated through an NHS care and treatment passport, which would be a record designed to help communicate their particular needs to doctors, nurses and other healthcare professionals.

Ongoing longer term assistance

532. A recommendation is sought that public funding be provided to the Society, and to other Haemophilia Societies in the UK and other charities supporting the infected, to provide advice and advocacy services to those affected in relation to the report, its implementation, and any scrutiny of that report in pursuance of the proposed recommendation above, and generally. Public funding should also be provided to ensure that the Haemophilia Societies, and charities working in this sector, have an ongoing ability to assist those affected by the issues covered by this Inquiry.

533. What is clear is that those affected by the conditions considered by this Inquiry will need ongoing assistance and care from the health and social care systems, customised to individual need. A specific recommendation is therefore sought that the Social Care system is geared to accommodate these individual needs, and to properly fund them. Such a recommendation may need to encompass appropriate swift mechanisms to challenge any refusal of such identified needs to ensure that any difficulties are quickly addressed, and resolved, without the need for litigation. For example, a Case Manager could assist individuals from a financial perspective and support them in making claims for benefits and support generally.

534. In relation to litigation and dispute resolution more generally, a recommendation is sought that the government/public bodies should consult with individuals regarding the use of non-disclosure agreements, and/or waivers of rights a part of any settlement agreements reached. Non-disclosure agreements, and/or waivers of rights should only be used if an individual agrees to their use.

Research on future care and palliative care

535. The Society seeks a recommendation that there be research into the needs of those infected by contaminated blood and blood products with particular reference to changing needs and health risks as those infected age, the specific needs of people with bleeding disorders who are dually infected, the long term effects of treatment for AIDS and Hepatitis C and the needs of infected women as they age particularly in relation to bone density.

536. Public funding should also be made available to consider and analyse the as yet unknown long term impacts of living with bleeding disorders/ HIV/ AIDS/ Hepatitis, to include the social impact as well as the clinical needs and to report onwards to government.

Training and education

537. On the basis of past patient experience, a recommendation is sought that all relevant medical professionals, to include doctors, nurses and dentists, should have included in their mandatory training:

a. advanced patient communication skills, to include direction as to how to liaise with patients to avoid them feeling that they are a burden on the NHS due to their condition;
b. ethical training, to include obligations of confidentiality, and restrictions on use of patient information;
c. the ability of patients to demand, and be provided with, full access to their medical records; and

d. on the lessons to be learned from the contaminated blood scandal, as outlined in this Inquiry's final report (addressed further below).

Education about the contaminated blood scandal

538. The Society seeks a recommendation that the contaminated blood scandal is part of core teaching of all healthcare professionals, all NHS managers, all non-medical staff in NHS leadership roles and all civil servants in leadership roles at the Department of Health so that the lessons to be learned from this Inquiry, not only in relation to delay in implementation of the patient safety centred Government policy of self-sufficiency with its many catastrophic consequences, but also subsequent lack of communication with patients and patient advocacy groups, lack of candour and cover-up within the NHS, the civil service and Government are embedded now and in the future.

Apology / Memorial

539. There can be no doubt that the issues encompassed by this Inquiry, and the approach of successive governments to them, has been one of the most disgraceful scandals of recent years. A recommendation is sought that this be acknowledged by Government; first in its acceptance and implementation of this Inquiry's eventual recommendations; secondly by appropriate apology, and thirdly a permanent memorial to those so tragically affected.

540. The Society draws to the Inquiry's attention other submissions to this Inquiry related to the topic of an apology/memorial.[587]

[587] SUBS0000003/23; SUBS0000011/5; SUBS0000015/4

SECTION C2: SUBMISSIONS ON COMPENSATION

541. The Society draws to the attention of the Inquiry to The Haemophilia Society's submission on compensation to Sir Robert Francis' Compensation Framework Study, dated December 2021, which is attached to this submission at Appendix 1.

542. The Society repeats, in summary, what the Society called for in this submission in relation to any compensation scheme that is established:

a. anyone who has been significantly affected by the contaminated blood scandal has the right to make a claim;
b. to continue existing support schemes alongside any compensation scheme;
c. compensation must be sufficiently personalised to ensure that it reflects the loss and damage suffered by an individual, but the framework should include set tariffs to allow a faster yet robust system;
d. to fast-track an emergency payment for those in urgent need to alleviate their suffering;
e. an up-front lump sum to be paid to the infected and affected community in advance of the full amount;
f. a clear, straightforward process which is easy to use;
g. to provide specialist support for people making applications, particularly where evidence has been lost or destroyed. These claims should be approved on the balance of probabilities;
h. to ensure total parity across the devolved nations;
i. any compensation package to be funded by the Westminster government in recognition that this scandal happened before devolution;
j. to maintain a system which allows transfer of information from support administrators to compensation schemes to reduce burden on claimants to provide information;
k. a transparent appeals system;
l. to ensure that previous payments should not be taken into consideration; inclusion of non-financial elements in the compensation package, such as psychological support, health passporting and government-underwritten life insurance;

m. free independent financial advice to be available to all receiving compensation;
n. any individual assessment to be made by a judge-led panel but must include representation from the infected/affected community;
o. to widen eligibility to include impact from viruses or exposure to viruses currently outside support schemes, such as hepatitis B, and the impact of vCJD.

543. On 25 July 2022, the Society welcomed the opportunity to make submissions on interim payments,[588] following the publication of Sir Robert's Infected Blood Compensation Study report on 7 June 2022.[589] the Society submits that the general principles on the recommendations laid out by Sir Robert Francis should be accepted. The Society would like to emphasise that it is imperative that any compensation scheme includes input from the community of infected and affected.

544. The Society makes the following commentary in relation to Sir Robert's Infected Blood Compensation Study report:

a. The eligibility criteria and proof of eligibility for infected persons as laid out in the Sir Robert Francis Report at paragraph 2.13 should be implemented immediately by all current support schemes:

Eligibility for infected persons
2.13 The conditions for eligibility for the directly infected should be:
1. the applicant has been diagnosed as being infected with either or both of HCV or HIV [the relevant disease].
2. the applicant received one or more blood transfusions or blood products known to be capable of transmitting one or more of the relevant diseases [the relevant treatment].
3. the applicant received the relevant treatment within - or from stocks created within - the periods of eligibility employed by the current support schemes,
OR
a period to be defined [subject to any findings of the Inquiry with regard to such dates] during which in retrospect, and without necessary attribution of

[588] SUBS0000024/1-2
[589] RLIT0001129

culpability or negligence, in the light of the knowledge at the time or subsequently, the relevant technology or science could have been available to avoid infection/contamination of blood or blood products and/or of transmitting such infection to patients [the relevant period].

4. the applicant's infection was likely to have been caused by the administration of a relevant treatment.[590]

b. The Society supports the concept of proof of eligibility as set out in paragraph 2.15 of Sir Robert's report that *"it is important that a sympathetic and sensitive attitude is taken to the processing of applications without rigid adherence to legal concepts of proof"*[591]

c. In relation to eligibility criteria, when some people apply to current support schemes, they are denied access to the schemes often due to a lack of records or accurate testing. This may be due to many reasons including missing medical records, which has been highlighted in evidence many times. There is a requirement to provide evidence of Hepatitis C infection prior to this being available despite there being proof on having had Hepatitis C. This the case for many people who have self-cleared this infection but cannot know for how long they lived with this infection. If they fit the eligibility criteria as specified above, they should be accepted immediately.

d. At paragraphs 4.83 to 4.90,[592] Sir Robert sets out his "Conclusions on coverage" and addresses eligibility of people infected with HBV and HDV for his recommended compensation scheme. Sir Robert concludes that he is unable to recommend that HBV infection be included in a compensation scheme as a separate category (noting one exception, which is HBV sufferers who develop an infection with serious symptoms who require treatment to prevent cirrhosis, or who have actually contracted cirrhosis.). His conclusion on HDV is the same. If individuals without HCV but who have suffered chronic HBV only and those

[590] RLIT0001129/17
[591] RLIT0001129/
[592] RLIT0001129/62-64

with HBV and HDV who can demonstrate chronic impacts of infection, they should be able to access compensation under this framework.

e. At paragraph 4.89,[593] Sir Robert's report states, *"A number of infected persons have received written warnings that there is a risk of their having contracted vCJD. However, the distress and suffering caused by being informed of the risk of contracting this disease is not compensatable under the vCJD scheme: this is a risk shared with all those who have received all relevant blood products ,whether or not they have been infected with the principle infections with which my terms of reference are concerned. Therefore, I suggest that, apart from the extent to which the general concern about the risk of vCJD applies to all infected persons otherwise eligible for compensation, this disease is left out of account in this scheme."* Evidence in witness statements to this Inquiry illustrate that the two vCJD notifications caused some people severe psychological trauma. For these people, this was an additional worry to live with as there were no tests available to confirm infection (and therefore, their future life course). There should be recognition of the trauma and psychological impact caused by the two vCJD notifications, including people living in fear of the future and the impact this had on gaining access to future treatments, for example dentistry, endoscopy, surgery.

f. The UK Government should direct and finance the current support schemes to adopt the uplift to payments, as stated in Sir Robert's report at paragraph 2.53[594] and later paragraphs 9.88 to 9.93.[595] These paragraphs are set out below:

2.53… all annual support payments (which include the heating allowance) should be brought up to at least a level 5% above net national median earnings, and those already at that level should be increased proportionately to maintain the differential between categories of award. A lump sum supplement should be added to all annual payments of, say £10,000, to cover other items such as increased insurance costs, additional transport costs and so on. [596]

[593] RLIT0001129/63
[594] RLIT0001129/26
[595] RLIT0001129/115–116
[596] RLIT0001129/26

...

9.88 In my view, unless they already exceed this figure - and some do - the regular, guaranteed annual payments under the support schemes should be brought to a level where it equates to a total of the following:

- *5 % above national median earnings - net, as these payments are and should remain, exempt from tax. Median national full time earnings in April 2021 were £31,772 per year (£611 per week). 116 If that were taken as the base figure the 5% enhancement would make a total of £33,361. 117*
- *A tax free sum in recognition of additional financial issues caused by the diagnosis of HIV or HCV, for example, increased or hard to get insurance cover, convenient medical treatment, additional transport costs, etc. of, say, £10,000.*

9.89 Payment categories in the support schemes which already exceed this level should be increased by the same proportion to preserve the differential.

9.90 I recommend that in exchange for the lifetime guarantee of this increased annual sum, uprated annually for inflation, by reference to the annual increase in median earnings equivalent to ASHE 80%118 , such payments should be taken into account in the assessment of entitlement to any means tested state benefits. The payments should still be disregarded against any entitlement to non-means tested benefits such as disability living allowance.

9.91 Therefore, I recommend that this sum (including, as is currently the case, the winter heating allowance) should be awarded within a continued support scheme, which is underpinned by a statutory authority and obligation to continue such payments for the life of the beneficiary. Alternatively, the support schemes annual payments could be merged into the compensation scheme as a minimum sum for financial loss payable to all eligible infected persons annually for life, under the same strength of guarantee as applies to court ordered periodical payments payable by a government department or State body.

