THE INFECTED BLOOD INQUIRY

CLOSING SUBMISSIONS ON BEHALF OF THOSE REPRESENTED

BY MILNERS SOLICITORS

TABLE OF CONTENTS

INTRODUCTION

1. The final hearing of evidence in November marked a milestone that many of our clients have fought to reach for decades. The fact that, at the point of making these submissions, a public inquiry has taken place and has concluded its hearing of evidence is a monumental achievement for those who have battled for a thorough investigation of the circumstances of how they and those they love came to be infected with viruses through the use of contaminated blood products.

Remit of these Submissions

2. We act on behalf of a group of core participants who were all infected through (directly or indirectly), or affected by, the use of contaminated blood products, namely contaminated Factor VIII ("FVIII") or Factor ("FIX") concentrates.

3. We do not act on behalf of anyone who became infected by, or who was affected as a result of, whole blood transfusions and as such, save where there is relevant crossover, we deal only with issues relevant to infections arising from FVIII or FIX concentrates, whether those infections be via direct use of the concentrate or indirect via sexual contact with someone directly infected.

4. In omitting any discussion which is solely relevant to infection via whole blood transfusion, we intend no disrespect nor discourtesy to those infected and affected in such a way. Any such omission should not be read as a lack of support for what is said on behalf of this group of people by those properly instructed to act on their behalf and in their interests.

Our Clients

5. All of our infected clients became infected with HIV and/or HCV through the use of contaminated FVIII and FIX concentrates. They acquired their infection(s) via one of four different paths:

    a) Through being diagnosed with Haemophilia A, Haemophilia B and/or Haemophilia C;

    b) Through being diagnosed with Von Willebrand's Disease;

    c) Through being misdiagnosed as suffering from one of the conditions at (i) or (ii) above.; or

    d) Through sexual contact with someone infected via (i) to (iii) above.

6. Where we refer to haemophilia and haemophiliacs throughout this submission, it is for ease of reading and should be construed as referring to all of those with a bleeding disorder, or misdiagnosed as suffering from a bleeding disorder which resulted in transfusion with contaminated FVIII or FIX concentrates.

7. Our affected clients are the partners, parents, and children of those who were infected through the use of contaminated concentrates. The lives of our affected clients have been forever changed as a result of the infections of those they love. Some of our affected clients have also suffered psychological and physical injuries of their own.

8. Many amongst our client group, both infected and affected, have been involved in supporting the infected haemophilia community whether through participation in the running of the MacFarlane Trust (or its Partnership Group) and the Haemophilia Society or through their founding of, and participation in, numerous campaign organisations.

9. We are privileged to represent some of the longest standing campaigners who have made it their life's work to achieve justice for the infected and affected. Their efforts and the numerous ways in which they sought to shine a light on the infected blood scandal are too numerous to capture adequately in this introduction. Their research, lobbying, and relentless campaigning has in no small part ensured that such a vast array of documentary evidence has been preserved for the Inquiry's scrutiny.

10. For our part, it has been astonishing to see how so much of what those campaigners have said, over the course of decades, has been shown through the Inquiry's examination of the evidence to be correct. This is particularly remarkable when one considers how, for so long, our clients and other campaigners were so often dismissed as fantasists and conspiracy theorists; even in one case, hospitalised and diagnosed as delusional for simply telling his story.

Structure

11. Insofar as we have been able, in the interests of brevity, we have adopted much of what has been set out by Counsel to the Inquiry ("CTI") in their numerous, excellent presentations. What is written herein is intended to supplement and complement the work of CTI. This submission should be read as agreeing with the content of the presentations, save where we expressly indicate to the contrary.

12. We have attempted to take a chronological approach. At times, for ease of reading, it is necessary to deviate from the chronology to explore a discrete issue in more detail: the statutory framework surrounding product licensing being a prime example.

13. It goes without saying that it would be an impossible task to try to summarise the entirety of the history of the infected blood scandal; even with the adoption of CTI's presentations, themselves summaries in many cases, we barely scratch the surface. As such, it would be impossible to set out every misdeed visited upon the infected and affected core participants, and impossible to list out every person, body, and organisation responsible for those misdeeds.

14. We have, therefore, adopted a thematic approach which highlights the significant strands of serious wrongdoing that caused or contributed to both the scale of infections amongst those diagnosed with bleeding disorders, as well as to the physical and psychological harm sustained by the infected and affected, often over years and even decades.

Thanks

15. Before we proceed with the substance of our submission, we and our clients wish to acknowledge the tremendous amount of work undertaken by the Inquiry and the manner in which it has been undertaken.

16. The kind, respectful and approachable way in which the Inquiry's solicitor and counsel teams and secretariat have dealt not just with all core participants and witnesses, but also those representing them, has made engagement with the Inquiry a pleasure.