9.92 This sum, and the entitlement to it, should be substituted for the annual payments currently made under the support scheme and should be credited against any additional claim, whether under the compensation scheme, or in any civil action based on injury caused by the infection, for future financial losses, including loss of earnings, loss of earning capacity or other costs.

9.93 The lump sum payable under the support scheme should be paid to new applicants to bring parity with existing beneficiaries of support schemes, and should be disregarded in assessment of compensation awards. [597]

g. It is vital that paragraph 2.86 is implemented.[598] Victims' groups, including those infected and affected should be offered the opportunity to provide feedback and have impact on the running of any scheme. Paragraph 2.86 states:

2.86 Victims' groups should be involved in offering feedback on the running of the scheme through a forum or committee with membership representative of all relevant conditions and all devolved nations. The scheme should be obliged to have regard to the views of this body in its management.[599]

h. At paragraph 2.55,[600] Sir Robert recommends that *"Where a claim for loss of earnings is made, the applicant should either have to prove an actual loss by reference to a pay or employment history, or where this is not available, by reference to relevant statistical evidence in relation to the class of employment they would have had but for the infection. Where the prospects of the applicant are too speculative, such as in the case of young children, resort would have to be had to general median earnings figures - which should already be covered by the support payments."* Access to independent expert advice on loss of earnings should be made available to all that require support, in order to be able to submit a full picture of the impact of infection/affection.

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[597] RLIT0001129/115–116
[598] RLIT0001129/32
[599] RLIT0001129/32
[600] RLIT0001129/27

545. Sir Robert provided written and oral evidence to the Inquiry, based on what he had read and what he was told by the infected and affected when he met with them, that there was a moral case for the interim payments he recommended. Further, he stressed the urgency of the unmet need and thus the urgent need for interim payments to be made. Not for the first time, the Inquiry Chair highlighted in his July 2022 invitation, that for the infected and affected, *'time is not on their side'*. The urgency of the situation is incontrovertible, considering the age of many of the people affected and infected.

546. The Society welcomed the announcement by Government in August 2022 that payments would be made to those who have been infected and bereaved partners in England, Scotland, Wales and Northern Ireland.[601] If a compensation scheme is not immediately implemented by Government, then interim compensation should also be made to bereaved children and parents. Those who have lost children and parents still have received no compensation.

547. A review of the current support schemes across the four home nations should be carried out to address any outstanding disparities in support, including those which are non-financial. Elements of inequality remain between the schemes, such as a unilateral change introduced by the Wales Infected Blood Support Scheme on 6 December 2022, which announced new child support payments. Scotland and Northern Ireland have no equivalent scheme and England offers a means-tested child support payment. Where someone received infected blood or blood products over 30 years ago should not continue to determine the level of support they receive. True parity and continued parity of support should be achieved and maintained across the UK.

[601] https://www.gov.uk/government/news/infected-blood-victims-to-receive-100000-interim-compensation-payment

CONCLUSION

548. Overall, the Society submits that during the period reviewed by this Inquiry, the Society did its best, bearing in mind its resources, and the immediate concerns of its members, to share views and thinking on relevant blood related infections; to lobby for better financing, research, and support for those infected and affected, in the wider sense of the word.

549. The Society has a unique role in the Inquiry. As the only UK-wide charity for people affected by a genetic bleeding disorder, it is made up of members and staff with a diversity of perspectives, backgrounds, interests and medical needs. It knows that not all members feel able to speak publicly about how the contaminated blood scandal has affected their lives and, for those who want it, the Society is pleased to speak on their behalf. The Society acknowledges that those perspectives will inevitably differ amongst the membership but it has done its best to represent all in this submission.

550. As is a matter of public record, the Society campaigned for many years for a public inquiry to be held into the Infected Blood scandal. It has been pleased that a light has finally been shone on all of the circumstances that led to infection and misery for so many of its members.

551. The Society trusts that the Inquiry would agree that it has participated and cooperated fully with the Inquiry's work. The Society has from the outset understood the importance of the Inquiry operating with the benefit of the fullest evidence base and understanding of the issues which have confronted it, and has approached the exercise of providing material and evidence in that spirit.

552. The Society and its members also acknowledge that the Inquiry is constrained in that it cannot make findings of criminal and civil liability, but that it can and should make findings of fact as to what went wrong and why. In doing so, one of the paramount objectives of the Inquiry will be to identify steps that can and should be taken to improve the position of those infected or affected, and to identify lessons to prevent any similar events occurring in the future. The Society hopes that the Inquiry will

consider these submissions in the spirit of that exercise; it would be easy (for any core participants) to fall into 'finger pointing' behaviour, but the Society's own objectives mirror those entrusted to the Inquiry – to improve life for those affected, and to learn lessons for the future. To the extent that the Society has identified what it perceives as failings in these submissions, it has done so only in the pursuit of these objectives.

553. Of course, as part of the Inquiry's investigations, the Society's role during the contaminated blood scandal is being scrutinised. Evidence from its archives is being studied and former staff and trustees have appeared before the Inquiry to talk about the charity's actions and advice during this period.

554. It is a matter of public record that during the contaminated blood scandal the Society issued statements reassuring people with bleeding disorders that the new factor treatments were safe and to continue using them.

555. The advice the Society gave to its members was based on guidance from Haemophilia Centre Directors (now known as the UKHCDO) and from the Government; it was not a lone voice. The Society accepts that its actions and statements at the time, whilst well intentioned and based on expert advice, have subsequently been shown to be damaging to the community and false. For this failing the Society has apologised unreservedly. It has also taken steps to guard against any future over reliance on a specific source of information.

556. The Society has always welcomed scrutiny of its role, and that of other organisations, in order to ensure that this investigation is thorough and effective. Only then can the victims of the contaminated blood scandal get the truth and justice that they deserve. The Society has played its full part in helping this to happen.

557. The Society know that some of its members are angry and disappointed by actions taken by the Society in the past. Some felt unsupported and believe more should have been done more to help them. The Society hopes that by opening up its archives to the Inquiry and fully engaging with its investigation, criticism can be dealt with openly and honestly.

558. The Society hopes this inquiry will finally deliver closure, justice and recognition of what has happened and the suffering it has caused.

559. The Society repeats the submissions made in Section C above and submits that the following (as set out on its website[602]) must result from the Infected Blood Inquiry:

Truth and justice

- *Full exposure of who knew what, when and a clear understanding of what motivated the decisions made*
- *Those shown to be responsible must be held to account, if appropriate through further legal action*
- *An acknowledgement of the pain and hurt caused by this scandal*
- *A thorough and credible investigation which gives the community confidence that the truth has been uncovered*
- *A Government-funded national memorial established as a permanent tribute to those who died*
- *A meaningful government apology.*

Compensation

- *The infected and affected must be properly financially compensated for the effect that receiving infected blood has had on their lives, including lost opportunities*
- *Compensation should be based on the financial, psychological, physical and social impact the infections have caused*
- *Work should begin now, before the end of the inquiry, through the Cabinet Office in consultation with the affected community, to establish a framework for awarding compensation. *We are pleased that since calling for this, an Infected Blood Compensation Framework Study has been announced…*
- *There should be no delay in distributing compensation once the inquiry completes its investigation and publishes its findings*

[602] https://haemophilia.org.uk/public-inquiry/the-infected-blood-inquiry/what-do-we-want-from-the-infected-blood-inquiry/

- *There must be fair and equal funding through the UK's four infected blood support schemes, eligibility should be widened to include bereaved parents and children.*

Psychological support

Those infected and affected should be entitled to free, accessible, long-term, specialist psychological support for as long as they need it.

Continuing care for those infected

- *A clear set of national guidelines must be established on best-practice for monitoring chronic hepatitis C patients. This should include regular scans and regular follow-up appointments*
- *Funds must be made available to support those infected with HIV. There is very little research on the long-term impact of early HIV treatments, especially when coupled with harsh hepatitis C treatments. This is a unique community which needs specialist medical support and understanding*
- *Access to insurances, including life cover, at fair and equitable rates.*

Future care for people with bleeding disorders

- *There must be access to the best currently available treatments for bleeding disorders for all, regardless of cost*
- *National guidelines must set out mandatory best-practice standards of care to ensure that everyone with a bleeding disorder receives the same high-quality treatment, regardless of which haemophilia centre they attend*
- *Universal access to a comprehensive care package, including physiotherapy, occupational therapy, social support and counselling*
- *Recombinant (or non-plasma derived) treatment must be available for all bleeding disorders, where it exists*
- *Government to champion future provision of new technologies and therapies for people with bleeding disorders and direct the NHS to proactively work to allow access*

- *Access to appropriate social care with a comprehensive understanding of needs for the ageing population to offer dignity and safety in old age."*

560. In closing, the Society repeats the words of its current Chief Executive, Kate Burt:

"*We were founded by two patients as a result of a conversation at St Thomas' Hospital in 1947 and we will always continue to be true to our founders and be a patient and member led organisation. We work proudly alongside others in the NHS, pharmaceutical companies and other haemophilia organisations, but we will never stop putting our members' interests first.*

We began life as an organisation targeted at haemophilia. We have grown into an organisation who very much in our heart represent people with infected blood and all genetic inherited bleeding disorders. We have adapted to devolution, and an aging membership, we promote diversity, women's bleeding disorders, equality and the best treatment/ healthcare for all of our members and we have managed all of this alongside campaigning for victims of the worst treatment disaster in the history of the NHS.

As a small charity we have had to contend with the biggest treatment disaster in the history of the NHS. We have had to fund for the most part all of our work and much of our work has been undertaken by volunteers whilst also fighting the impact of their own infections and bleeding disorder.

The impact of the contaminated blood scandal has inevitably had an enormous influence on the work, strategic thinking and values of The Society over the last four decades. The scale of the tragedy that engulfed our community cannot be underestimated and at times, it has been a challenge to ensure that the diverse needs of all our members were met to everyone's satisfaction – as the letters to the editor in the fourth edition of The Bulletin in 1998 illustrate well.

Today this challenge persists. At a time of great financial challenges for all charities, we continue to have as a key priority the need to invest time and resources in the Infected Blood Inquiry and the support of those impacted. I consider this to be an essential, non-negotiable part of our work. However, the needs of our members

untouched by the scandal are equally important as we strive to support our whole community as summed up as "Together for Life". We will continue to work to bring our community together in recognition of what has happened and the need to move forward with clear answers about what went wrong in the past and to shape a better future for all."[603]

KATIE GOLLOP KC

Serjeants' Inn Chambers

EVERSHEDS SUTHERLAND (INTERNATIONAL) LLP

16 December 2022

[603] WITN6392001/127-128, paragraphs 296 to 300

INFECTED BLOOD INQUIRY

CLOSING SUBMISSIONS

ON BEHALF OF THE HAEMOPHILIA SOCIETY

APPENDIX 1

The Haemophilia Society

Finding a fair and just compensation scheme

The Haemophilia Society's submission to the Infected Blood Compensation Framework Study, December 2021

Charity reg. no: 288260 in England & Wales SC039732 in Scotland.