17. The Chair's patient, compassionate, and empathetic approach to his task has endeared him to all involved in the Inquiry; it has also given confidence to, and inspired trust amongst, those whose faith in government and legal process has been shaken. On behalf of ourselves and our clients, we offer our sincere thanks and gratitude.

Summary of Closing Submissions

18. One of the most unnerving things to have emerged from this Inquiry is the extent of early awareness of the spread of hepatitis through blood. From as early as 1946, the knowledge that blood and blood products (particularly those involving larger plasma pools) could result in the spread of infection had crystallised. It is from this pivotal moment that many of the evils of the infected blood scandal flowed.

19. Throughout the 1940s, 1950s and 1960s, "large pools" of plasma were considered, at least in the UK, to be those which had been derived from ten or more donors. In addition to restricting plasma pools to ten or fewer for safety, as early as 1950 Dr Maycock, on behalf of the Ministry of Health, was monitoring forms of viral inactivation to mitigate the risks posed by blood.

20. Yet, despite that knowledge, plasma pool sizes became inexplicably larger, by many, many factors of ten. A significant milestone in this Inquiry's chronology is the licensing of Hemofil and Kryobulin between November 1972 and April 1973, both of which had plasma pools of at least 1,000 donations. Our submission on this is simple: that expansion in donor exposure could never have been justified if patient safety were to be a central or critical component of the licensing regime. There was a complete absence of any scientific or empirical evidence which warranted or justified an expansion in pool sizes and risk.

21. Furthermore, and as would have been easily identifiable with adequate scrutiny, blood and plasma collection practices in the US were a matter of deep concern. Meaningful risk controls were thrown to abandon which, as we explain in these submissions, resulted in US products posing a much higher risk of transmission of hepatitis and, subsequently, HIV.

22. However, it is important to remember that damage had already been done to haemophiliac patients prior to 1972, as a result of the licensing regime's "named patient" exemption. In summary, the exemption permitted doctors to order unlicensed products for their patients without any form of scrutiny or safeguards. Thus, what the Medicines Act 1968 gave with one hand, it took away with the other: this was a complete 'by the back door' approach to regulatory restrictions, which were not controlled by any meaningful safety measures until the Medicines (Exemption from Licences) (Importation) Order 1984.

23. These issues point, in our submission, to significant deficiencies in the licensing regime, including the bodies charged with its application. Although the language of the 1968 Act legislated for safety to be a pivotal aspect of licensing decisions, the licensing and decision making on the ground did not reflect a 'safety first' attitude. The only factors in favour of approving products made from larger plasma pools (and failing to revoke them when problems were identified) were ease, efficacy, and mass production. None of those factors should ever have trumped patient safety.

24. As the successful licences rolled on in, plasma pools grew from 10, to 10,000, and ultimately to more than 400,000 with the advent of re-pooling and combining batches. The US products led the way in pool size growth, but where the commercial manufacturers went, the NHS followed. It is, in our submission, telling that the contemporaneous documentation failed to actually address or justify the increased pool size: this points to a failure to engage with the question of risk, and to ask whether it could be tolerated and mitigated.

25. Notwithstanding the expansion in pool sizes in NHS products, those products were demonstrably safer than imported commercial products. As we explain in our submissions, US products were approximately 9 times more likely to cause HIV infections than products manufactured by the NHS. It is therefore clear that had the UK made self-sufficiency a priority – and actually delivered on it – the scale of the infected blood scandal and human suffering could have been substantially reduced. There was a failure by successive governments to get to grips with the problem, and to make sure that self-sufficiency resource and investment was non-negotiable.

26. The results of this catalogue of failings were that, over the years, bleeding disorder patients (including those misdiagnosed as having mild forms of bleeding disorders) contracted hepatitis and HIV infections on a shocking scale. Even as the links between blood products and these infections were put beyond doubt as of 1982 onwards, dangerous blood products continued to be administered in vast quantities.

27. The treatment of haemophiliac patients repeatedly flew in the face of good practice and ethical treatment:

    a) There was a failure to conduct risk benefit analyses to ensure that the patient really required the blood products which were being administered. This is particularly problematic for our clients who were misdiagnosed or who had mild forms of haemophilia: given the risks posed by the products, and the relatively little benefit, the treatment should never have been administered. Instead, clinicians took a slapdash, one size fits all approach, apparently preferring the ease that factor concentrates brought to a patient-centric approach;

    b) Risks were not communicated to, nor explained to, patients who, in some instances, were told that only good things would arise from their treatment;

    c) Doctors believed that treatment decisions were for them, as the experts. The temporal context in which these events occurred is not an excuse for such an approach: patient choice and patient care were, even in the 1960s and 1970s, paramount principles;

    d) Patients were deployed in studies without their knowledge or consent, with their lives considered dispensable by clinicians who saw their role as playing God;

    e) There was a total failure to explore and utilise alternatives, particularly synthetic treatments such as DDAVP. There was no explanation for this, beyond a lack of medical and professional curiosity, which could have saved many lives.

28. The way in which clinicians treated patients, and continued to prescribe and push for treatment with imported blood products once the risks were beyond doubt, was morally, ethically and criminally wrong.

29. There were – and in some cases remain – strong bases for challenging both the actions of the individual doctors and the state's licensing decisions in tort law and in public law, including in reliance on Article 2 of the European Convention of Human Rights and the subsequent Human Rights Act 1998. The compensation that is owed to our clients – and which was strenuously fought against at the time – far eclipses that which was given to them through the various trusts and schemes. Those schemes were not only dysfunctional in their execution and management, but also neglected the needs and interests of those who had become infected in the absence of a bleeding disorder and those who had been bereaved. This was but one of the many planks of the misogynistic approach adopted by the state and society at that time, which left suffering women out in the cold.

30. For four decades, the state failed to protect the lives of its citizens, and failed to govern effectively, transparently, and with principle. The machinations of government, particularly an overreliance on unelected but powerful civil servants, resulted in ministers being shielded from the true scale of the problem, and in senior figures repeatedly failing to scrutinise, question and probe the averment that the state had done no wrong, even against a rising chorus. Make no mistake: government chose to fight, rather than serve, its victims every step of the way, eerily mirroring the notorious approach of multinational pharmaceutical companies.

31. The campaigners behind this Inquiry have fought for justice at every twist and turn. Many of them sacrificed their own health to do so. Many of them are not alive to see the results of this Inquiry, for which they fought so hard. The victims of the infected blood scandal went through horrors that no citizen of a first world country should ever have endured at the hands of our state and health service. That they then spent decades fighting for truth and justice is an immense and stupendous achievement, but also a sad indictment on our society.

1. KNOWLEDGE OF HEPATITIS AND BLOOD PRODUCT DEVELOPMENT

Knowledge of Hepatitis

32. To trace the history of the knowledge of viral hepatitis, one must first trace the historical language used to describe hepatitis or jaundice. The 1952 report of the Expert Committee on Hepatitis of the World Health Organisation[1] begins with an explanation that it had become recognised that catarrhal jaundice was a form of infectious hepatitis (also known as infective hepatitis or epidemic hepatitis). The report labelled catarrhal jaundice as Hepatitis A, and serum hepatitis, or homologous serum jaundice, as Hepatitis B.[2]

33. It is trite that following the increased ability of pathologists to identify and distinguish hepatitis A and B, it became apparent that another form of serum hepatitis existed; given that it was neither of the identified viruses, it was labelled Non-A-Non-B Hepatitis ("NANB"). In the latter half of the 1980s, the virus causing NANB was isolated and labelled Hepatitis C. For the purposes of these submissions, it is sufficient to note that the terms 'serum hepatitis' and 'post-transfusion hepatitis' must be treated with caution and taken as including both HBV and HCV.[3]

34. The earliest scientific material relevant to serum hepatitis that we have located amongst the documents available to core participants, is a report from the Ministry of Health dated 29 June 1942, though concerning events which took place in 1937.[4] The report details an outbreak of jaundice amongst children following the administration of a batch of measles convalescent serum, referred to as batch K60, pooled from the sera of 26 donors. The report noted that the committee convened to consider the cases reached *"no conclusion as to the cause of the disease […] but the majority opinion attributed it directly to the 'measles' serum."*. It short, the committee found 'no conclusive proof' that the serum had transmitted hepatitis, but had sufficient evidence to warrant a full investigation and the recall of the implicated batch.

35. In August 1942, a clear link between the use of blood and blood products and the development of jaundice was being drawn by the Ministry of Health's Senior Medical Officer ("SMO"). In a letter dated 4 August 1945, the SMO summarised the 1937 K60

---

[1] RLIT0000215

[2] The point is further confirmed in the oral evidence of the Hepatitis Expert Group– Transcript 26/02/2020 Pg33, L4+

[3] Hepatitis Expert Group Transcript 26/02/2020 Pg60, L3+ Prof. Dillon said *"So almost all non-A non-B hepatitis was hepatitis C, so we were in the situation in the early 1970s where we could test for hepatitis B. There were patients who were receiving blood transfusion and they were still getting what had been described as serum hepatitis. We knew it wasn't hepatitis B because their tests were negative."*

[4] DHSC0100008_008.

incident, and noted that, more recently, attacks of jaundice had followed the administration of mumps convalescent serum, yellow fever vaccine, and whole blood and plasma transfusion.[5] The SMO encouraged the follow-up of patients who had received blood or plasma transfusions in order to determine whether there was an association between transfusion and hepatitis, which may have been overlooked previously owing to the period of latency of the jaundice prior to the onset of symptoms.