Executive Summary

The process of trying to place a monetary value on the life of a beloved parent, sibling, spouse, partner or child is something no one should be faced with. Nor the torment of reflecting on the unknowable - the 'what might have been' if chronic ill-health, loss and stigma had not permanently altered life's path.

Compensation has long been a major goal of all those who have suffered because of contaminated blood and blood products, yet the reality is complex, with the potential to worsen existing trauma if handled badly. We ask that the compensation process is underpinned by compassion, and that each claimant is treated respectfully with the understanding that they have suffered irreparable damage as a result of this scandal.

For many, compensation is about far more than money. Meaningful compensation must include explicit recognition of the pain and suffering each individual has experienced.

We cannot continue without paying tribute to all the dedicated campaigners who have fought for compensation over the last three decades, many of whom have died as a result of their infections before any government was prepared to face up to its responsibilities.

Our thanks go to everyone who has taken the time to share their thoughts with us on this most difficult and emotive issue. We have worked hard to reflect those conversations, coupled with the results of our own survey on this issue, in this submission.

We would like to thank Sir Robert Francis QC and his team for the opportunity to contribute to the Compensation Framework Study.

In summary, we call for the following:

- anyone who has been significantly affected by the contaminated blood scandal has the right to make a claim
- continue existing support schemes alongside any compensation scheme
- compensation must be sufficiently personalised to ensure that it reflects the loss and damage suffered by an individual, but the framework should include set tariffs to allow a faster yet robust system
- fast-track an emergency payment for those in urgent need to alleviate their suffering
- an up-front lump sum to be paid to the infected and affected community in advance of the full amount
- a clear, straightforward process which is easy to use
- specialist support for people making applications, particularly where evidence has been lost or destroyed. These claims should be approved on the balance of probabilities
- total parity across the devolved nations
- any compensation package to be funded by the Westminster government in recognition that this scandal happened before devolution
- a system which allows transfer of information from support administrators to compensation schemes to reduce burden on claimants to provide information
- a transparent appeals system
- previous payments should not be taken into consideration
- inclusion of non-financial elements in the compensation package, such as psychological support, health passporting and government-underwritten life insurance

- free independent financial advice to be available to all receiving compensation
- any individual assessment to be made by a judge-led panel but must include representation from the infected/affected community
- widen eligibility to include impact from viruses or exposure to viruses currently outside support schemes, such as hepatitis B, and the impact of vCJD.

Introduction and Background

The Haemophilia Society has represented people living with inherited bleeding disorders across the UK for over 70 years and has multi-generational relationships with many families, a significant proportion of whom have been affected by the impact of infected blood products. A large part of the community has suffered the stigma of living with the viruses and want to remain anonymous, but still have a desire and right to have their voices heard. Therefore, we decided to send out a survey that could be filled out anonymously.

This was distributed as a hard copy and emailed to all members with an interest in the inquiry and was freely available online and through social media. Those responding are not exclusively from the infected, haemophilia community, but also include the affected and people infected through blood transfusion.

We based the questions on some of the key themes that emerged from virtual meetings about the compensation review and from speaking to individuals and campaign groups. Due to the complex nature of this issue, we felt it was useful to ask discrete and, in some places, presumptive questions to give a framework to aid peoples' thinking. We did have the option for free text, with no word limit, so individuals were free to express their opinions fully.

We received a total of 405 replies, and the full breakdown of the results can be found in the appendix.

We held 3 virtual meetings about compensation to assess our members' views. The first was about the compensation review's terms of reference and attracted about 30 people, the second, which about 35 people joined, included a presentation from Brian O'Mahoney, Chief Executive of the Irish Haemophilia Society about the compensation system in the Republic of Ireland. The last meeting was attended by about 45 people and discussed the results of our survey.

We have used the answers to the survey, as well as thoughts and opinions gained through conversations with our members individually and through online meetings, to inform the content of this submission. We recognise there are a range of views on many issues and that all individuals and other groups have a right to submit their own opinions. We look to make a submission on behalf of those who have interacted with us.

Support schemes and long-term payments

On the question of ongoing support payments alongside compensation payments, there was a large majority who wanted these to continue (81%). Many people who are already beneficiaries are keen to have the support schemes continued as they see them as separate from compensation: All text in italics are direct quotes from respondents.

Yes, support schemes are not 'compensation'. They should not be conflated together. Compensation should be completely separate and be from point of infection(s) and compensate for past, current and future impacts.

There were comments from those who have never been part of a support scheme that they would prefer a lump sum payment as they were a parent or child of a lost loved one, with acknowledgement that those living with infections may want regular payments to continue.

There was also a recognition that people at different stages of life may have different needs and there were many comments suggesting that there should be options available to suit individual circumstances.

Younger people would benefit from an ongoing payment but older people (or relatives of people who have suffered but are already deceased) may prefer a single lump sum. I therefore feel it should be based on individual circumstances.

One area that did provide a consensus was that ongoing support should be on a statutory footing and guaranteed for life, with 96% answering yes to this question.

The existing ex gratia schemes must be maintained and protected. They should be guaranteed for life, and this should be secured by primary legislation.

People deserve security and to be able to plan their futures with certainty.

When it came to the question of whether the support payments should continue to be administered through the current organisations there was a mixed response, 41% preferring the current administrators, 18% wanting it to be via a compensation scheme whilst 35% not expressing a preference.

Based on the interactions over the years with members there are many who agreed with the quote below,

Better the devil you know.

This is a phrase we have heard numerous times, with members fearful of being taken back to square one by new administrators. They do not necessarily endorse the current schemes, but rather do not want to risk getting something worse. There were comments suggesting differences between the devolved nations systems some being easier to navigate or more efficient than others.

Many people who replied have not previously been involved with the schemes due to being ineligible under current criteria so were not able to comment on this. There were a few comments wanting any scheme to be separate from government.

Should be independent from government and guaranteed.

Another comment perhaps reflects some experiences of the past and not wanting to feel, as many have, that they are going "cap in hand" to either a charity or government department for money that they consider is rightfully theirs.

Some system that doesn't feel like a government benefit that you have to apply for!

The final comment seems to best summarise what people want:

Something that works. An organisation that respects us and just ensures payments are made with ease.

Assessment of compensation awarded

In asking this question we attempted to understand the sort of process people would prefer to be used to assess the levels of compensation awarded. We had to make assumptions about which options would be under consideration. We looked at other compensation schemes to help select potential scenarios. On this question there was perhaps a predictably mixed response, however there were many comments that give a helpful insight into peoples' thinking.

Less than 10% of those answering favoured a tribunal system in isolation where decisions are made on a one-to-one basis.

Claimants should not be put through a tribunal system, they have suffered enough.

Some felt that an individualised system would best reflect peoples' circumstances but were concerned about the length of time that would take, recognising that not all the community has time on their side, some had concerns over further psychological damage 'this process might cause'.

There seems to be more appetite for a system that at least in part involves either a tariff system (31%), a broader set of classifications (18%) or a hybrid system (31%).

There should be certain criteria for a minimum payment and then there should be an assessment part to reflect individual loss.

There were many comments advocating equal compensation for all.

A single flat rate paid to both infected and affected.

It should be a fixed amount and not decided on individual circumstances or condition. If you are affected, then the payments should be made the same

Dead or alive the payment should be the same

Some thought this should be based on the infections people had or the severity of infection and health needs.

Standard payment for each infection

Depending on the severity of illness and ongoing health problems related to infection.

It is also worth noting that a minority felt the infected should take priority over the affected in terms of both size and speed of payments.

It is more difficult to reach a conclusion on this section as there are a range of views which are more than likely powered by individual circumstances. However, there is an overriding call for fairness, which might mean equality in payments between people in equivalent circumstances. It could also reflect a desire for individuals' circumstances to be looked at in a fair and impartial way.

Perhaps this final quote sums up the key message:

Whichever method is used it needs to be prompt and efficient and not force people to dig over old ground.

Urgent need

There was almost universal agreement (96%) for the need to provide a significant up-front interim lump sum to alleviate immediate need. We know of many cases of people who are living in extreme hardship, many of whom are dealing with severe illness – either their own or that of a loved one. There are also the children of those infected whose parents have recently died who must suddenly rebuild their lives after years in a caring capacity and are having to cope with both the emotional and financial burden of their loss. Financial insecurity impacts so many aspects of life and can have devastating consequences on mental health.

A lump sum made available quickly could relieve the burden of many, including those who are elderly and have waited so long for compensation and recognition of their loss.

Yes, but must also include parents of deceased who have waited 40 years for recognition and compensation e.g., my mum who is now 94.

Eligibility and proof

We asked about proof of eligibility for compensation payments. Most people (61%) thought that if people can demonstrate they meet the criteria for support payments, then they should receive it without need of further proof. Only a smaller group (10%) thought it should be the responsibility of the individual to show on the balance of probabilities that they are entitled to compensation. Only 11% were in favour of self-assessment.

Many people commented that as they were already part of a support scheme there should be no need to prove eligibility. We know that those who have been accepted onto schemes have had to provide significant proof which has been a tough and, for some, demeaning process. Strong emotions were expressed that a simple system to transfer existing data needs to be found.

The payments should automatically be made to anyone who has been assessed already and been found to be eligible for any of the existing payment schemes. It is stressful enough having to live with the effects of contaminated blood products without the added stress of going through another assessment.

Do not ask victims to do the work here!

For those not already registered on a scheme, the prevailing comments were that they be treated compassionately and supported in making a claim. Understanding is needed where family members died many years ago or where evidence has been lost or destroyed. Any scheme also needs to provide a process for those who do not have the ability or desire to communicate electronically.

Later in the survey, 93% of respondents agreed that anyone who has been "significantly" affected by contaminated blood should have access to submit a claim.

Conversely there were some who wanted to exclude certain groups of potential beneficiaries and would prefer a restricted list of people who could claim compensation. Some rationale was given that this might speed up payments or that if there is a finite fund then limiting the applicants would mean more substantial payments to those who fall within the restricted list.

As an organisation which represents all those infected and affected with an inherited bleeding disorder directly or indirectly, we believe that anyone who is significantly impacted should be able to submit a claim and the system should be properly resourced to cope with the demands of all of those who want to apply.

We asked if people who have been impacted by viruses other than HIV or Hep C contracted via infected blood should be included in the scheme and many agreed. We know people been impacted by a range of viruses contracted through infected blood who have suffered chronic health conditions as a result. Inquiry evidence and contact with our members has made clear the psychological damage of living under the threat of vCJD. Also, being flagged as being at risk of vCJD impacts on access to dental and surgical procedures and in some cases have caused delays in treatment.