36. The Second World War, through its horrors, provided a wealth of information which established clear links between transfusion and hepatitis[6]. In the USA, John R. Paul described the 1942 "great epidemic" [7]which "fell upon the troops" as a result of hepatitis contaminated yellow-fever vaccine.[8]

37. In December 1942, WH Bradley and ECG Maddock prepared a report which, to the best of our research, coined the phrase "homologous serum jaundice". The opening paragraph of the report, which was sent to Dr Panton of the Ministry of Health, read: *"It must now be recognised that under certain circumstances at present undefined hepatic necrosis may follow the parenteral administration of human blood products."*.[9]

38. In the body of their report, Bradley and Maddock recited the known history of instances of jaundice following transfusion, beginning in 1885 with the Bremen shipyard incident, which saw 191 cases of jaundice following the administration of human lymph to workmen who had received it as a vaccine. They concluded that there was *"a disturbing probability that large amounts of icterogenic plasma and serum remains in store awaiting use"* and that whilst there was no question of withholding the products from use, *"it follows that, although further field studies may enable a measure of control and will certainly permit deductions as to the probable mechanism of this new disease, they are unlikely to bring to light a total solution."* The December 1942 Bradley and Maddock report was then translated into a paper

[5] DHSC0100008_003.
[6] The Second World War coincided with and accelerated the development of blood banking which, in the UK, was led by Dr Charles Drew; HSOC0019915_0110
[7] "Viral Hepatitis" in Preventative Medicine in WW11 vol. 5 (Washington DC: Office of the Surgeon General; U.S. Army 1960) 411. It is suggested that many soldiers who did not receive in -patient care may have taken the numbers up to 330,000; Serologic Follow-up of the 1942 Epidemic of Post-vaccination Hepatitis in the US Army; New England Journal of Medicine 316, No.16 (April 16 th, 1967); 965.
[8] "Jaundice Danger in Army from Yellow Fever Vaccine Now Over" issued by the War Department Bureau of Public Relations, July 28th 1942, NARA OTSG Diseases, Box 1125, Folder: Virus Disease, Jaundice– Publicity on the Effect of the Yellow Fever Vaccine.
[9] DHSC0100008_020

prepared by 'Medical Officers of the Ministry of Health', which appeared in the Lancet on 16 January 1943.[10]

39. By 1946, some three years later, the knowledge of the risk posed by blood and blood products (particularly those which had been pooled) had, in our submission, crystalised. The article entitled *"The incidence, incubation period and symptomology of homologous serum jaundice"*,[11] published in the BMJ on 21 September 1946, concluded as follows:

> *"It is suggested that to minimize the risk of homologous serum jaundice after transfusion the following procedure should be adopted: (i) human serum for prophylactic purposes should not be pooled; (ii) for transfusion purposes only small pools should be used*; (iii) all blood products issued should carry an identification number; (iv) records should be kept of the number of any bottle given to a particular patient; (v) machinery should be maintained and strengthened for the notification to the regional transfusion officer of jaundice following transfusion, thus enabling icterogenic material to be withdrawn from circulation. *We understand that only small pools are now used by the Ministry of Health for the preparation of blood products."*

40. In a letter dated 19 August 1946, Dr William Maycock, the Ministry of Health's consultant adviser on blood transfusions between 1946 and 1978, wrote:

> *"The question raised about plasma by Janet Vaughan has been worrying me for some months. We had already discussed it with Sir Wilson Jameson, and agreed that users must be told that it is a potentially lethal fluid which should be used with discretion…"*[12]

41. In addition, a Ministry of Health memo dated 22 August 1946[13] cited Dr Maycock's thoughts on the dangers of pooled plasma:

> *"…While homologous serum jaundice follows the use of whole blood in very few of the recipients, the use of dried plasma is followed by the development of jaundice in about 10% of those receiving it. This incidence is probably halved if plasma is used which is made from plasma pools derived from the blood of only ten donors, instead of from large pools derived from the blood of greater numbers. This lower incidence has yet to be confirmed by the completion of surveys now in hand. All plasma being dried for the Ministry by M.R.C. is made from small pools, but "large pool" plasma is still in use. The jaundice is usually mild and rarely fatal. […] It must be assumed that all batches of plasma are potentially icterogenic until experience has shown that they are not."*

[10] NHBT0000091_011.
[11] RLIT0000052_0003
[12] DHSC0100008_190
[13] DHSC0100008_191

42. It is worth specifically highlighting that the Ministry of Health, in 1946, operated on the basis that plasma pools involving more than ten donors were "large pools". As the evidence examined by the Inquiry has shown, with time the common understanding of a "large pool" shifted toward pools involving significantly greater numbers of donors. This in itself is suggestive of an increased tolerance to the risk posed by large pool plasma products, despite an increasing knowledge of the risks associated with blood products (particularly large pool plasma products), which emerged over time.