The process

We asked a series of questions about the process of application and how any review of compensation awards would be carried out. In summary, if an individual assessment is required at any point in the process, it was preferred that this be carried out by a panel of 'experts'. Some preferred this to be led by a judge (45%) but there was a wide range of views on what would constitute 'experts.' The highest score was to ensure that the group includes a person who is affected or infected (91%) and it would be important that anyone representing the community acts as an advocate for all those infected and affected. The second point with a high response was to include a healthcare professional on any panel (74%) followed by a psychologist (62%). It was also agreed by the majority that any system should be inquisitorial rather than adversarial (79%).

It should be noted that this section did lead to many more comments questioning why an individual assessment should be required at all. Many would prefer not to have to go through this type of process.

Of the above I would say judge/panel however I really don't think that people should have to go through everything again.

People reiterated that any system should be easy to access, and comments suggested they would prefer a remote system so no one had to travel to attend hearings. Measures to protect anonymity would be needed, whatever the system.

A combination of remote/paper-based system depending on individual needs (not everyone has internet). It should not be at a venue as this requires travel and health issues may impact an ability to do this.

Only 3% of respondents did not believe an appeals system was necessary. However, for those people not on the support schemes, some of the more complex cases or where it has been very difficult to find documentation there may be a need for someone to challenge an initial decision and possibly provide new information. Whatever the system it needs to be easy to understand and be transparent.

Previous payments

There was clear agreement (91%) that no previous payments – such as support scheme ex gratia lump sums or pay-outs from court action - should be taken into account.

If somebody has been awarded previous payments why would they not be considered for future compensation payments?

What should compensation cover?

Our question covered general themes which have emerged from the inquiry as well as through conversations with our members. These included physical impact, consequences of treatment, mental health, loss of earnings and social impact. The overriding answer (77%) agreed that the compensation should cover these issues. Many people offered other issues that should be considered, and we received more comments on this question than any of the others.

Some of the additional themes highlighted include:

The mental impact on the individual and their family, and how in some cases their family or children have been brought into this.

Those who were financially dependent children need to be considered i.e., their loss of education and achievement and achieving their educational potential due to the effects of losing their parent.

Loss - how difficult to categorise the unnecessary loss of your child.

Many people continue to carry what they feel to be the stigma and shame of their infections in secret. Some of our members have not told people within their own family about their infections and live in fear of discovery. Some kept their bleeding disorder secret because haemophilia became so closely associated with AIDS. Whether infected with AIDS or hepatitis C, many people experienced discrimination and harassment in the workplace and within their communities.

Years of stigma as a family affected with AIDS.

Loss of income and opportunity. It is hard to calculate the loss of potential and to consider what someone might have been had they not become infected or had to care for someone infected. Many families could not get mortgages and life insurance, so had to live with long-term financial insecurity. What help was available was often seen as 'handouts' and many felt too ashamed to even apply for grants. Some were put off by the bureaucratic hurdles put in front of them. Many quite rightly resented having to go to support schemes with a 'begging bowl' for what they regarded as basic necessities.

A future has been lost, so future earnings. Also, loss of earning from a spouse due to their partners ill health impact and even death.

Handling of the tragedy. Some felt that compensation should also include government mismanagement. Others wanted recognition of the time and psychological toll the fight for justice has taken.

The personal and family costs of having to give so much time and energy to campaigning for justice because of the contaminated blood scandal.

Testing and non-consent. Many people were tested for infection without consent and, in some cases, not told the results for many years. The inquiry has heard some examples of people being used for medical research without their consent.

Longer term care and the future. People have spent their own money on issues relating to infected blood, such as IVF and psychological support. There is the uncertainty of the long-term impacts of living with infection and the side effects of treatments administered. Distrust of the medical profession has resulted in some not receiving adequate levels of care or withdrawing from the system altogether.

Many haemophiliacs, including myself, refused factor treatment when informed of infection status. I went several years without factor treatment and now suffering the consequences.

Others may not have received the appropriate hepatitis C treatment due to mistrust and fear. With so many unknowns, there needs to be provision within compensation that fully covers future obstacles and side-effects that may be experienced as a direct result of infected blood.

Just the fact we were infected, we have no knowledge of what our lives could have been only what it has been, and we have no idea on how we will be affected in the future.

What should be included in compensation package?

As well as the financial element of compensation, we asked whether there should be other aspects included within any package and over 70% of people in all cases agreed with the examples put forward.

Psychological support for all those infected and affected has been something we have been campaigning about for years. Not only is there a lack of psychological support through the haemophilia centres but there needs to be a system where anyone infected or affected can get the specialist support required.

Healthcare passporting. People who have complex health needs as a result of their infections and the subsequent side effects of the treatments they received should be given priority access, such as hepatology scans and monitoring.

GPs ignore the seriousness of the impact on one's health.

Access to dental services. People with bleeding disorders routinely experience poor and discriminatory dental treatment, which became significantly worse for those living with infections.

Teeth have been neglected for years, mostly due to the embarrassment of explaining/being greeted by people in space suits.

Many have had to spend personal money on rectifying issues caused by neglect.

I had all my teeth removed 20 years ago due to health issues with infections, implants back then were costing me £21,500.

Access to insurance and financial products. This community has been denied access to life insurance, travel insurance, mortgages, pensions and other financial products based on their past and current infection status. Where they have been able to secure such products, they have been forced to pay much higher premiums. There needs to be a system which does not penalise those living with infections and put them on an equal footing with the general population.

Financial Advice. There is a need for people to be able to access reliable and appropriate financial advice and planning. People may be affected by tax issues and other implications of a compensation package and will need free, independent and trustworthy expert advice.

Some respondents suggested access to careers advice would be beneficial.

Devolved nations

The compensation system should be a UK-wide system across the devolved nations, according to 83% of people. Parity across the four nations was paramount, but people were less concerned about the system as long as it was fair.

The infected and affected community have experienced gross inequalities in support payments between the four home nations. Some of these differences persist today, despite a long campaign for parity from the Haemophilia Society and many others. This has been extremely divisive and has left a mistrust that similar irregularities could emerge in a compensation package. It is imperative that any compensation is funded by the UK government and there must be absolute parity between England, Scotland, Northern Ireland and Wales.

Priorities

We gave respondents 3 options and asked them to name their top priority, although we appreciate that all three issues are important. They were asked to decide between speed of payment, ease of use and a chance to tell their story.

The answers were:

53% ease of use

39% speed of payment

8% chance to tell your story at a tribunal

The message from this is clear and reflects what we are hearing, people are fatigued not only from living with infections, but years of campaigning and reliving the past. There is little appetite to have another long and complicated process to reiterate what is already well known. It falls to the compensation study to find a clear and fair way for people to access the compensation they deserve.

In recognition of an urgent need for financial support, we call for a fast-track interim payment of a significant amount as soon as possible.

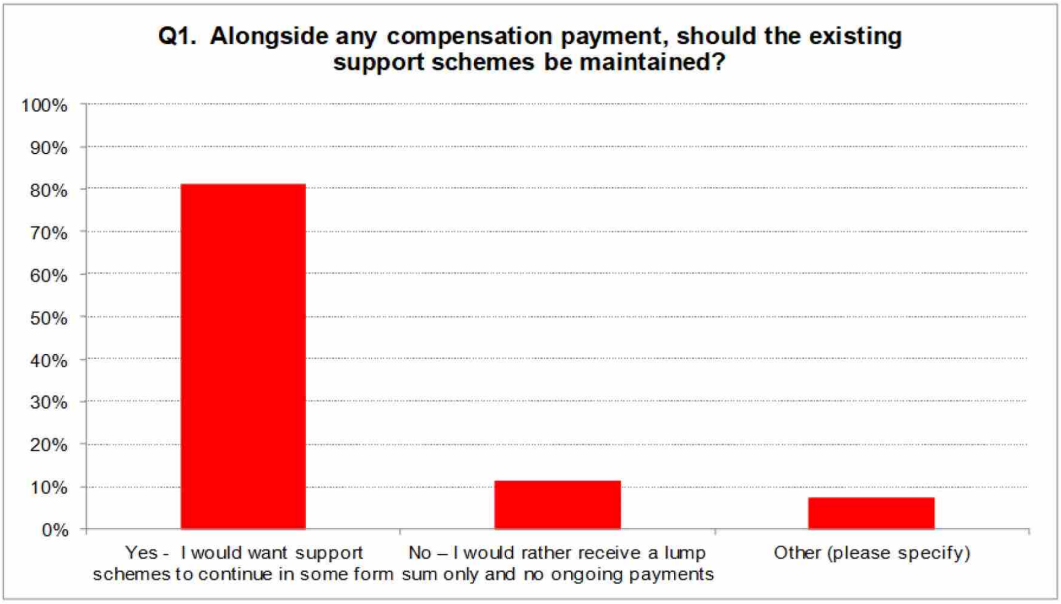
Appendix

Compensation Framework Survey Results

Question 1

Alongside any compensation payment, should the existing support schemes be maintained?

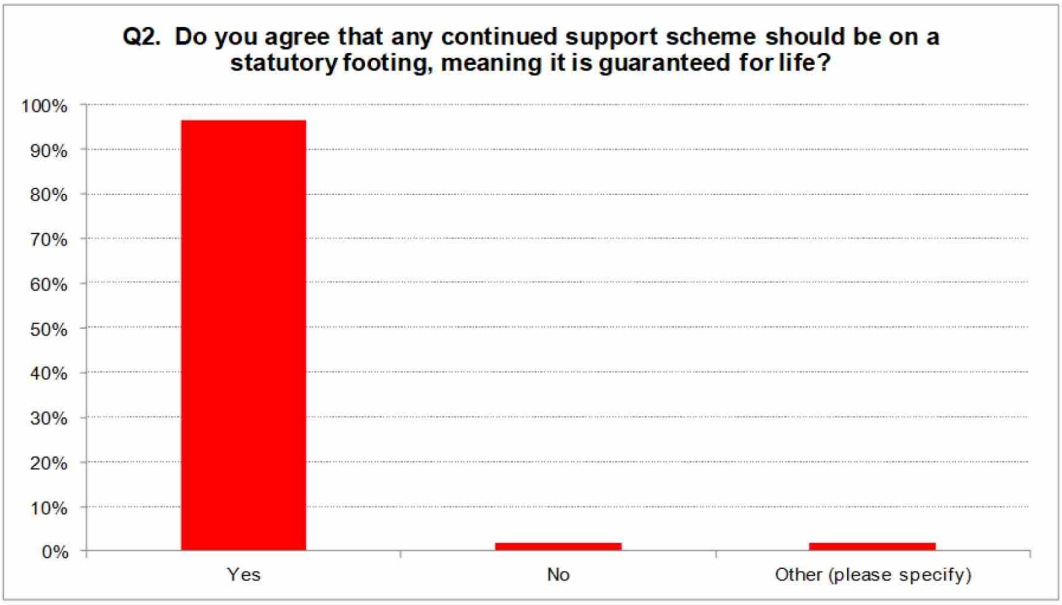
Answer Choices	Responses	
Yes - I would want support schemes to continue in some form.	81.23%	329
No – I would rather receive a lump sum only and no ongoing payments	11.36%	46
Other (please specify)	7.41%	30
	Answered	405
	Skipped	0



Question 2

Do you agree that any continued support scheme should be on a statutory footing, meaning it is guaranteed for life?