43. Around a similar time, there were UK studies into hepatis infections in wartime, such as the "*Discussion on Infective Hepatitis, Homologous Serum Hepatitis and Arsenotherapy Jaundice*" (June 1944),[14] which was subsequently considered in the "*Wartime Medical Council Jaundice Committee Experiments (2003)*".[15] The 2003 publication offered the following precis of the lessons to be learned from wartime, and what was then known by the medical profession:[16]

> *"The third lesson of major importance learned from vast wartime experience*
>
> *in the laboratory processing and clinical use of plasma was the danger of transmitting disease, particularly viral hepatitis, by large pool plasma. A single donation containing an infective agent may contaminate an entire plasma pool. When this occurs with a 500 donation pool, approximately 200 bottles of dried plasma prepared from the pool will contain the infective agent, whereas with the 10 donation pool only four bottles will harbour the infective agent. Theoretically therefore large pool plasma puts at risk many more recipients than does the small pool product. Wartime plasma had acquired a bad reputation for causing type B viral hepatitis—homologous serum jaundice or serum hepatitis, as it was termed at that time—and it was considered that the introduction of the small pool product would lower the incidence of transfusion-transmitted hepatitis (p. 273). The disease certainly became less prevalent following the introduction of small pool plasma, but other factors may have been responsible for, or may have contributed to, the reduced incidence. For example the prevalence of virus B infections in the general population in the UK may have fallen after the end of World War II, and certainly a higher standard in donor selection was adopted in that volunteers who had had overt hepatitis during the war were not accepted as donors (p. 273)."*

[14] Proceedings of the Royal Society of Medicine 37, No.8 (June 1944); 449-460.
[15] Useful Bodies: Humans in the Service of Medical Science in the Twentieth Century, Jenny Stanton, Hopkins University Press 2003, 109-132
[16] Wallace 1977, Blood Transfusions for Clinicians p.31 -32 (PRSE0002052_0005 & _0006)

44. In light of the risks which had been associated with blood and plasma products, in a 1947 article entitled '*Homologous Serum Jaundice in Recipients of Pooled Plasma*',[17] US authors Brightman and Korns recommended that:

> *"Plasma, as well as other forms of transfusion therapy, should be administered only when the clinical indications are absolute, so that the benefits to be derived clearly outweigh the risk of contracting homologous serum jaundice."*

45. The evidence has, therefore, demonstrated that by the end of the 1940s, there was a clear understanding of: the risk posed by the viral contamination of blood products; that this risk was severe; and that improved donor selection, small batch manufacturing, and cautious use were the only tools available to mitigate the risk.

46. By the 1950s, there was evidence of specific aversion to large pool plasma amongst civilian clinicians, as relayed to the Ministry of Health. In a memorandum to Dr Maycock on 2 May 1950, Dr Drummond of the Cardiff Regional Transfusion Centre ("RTC") wrote, upon finding stores of army plasma produced in 1945: *"This is all large pool plasma and we are averse to issuing it and our hospitals are, most of them, averse to using large pool plasma"*.[18]

47. The Inquiry has obtained a wealth of correspondence between Dr Maycock and others concerning the tracing of suspect batches of plasma throughout the 1950s, demonstrating that a rudimentary follow-up system had been implemented. Furthermore, and contrary to some of the evidence that has been heard that attempts at viral inactivation did not begin until the late 1970s, the evidence has demonstrated that Dr Maycock was monitoring experimentation with UV irradiation as a possible viral inactivation technique. Although that technique ultimately proved unsuccessful,[19] the evidence is clear that clinicians and the Ministry of Health alike were concerned about viral transmission via blood products, and of the risk that blood products produced from large plasma pools presented.

48. These early attempts at viral inactivation (including storage at room temperature and exposure to nitrogen mustard) were taken in tandem with practical and immediate steps to increase the security of the domestic donor panel: on 8 August 1952, Dr Maycock issued a directive to all Regional Transfusion Centres to exclude any donors with a history of jaundice (at any time) from donor panels.[20]

---

[17] RLIT0000054
[18] DHSC0100010_442
[19] DHSC0100010_439
[20] DHSC0100011_222

49. A paper produced by J. Garrott Allen and others, published in The Journal of the American Medical Association on 9 January 1954,[21] demonstrates what was known and understood in the USA at this point in time. Dr Allen's paper discussed the storage of pooled plasma at room temperature for six months as an effective viral inactivation technique. Although it is now understood that this process could never have led to effective viral inactivation in clotting factor products (because to retain potency, freezing must occur shortly after donation), the paper remains of significance for the following passage:

> *"Most viruses do not survive long when stored in a liquid cell-free medium at room temperature. Virologists carefully avoid exposing viruses to such conditions when they desire to perpetuate virus activity.* ***Had the biological principles governing virus survival been heeded, lyophilized, frozen, or refrigerated pooled plasma would not have been used until it could be demonstrated to be free of virus activity…****"*
>
> [Emphasis added]

50. If Dr Allen's warning had been heeded in 1954, and large-pool plasma products had been precluded from use until viral inactivation could be demonstrated, thousands of people would have been spared infection. Both Dr Allen's warning and the earlier concerns noted by or reported to Dr Maycock were significant, and should have played a pivotal role in the development and expansion of blood products in the decades to come.