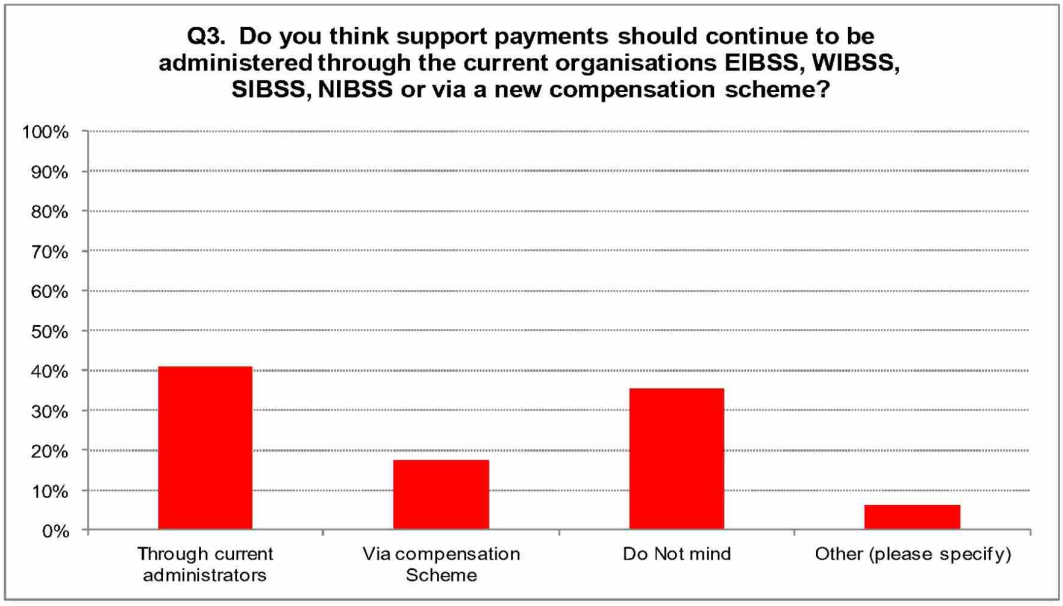
Answer Choices	Responses	
Yes	96.54%	391
No	1.73%	7
Other (please specify)	1.73%	7
	Answered	405
	Skipped	0



Question 3

Do you think support payments should continue to be administered through the current organisations EIBSS, WIBSS, SIBSS, NIBSS or via a new compensation scheme?

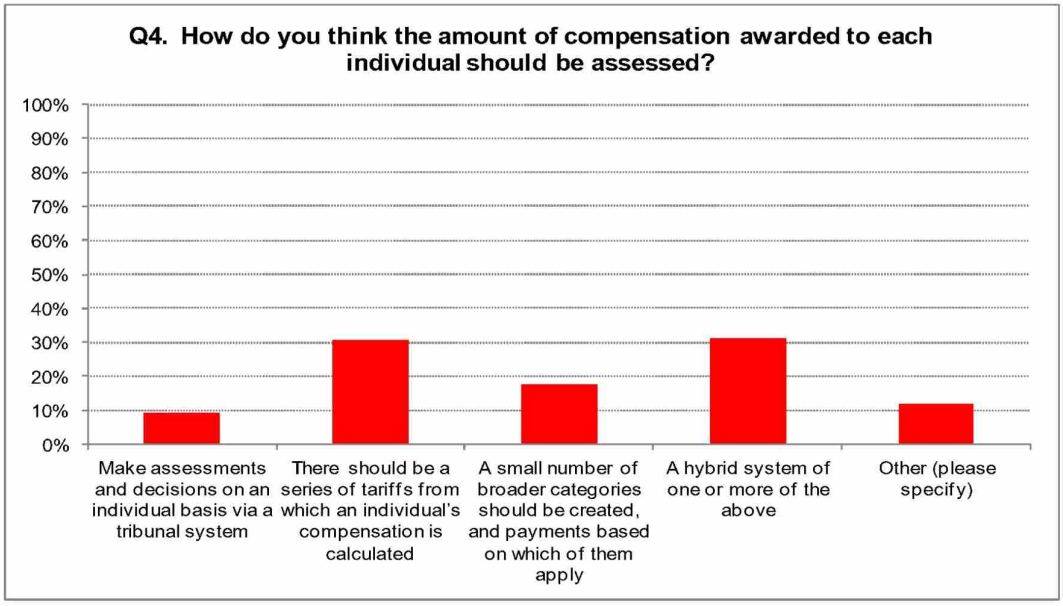
Answer Choices	Responses	
Through current administrators	40.99%	166
Via compensation Scheme	17.53%	71
Do Not mind	35.31%	143
Other (please specify)	6.17%	25
	Answered	405
	Skipped	0



Question 4

How do you think the amount of compensation awarded to each individual should be assessed?

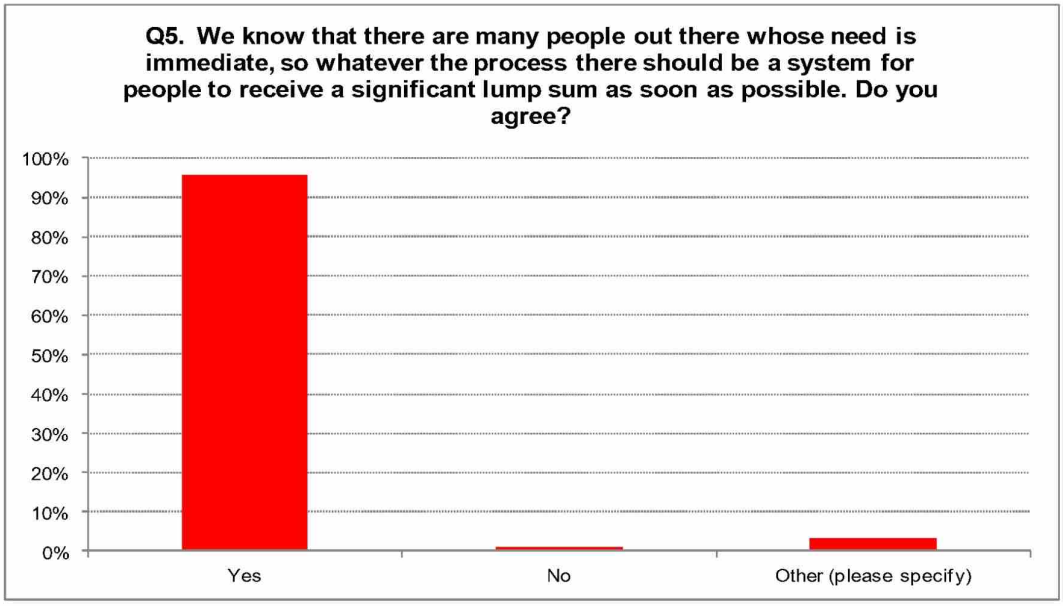
Answer Choices	Responses	
Make assessments and decisions on an individual basis via a tribunal system	9.38%	38
There should be a series of tariffs from which an individual's compensation is calculated	30.62%	124
A small number of broader categories should be created, and payments based on which of them apply	17.53%	71
A hybrid system of one or more of the above	30.86%	125
Other (please specify)	11.60%	47
	Answered	405
	Skipped	0



Question 5

We know that there are many people out there whose need is immediate, so whatever the process there should be a system for people to receive a significant lump sum as soon as possible. Do you agree?

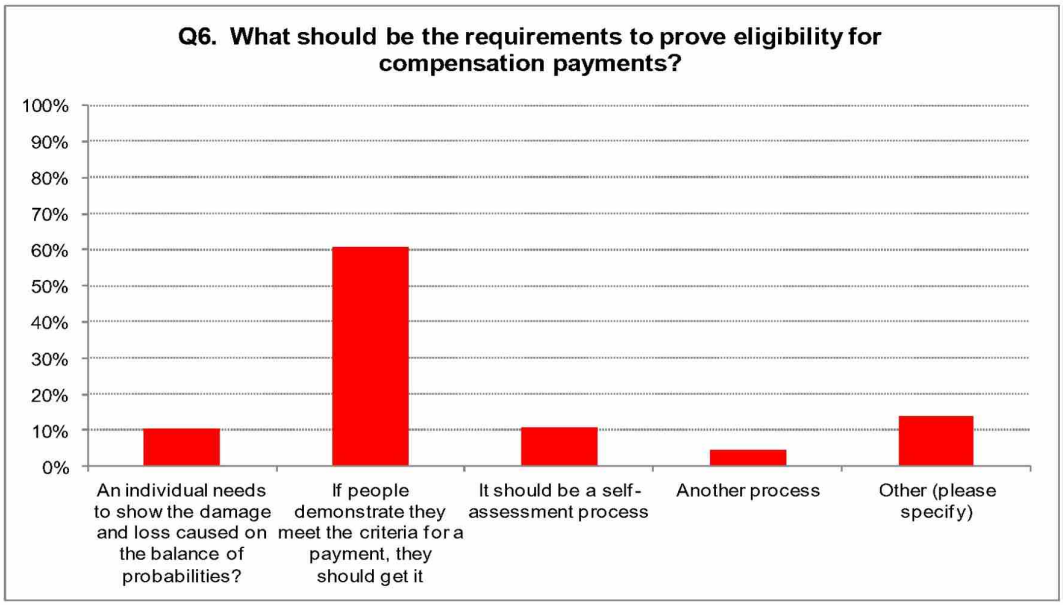
Answer Choices	Responses	
Yes	95.56%	387
No	1.23%	5
Other (please specify)	3.21%	13
	Answered	405
	Skipped	0



Question 6

What should be the requirements to prove eligibility for compensation payments?

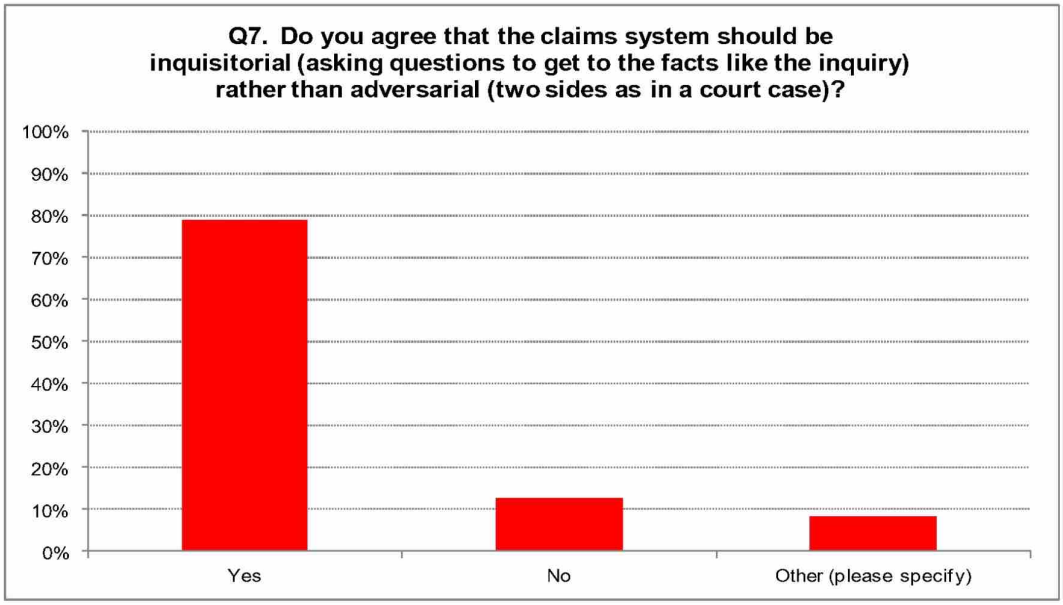
Answer Choices	Responses	
An individual needs to show the damage and loss caused on the balance of probabilities?	10.37%	42
If people demonstrate they meet the criteria for a payment, they should get it	60.74%	246
It should be a self-assessment process	10.62%	43
Another process	4.44%	18
Other (please specify)	13.83%	56
	Answered	405
	Skipped	0



Question 7

Do you agree that the claims system should be inquisitorial (asking questions to get to the facts like the inquiry) rather than adversarial (two sides as in a court case)?

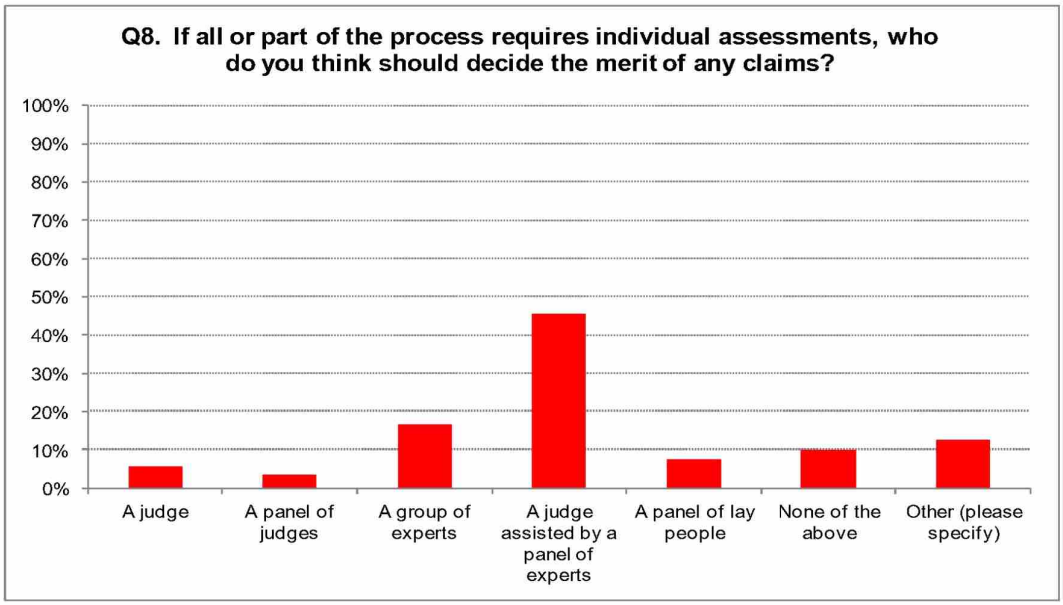
Answer Choices	Responses	
Yes	79.01%	320
No	12.59%	51
Other (please specify)	8.40%	34
	Answered	405
	Skipped	0



Question 8

If all or part of the process requires individual assessments, who do you think should decide the merit of any claims?

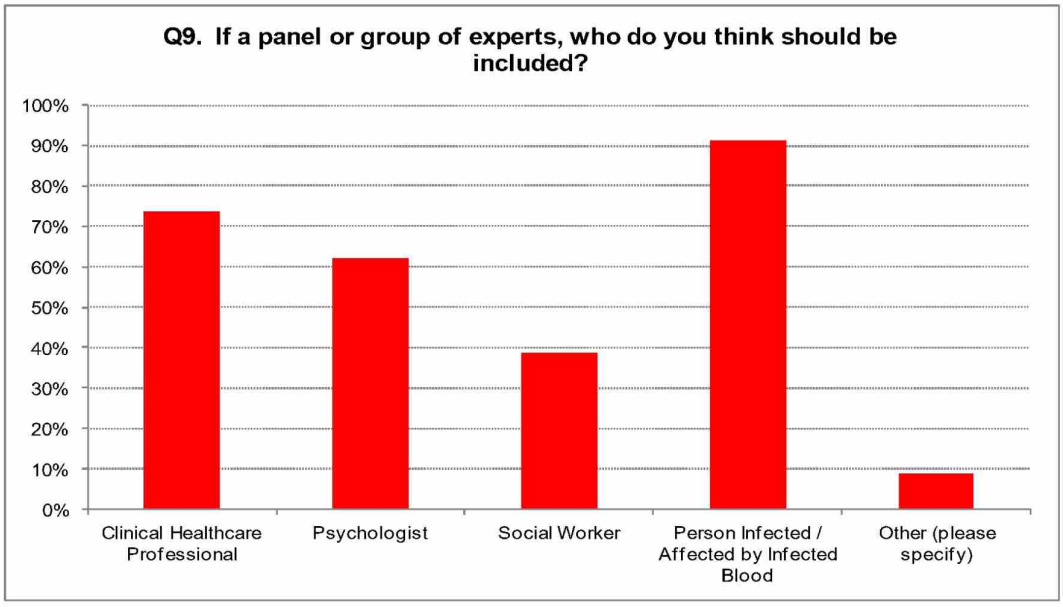
Answer Choices	Responses	
A judge	5.43%	22
A panel of judges	3.21%	13
A group of experts	16.54%	67
A judge assisted by a panel of experts	45.19%	183
A panel of lay people	7.41%	30
None of the above	9.88%	40
Other (please specify)	12.35%	50
	Answered	405
	Skipped	0



Question 9

If a panel or group of experts, who do you think should be included? (Tick all that apply)

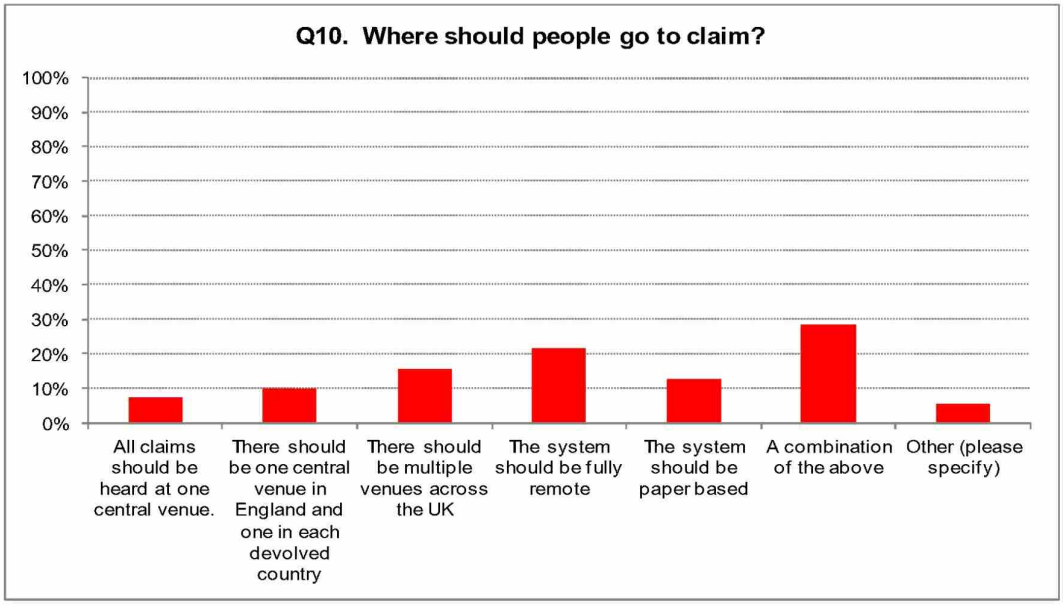
Answer Choices	Responses	
Clinical Healthcare Professional	73.58%	298
Psychologist	62.22%	252
Social Worker	38.52%	156
Person Infected / Affected by Infected Blood	91.36%	370
Other (please specify)	8.89%	36
	Answered	405
	Skipped	0



Question 10

Where should people go to claim? (select one)

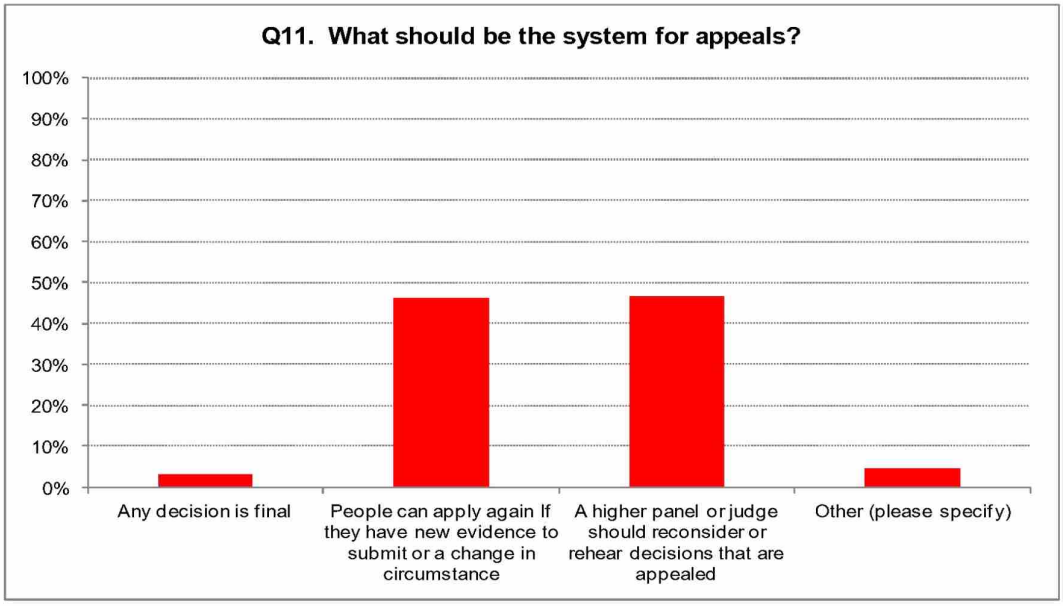
Answer Choices	Responses	
All claims should be heard at one central venue.	7.16%	29
There should be one central venue in England and one in each devolved country	9.63%	39
There should be multiple venues across the UK	15.56%	63
The system should be fully remote	21.48%	87
The system should be paper based	12.59%	51
A combination of the above	28.40%	115
Other (please specify)	5.19%	21
	Answered	405
	Skipped	0



Question 11

What should be the system for appeals?