51. By 1963, the knowledge of homologous serum jaundice/serum hepatitis/post transfusion hepatitis had progressed little from that which was known in 1954. A booklet published by the Ministry of Health in 1963 sets out:

> *"Homologous Serum Jaundice: This complication is a risk attaching to the use of blood, plasma or serum. As far as is known the case incidence after the transfusion of dried small pool plasma or serum is little if any greater than that after whole blood (see Report, Lancet, 1954, I, 1328)*
>
> *All dried plasma or serum issued in the United Kingdom is prepared from pools made from not more than 10 blood donations…*
>
> *Homologous serum jaundice is clinically indistinguishable from infective hepatitis and occurs 40-150 days after transfusion. It is thought to be caused by a virus."*[22]

52. The link between the incidence of HBV and plasma pool size was made in a journal article authored by Dr Maycock in November 1964, entitled "*Transmission of Hepatitis*

[21] RLIT0000057
[22] JPAC0000162_021, page 22

by Blood and Blood Products".[23] After making that link, Dr Maycock suggested that until the virus could be identified, the use of sterile tools, the careful selection of donors, and the discriminating use of blood and blood products were the best ways to reduce the risk of transmission.

53. Shortly thereafter, on 15 February 1965, Blumberg et al published their article "*A "New" Antigen in Leukemia Sera*" in the Journal of the American Medical Association,[24] which described the Australia antigen or, as it would become, Hepatitis B surface antigen ("HBsAG"). It is of note that it was via the cross reaction of the sera of two haemophiliacs with that of an Australian First Nation person that the antigen came to be detected and named. Whilst Blumberg et al failed to recognise that the Australia antigen was HBsAG, they did conclude the article by noting:

> *"An isoprecipitin is present in the sera of many patients with hemophilia who have received transfusions. It reacts with a protein (the "Australia antigen") that is found in the sera of some normal individuals from foreign populations but is absent in sera of the United States populations studied. It is found in approximately 10% of patients with Leukemia."*

It would be a further three years before the significance of the heightened presence of the antigen in those receiving large numbers of transfusions was recognised.

54. Elsewhere in 1965, Jean Grant, the Director of the Oxford RTC published an article in The Practitioner titled "*Complications of Blood Transfusion*".[25] Under the heading 'Transmission of Disease', Grant stated:

> *"It has been found that a minute fraction of a millilitre of virus-laden blood was enough to cause hepatitis (Murray 1955) and it was for this reason that the production of large-pool plasma, made from contributions of more than 300 donors, was abandoned in favour of limited pools derived from not more than 10 donors."*

55. Although Grant attributed the knowledge of the danger of large plasma pools to research from 1955, the evidence set out in these submissions thus far has demonstrated that this danger was appreciated much earlier, and by at least 1946, when the articles '*The incidence, incubation period, and symptomology of homologous*

[23] RLIT0000065
[24] PRSE0001518
[25] PRSE0003897

serum jaundice' (BMJ, 1946)[26] and '*Homologous Serum Jaundice in Recipients of Pooled Plasma*' (JAMA, 1947) were published, as set out above.

56. Grant's article went on to set out the understanding of the risk posed by serum hepatitis: *"Some patients suffer no upset from the transmitted virus, some may have only a transient liver dysfunction with or without jaundice and yet others may develop a rapidly fatal hepatic necrosis."* In short, by 1965 (or by 1946 for that matter), serum jaundice was not considered an inconsequential infection.

57. In this vein, an article in 1965 found an overall mortality rate of 11.2% from cases of post-transfusion hepatitis (Mosley).[27] This was similar to fatality rates recorded in other studies by Allen and Sayman (11.1%) and Grady et al (12.3%). Although Mosley's article contained the caveat that the fatality rate for those under 40 reduced to 5.5%, the application of these percentages to a cohort of 100 infected haemophiliacs in 1965 would result in the expectation that between 5 and 12 of them were going to die. These statistics make it clear that the risk posed by post-transfusion hepatitis in 1965 could never responsibly have been described as analogous to a mild flu as it was so often described to those with bleeding disorders.