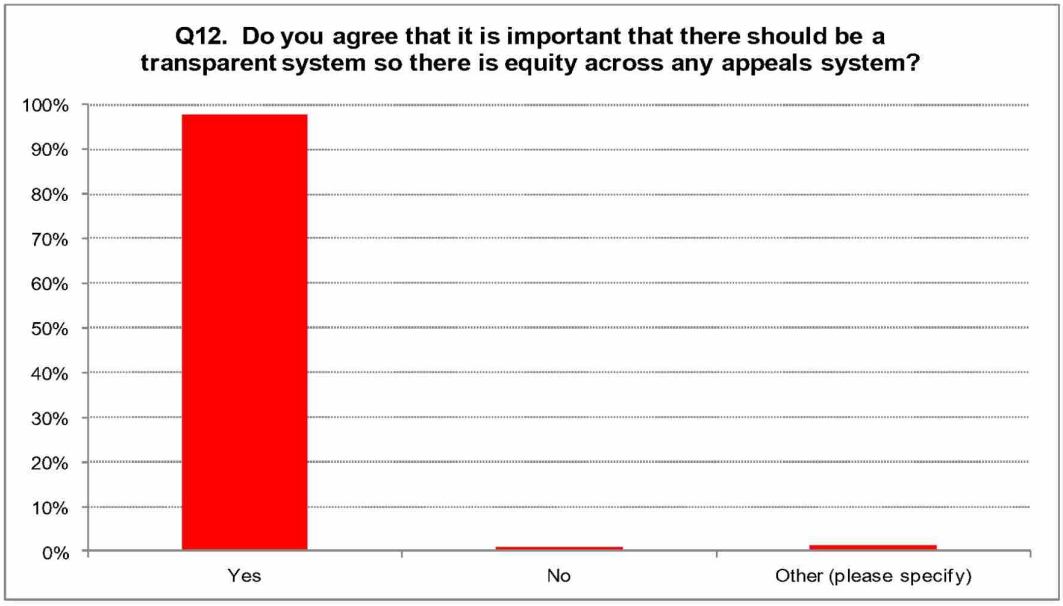
Answer Choices	Responses	
Any decision is final	2.96%	12
People can apply again If they have new evidence to submit or a change in circumstance	46.17%	187
A higher panel or judge should reconsider or rehear decisions that are appealed	46.42%	188
Other (please specify)	4.44%	18
	Answered	405
	Skipped	0



Question 12

Do you agree that it is important that there should be a transparent system so there is equity across any appeals system?

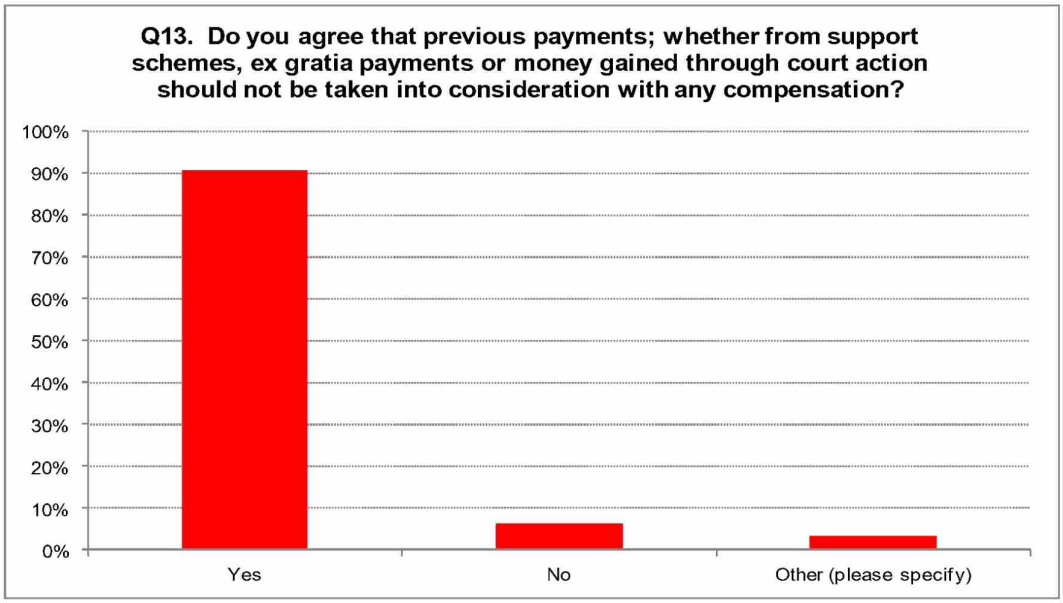
Answer Choices	Responses	
Yes	97.78%	396
No	0.99%	4
Other (please specify)	1.23%	5
	Answered	405
	Skipped	0



Question 13

Previous Payments. Do you agree that previous payments; whether from support schemes, ex gratia payments or money gained through court action should not be taken into consideration with any compensation?

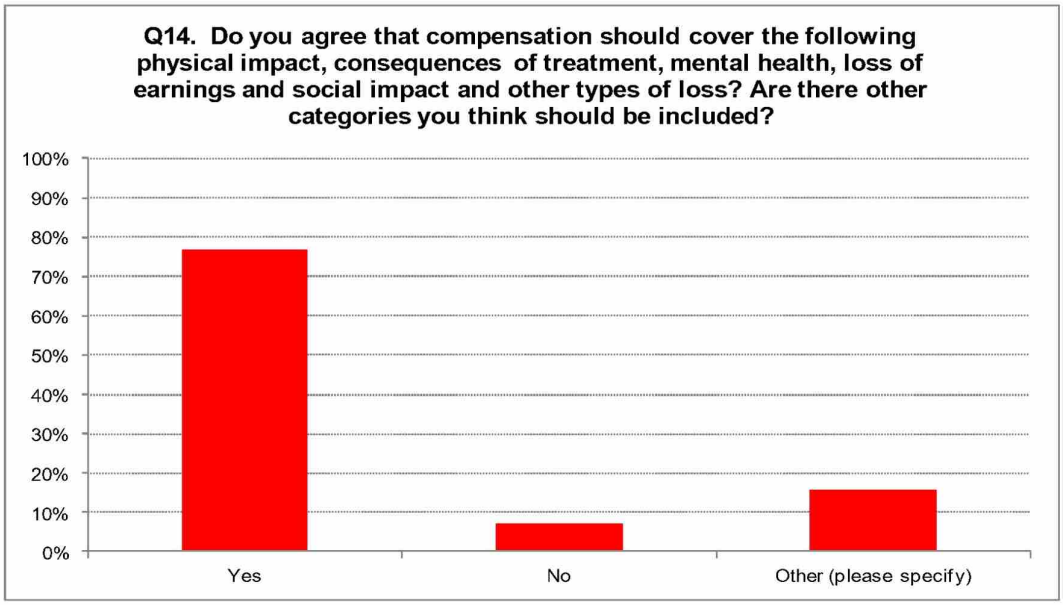
Answer Choices	Responses	
Yes	90.62%	367
No	6.17%	25
Other (please specify)	3.21%	13
	Answered	405
	Skipped	0



Question 14

Do you agree that compensation should cover the following physical impact, consequences of treatment, mental health, loss of earnings and social impact and other types of loss? Are there other categories you think should be included?

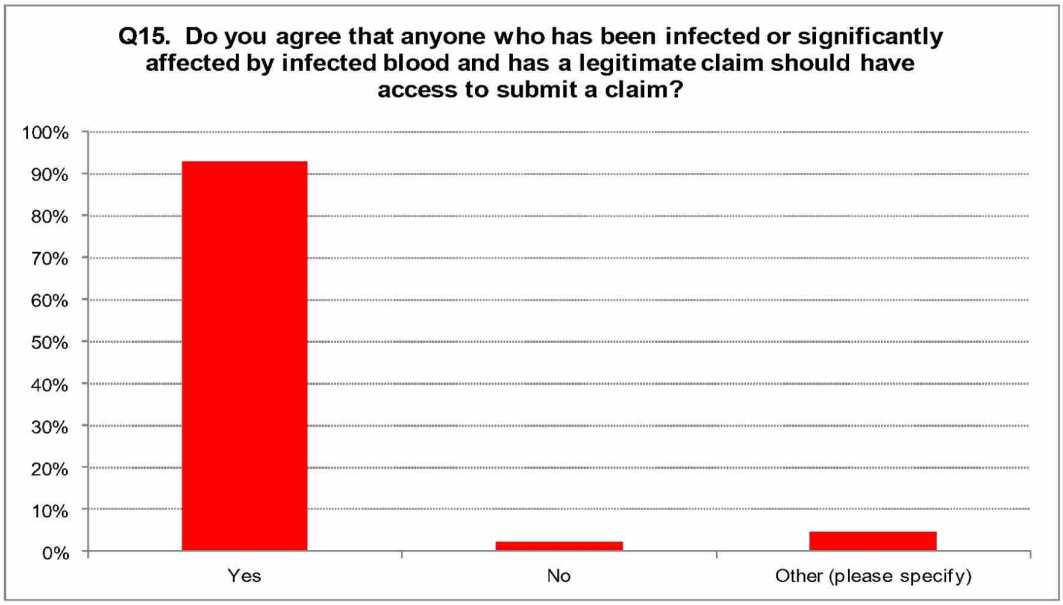
Answer Choices	Responses	
Yes	77.04%	312
No	7.16%	29
Other (please specify)	15.80%	64
	Answered	405
	Skipped	0



Question 15

Who can claim compensation? Do you agree that anyone who has been infected or significantly affected by infected blood and has a legitimate claim should have access to submit a claim?

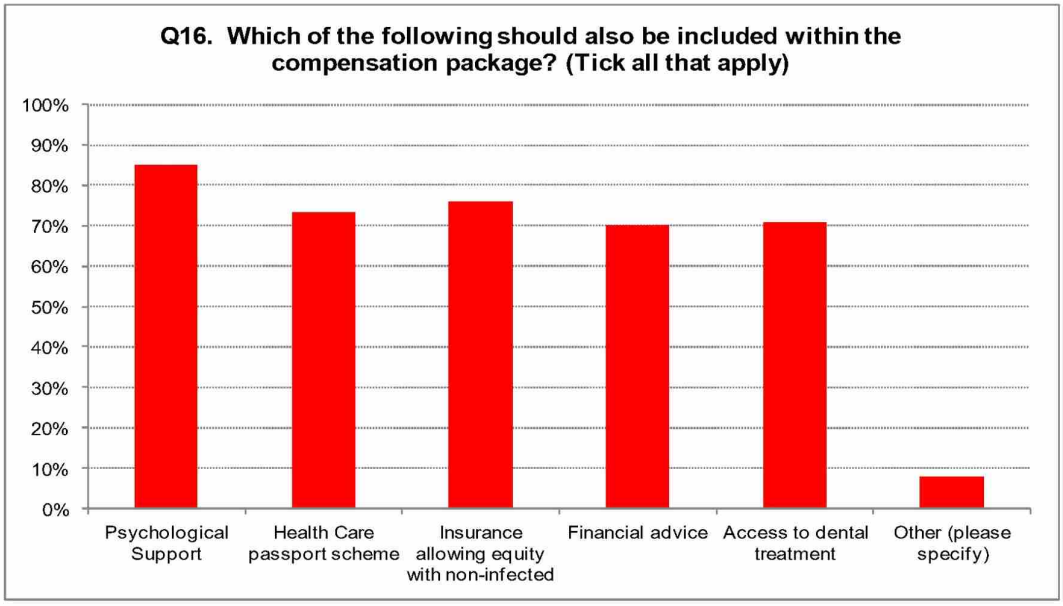
Answer Choices	Responses	
Yes	93.09%	377
No	2.22%	9
Other (please specify)	4.69%	19
	Answered	405
	Skipped	0



Question 16

Which of the following should also be included within the compensation package? (Tick all that apply)

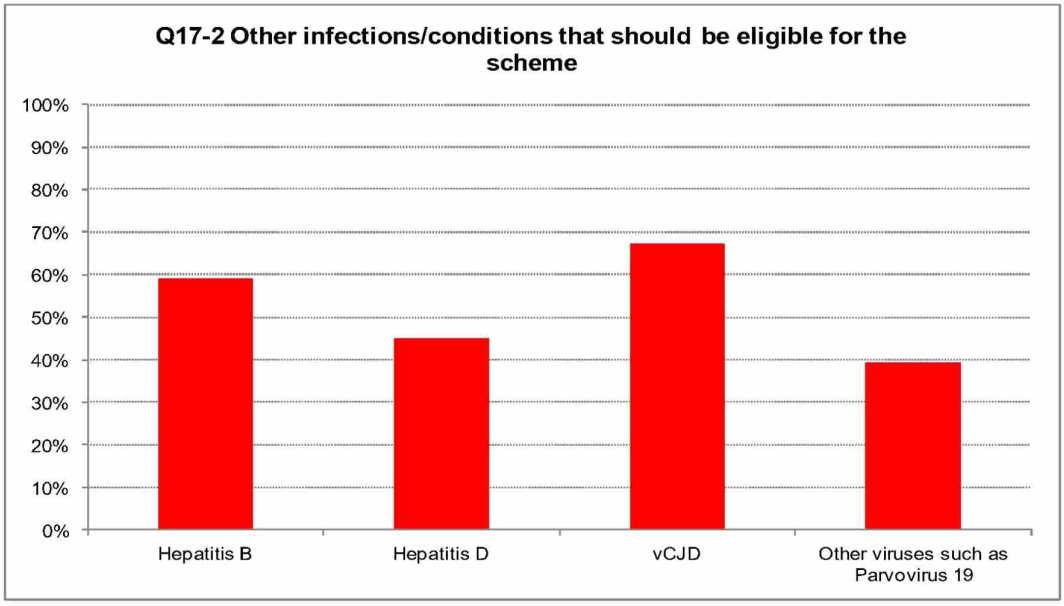
Answer Choices	Responses	
Psychological Support	84.94%	344
Health Care passport scheme	73.33%	297
Insurance allowing equity with non-infected	76.05%	308
Financial advice	70.12%	284
Access to dental treatment	70.62%	286
Other (please specify)	7.90%	32
	Answered	405
	Skipped	0



Question 17

Do you think that people who have suffered the impact of the following should be included in the scheme? (Tick all that apply)?

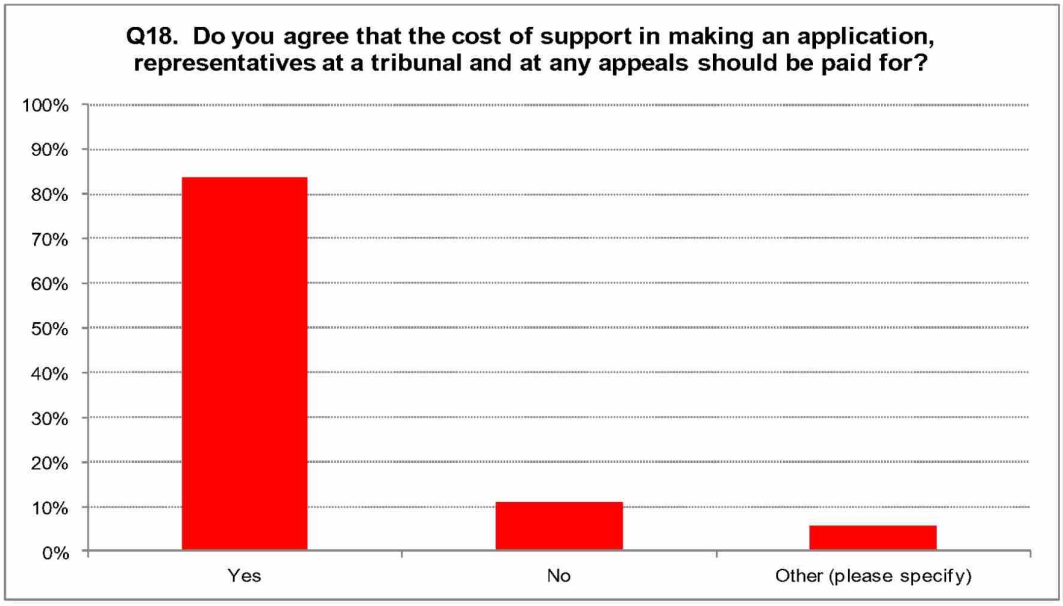
Answer Choices	Responses	
Hepatitis B	59.01%	239
Hepatitis D	44.94%	182
vCJD	67.41%	273
Other viruses such as Parvovirus 19	39.26%	159
None of the above	22.72%	92
	Answered	405
	Skipped	0



Question 18

Do you agree that the cost of support in making an application, representatives at a tribunal and at any appeals should be paid for?

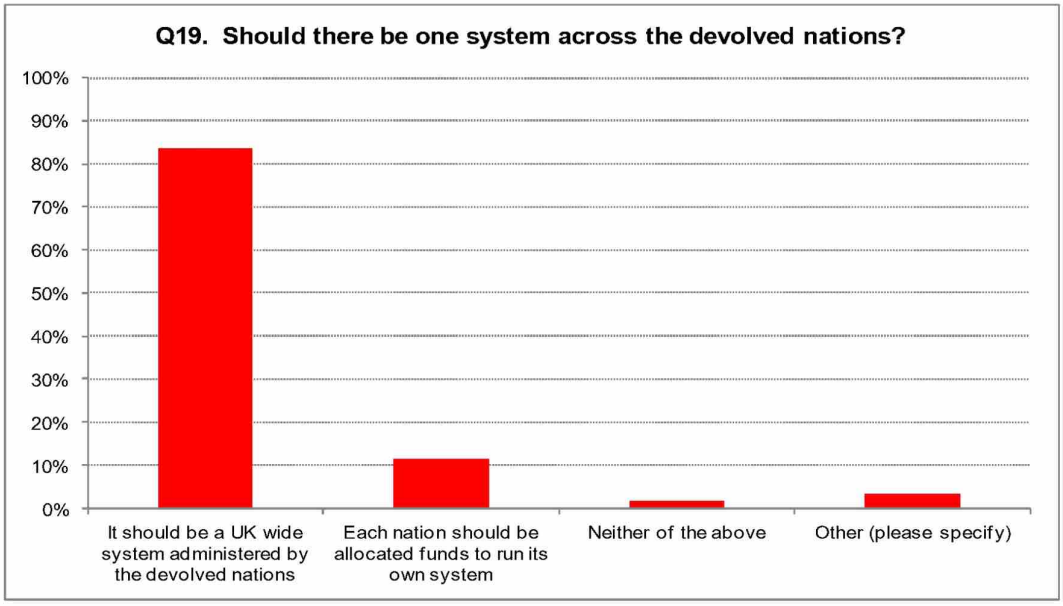
Answer Choices	Responses	
Yes	83.46%	338
No	10.86%	44
Other (please specify)	5.68%	23
	Answered	405
	Skipped	0



Question 19

Should there be one system across the devolved nations?

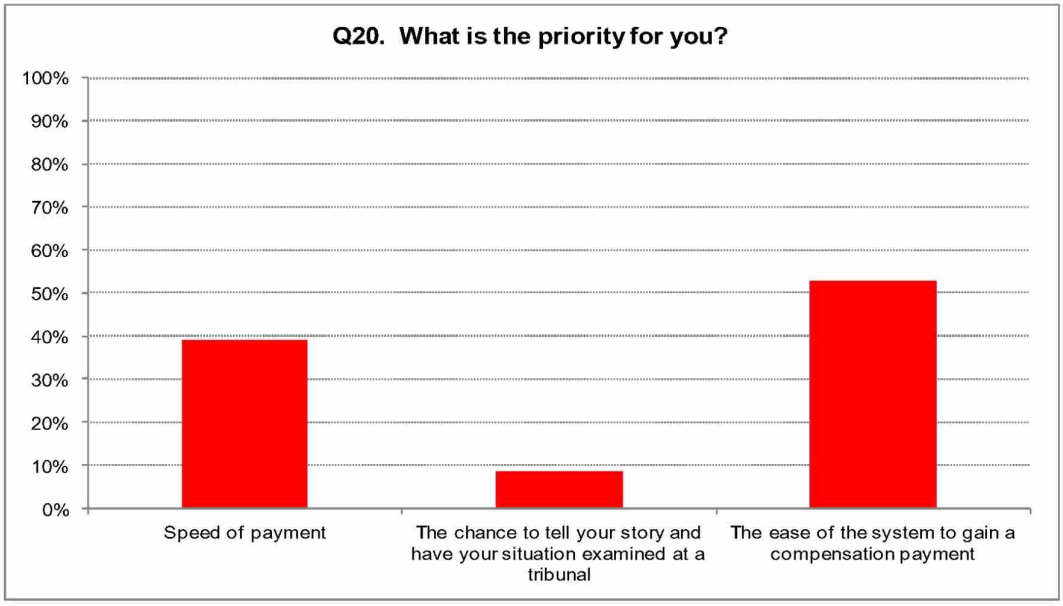
Answer Choices	Responses	
It should be a UK wide system administered by the devolved nations	83.46%	338
Each nation should be allocated funds to run its own system	11.60%	47
Neither of the above	1.73%	7
Other (please specify)	3.21%	13
	Answered	405
	Skipped	0



Question 20

What is the priority for you? (Select one)

Answer Choices	Responses	
Speed of Payment	39.01%	158
The chance to tell your story and have your situation examined at a tribunal	8.40%	34
The ease of the system to gain a compensation pay-out	52.59%	213
	Answered	405
	Skipped	0


Q20. What is the priority for you?
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Speed of payment
The chance to tell your story and have your situation examined at a tribunal
The ease of the system to gain a compensation payment