58. Blumberg et al reported again in 1967 in the Annals of Internal Medicine, and came tantalisingly close to drawing a connection between Australia antigen and HBV. The article said:

> *"Most of the disease associations could be explained by the association of Au(l) with a virus, as suggested in our previous publications. The discovery of the frequent occurrence of Au(l) in patients with virus hepatitis raises the possibility that the agent present in some cases of this disease may be Australia antigen or be responsible for its presence. The presence of Australia Antigen in the thalassemia and haemophilia patients could be due to virus introduced by transfusions. This however could not be the only explanation, since many transfused patients neither have the antigen nor the antibody against it…"*[28]

59. Finally, in April 1968, Prince's work was published confirming the identification of an antigen in the serum of a classic case of post-transfusion serum hepatitis.[29] Prince noted that the antigen was also found in the sera of people with haemophilia. Shortly

---

[26] RLIT0000052 – The Incidence, incubation period, and symptomology of homologous serum jaundice", Spurling et al

[27] RLIT0000066 – JAMA, The Surveillance of Transfusion-Associated Viral Hepatitis, J.W. Mosley, 20/09/1965

[28] PRSE0000705 – 01/05/1967, A Serum Antigen (Australia Antigen) in Down's Syndrome, Leukemia, and Hepatitis, Blumberg et al

[29] PRSE0000430 08/04/1968, Prince, An Antigen Detected in Blood During the Incubation Period of Serum Hepatitis.

thereafter, in an article published in August 1968,[30] Prince noted that this antigen was closely related, if not identical to, Blumberg's Australia antigen. The combination of these findings by Blumberg et al and Prince paved the way for HBV screening and, ultimately, the realisation that there was more than one virus responsible for post-transfusion hepatitis.

60. Later in the same month, Professor Zuckerman wrote in the British Medical Journal in response to a suggestion that remuneration for blood donations be introduced in the UK.[31] He argued that the purchase of blood products carried significant risks of post-transfusion hepatitis, by reference to high levels of post-transfusion hepatitis in the United States, Germany and Japan. He also noted that the overall mortality rate from serum hepatitis could be as high as 28%.

61. If any doubt remained as to the level of knowledge of the severity of post-transfusion hepatitis by the end of the 1960s, the Annual Report for 1969/70 of the Royal Infirmary of Edinburgh was unequivocal:

> *"…Measures to prevent the transmission of disease through the transfusion of blood or blood products has always been a major problem. Hepatitis is one of the most important and dangerous of these illnesses…"*[32]

The Development of Blood Products

62. It is against this backdrop of a well-developed knowledge of the nature and risk of hepatitis transmission through blood and its derivatives that we ought to turn to look at the concomitant development of treatments for bleeding disorders.

63. In analysing the development of clotting factor treatments, the minutes of the third meeting of the Blood Products Laboratory and Blood Group Reference Laboratory Managing Committee on 25 April 1957 is a useful starting point. The minutes recorded:

> *"Until 1954, the only way of treating haemorrhage in haemophiliacs had been by introducing the necessary anti-haemophilic factor by transfusion of fresh blood, fresh plasma, or plasma which had been separated from fresh blood and stored at -20°c. Because of the normally low anti-haemophilic potency of normal human blood or plasma, massive transfusions were often necessary and involved a risk of circulatory overloading…"*[33]

[30] **PRSE0000430**
[31] RLIT0000072
[32] LOTH0000127_0007
[33] MRCO0005018

The minute then set out the work of Macfarlane et al in developing high potency anti-haemophilic factor from pig and ox blood, noting that the treatment could be used once with great success but that after one use, the patient became sensitised and they could not be used again, and so were only to be used if the patient's life was at imminent risk.

64. A letter from Dr Rosemary Biggs on 23 December 1958 set out the totality of treatment options for haemophilia as at that time, as well as the advantages and disadvantages of each.[34] Dr Biggs listed only three products:

    a) The human AHG of Kekwick's design, which she recorded was *"in very short supply"* and *"tends to give frightening and inexplicable reactions"*;

    b) Animal AHG, prepared by Dr Biggs and Dr Macfarlane. Dr Biggs noted that *"these preparations we reserve for unequivocally essential major surgery"*, and that the material was undoubtedly very effective within its limits but was antigenic; and

    c) Fresh frozen plasma which is said to be of very variable potency.

65. On 18 July 1964, Judith Pool described the production of a high potency antihaemophilic factor concentrate prepared from cryoglobulin precipitate derived from the white paste residue left over after carefully thawing frozen plasma.[35] This cryoprecipitate would revolutionise the treatment of haemophilia.

66. Building upon the work of Judith Pool, a press report in the Guardian from 25 May 1966 covered Edward Shanbrom's announcement of the development of Factor VIII concentrate.[36] It can be seen from internal Ministry of Health memoranda that issue was taken with the story on account of the fact that by 1966, Bio Products Laboratory ("BPL") had been producing a form of concentrate for a number of years.[37]

67. In 1967, the British Journal of Haematology published Ethel Bidwell's work on the preparation of a freeze-dried Factor IX concentrate. Bidwell's work established that it was possible to produce a FIX concentrate from the residue of an alcohol fractionation of plasma. This process made the production of FIX concentrate economical compared to the earlier production techniques which involved the wastage of all serum components but for FIX.

[34] **OXUH0003841_001**
[35] PRSE0002338
[36] MDIA0000001
[37] DHSC0100025_041

68. The development of cryoprecipitate and a FIX concentrate gave the promise of readily available treatment options for bleeding disorders which would revolutionise haemophilia care. In a letter published in The Lancet on 8 April 1967, Dr Peter Jones said:

> *"…We in this department have found it satisfactory to give cryoprecipitate directly using a disposable plastic syringe, rather than a giving set as used by Dr Prentice and his colleagues (March 4, P. 457)*
>
> *A further advantage is that parents may seek medical advice earlier knowing that one simple injection only may be required. In addition, nursing of small, often heavily sedated, children on long-continued intravenous-drip therapy will only rarely be needed…*
>
> ***Cryoprecipitate is now the method of choice in treating bleeding episodes in patients with haemophilia, but, when not available, adequate therapy with fresh frozen plasma is possible… Concentrated A.H.F. should be reserved for patients in whom haemostasis presents particular difficulty**."*[38]
>
> [Emphasis added]

69. The development of treatment options for Haemophilia A and Haemophilia B meant that it was necessary to plan for sufficient production of these products. it is notable that in August 1967, Dr Rosemary Biggs wrote to the Ministry of Health making the financial case for ramping up domestic fractionation capabilities in order to avoid the need to purchase costly American commercial products;[39] in short, Dr Biggs was calling for the UK to develop self-sufficiency in the production of blood products.

70. By 1969, the use of cryoprecipitate had become more common. An article in the British Medical Journal dated September 1969 highlighted the case of a fatal hepatitis infection following the transfusion of a haemophiliac with 162 units of cryoprecipitate.[40] The report concluded with a warning on the need to monitor the source of cryoprecipitate. In our submission, it follows (and could and should have been inferred) that the risk of infection would increase correspondingly with the level of donor exposure:

> *"Cryo represents a considerable advance in the management of the severe haemophiliac. This and other centres have used many thousands of units without mishap and we do not know of a similar case in Britain. It is important to re-emphasise the potential danger of cryo to ensure its use only when strictly*

[38] PJON0000136_001
[39] DHSC0100025_062
[40] PRSE0003714

needed. ***A check should be kept of the source of cryo to trace any serum hepatitis which may occur in the future****."*

[Emphasis added]

71. Elsewhere, in a 1970 article in Vox Sang, Gocke followed a number of patients who had been transfused with Australia antigen positive and negative blood variously, noting that cases of hepatitis remained in those who were Australia antigen negative.[41] This is one of the first articles – if not the first article – we have located which noted that other agents might also be responsible for post-transfusion hepatitis:

> *"…we must still explain the phenomenon of antigen-negative hepatitis in recipients of negative blood. We suspect, from the findings described above, that this is not just a problem of insufficient test sensitivity and that other agents are responsible for a significant proportion of post-transfusion hepatitis."*

72. The evidence and materials cited above demonstrates that the medical profession grew up on an unrestricted diet of warnings regarding the risks from blood and blood products. Furthermore, Dr Bevan's witness statement explained that "*like any British doctor trained during the 1970's, I was well aware of the Hepatitis outbreak that killed patients, nurses and renal surgeons*…."[42], but that his mentors described these infections *"to trainees as both inevitable and harmless".*

73. In 1970, Professor Zuckerman concluded that:

> *"it was not possible to regard infective hepatitis and serum hepatitis as distinct types as there was considerable overlap between them. It would be more correct to recognise short and long incubation types of infection, the short incubation type generally corresponding with infective hepatitis and the long incubation type with serum hepatitis".*[43]

74. Thus, in or around 1970 there was a large body of evidence warning: of the danger of transfusion transmitted hepatitis; that an increased incidence amongst those treated heavily with cryoprecipitate had been noted; and that there was a general rule in the UK that plasma products should be manufactured from pools of not more than ten donors, rather than from 'large pools'. It is against this backdrop that the flow of FVIII concentrates began to enter the UK from the United States and Austria.

---

[41] PRSE0004544

[42] WITN4106001_0015

[43] Symposium on Hepatitis 4th December 1970: DHSC0103394_095_0002. One of the issues appears to have been the lack of official recording of serum hepatitis as a notifiable disease, see Wallace's letter to the Glasgow and West of Scotland Blood Transfusion Service: PRSE0001967_0001

75. The Inquiry has disclosed a table produced by the Department of Health which summarises the early applications for product licences for FVIII Concentrates.[44] It shows that Travenol applied first on 3 November 1972, followed shortly thereafter by Serological Products Limited on 8 December 1972. Licences were granted on 19 February 1973 and 22 March 1973 respectively. In both instances, these novel products – which represented a wholesale departure from the previously received wisdom that plasma pool sizes should not exceed ten donors – were granted licences with a period of less than four months' consideration and scrutiny.

76. We will return to the reasonableness of those decisions in Section 3 of this submission, but note at this juncture that those decisions were in direct conflict with the 30+ years' worth of accumulated knowledge on the increasing risk of hepatitis associated with large pool plasma products, This inevitably raises the questions: were the licence applications given proper scrutiny? Were those considering the applications provided with sufficient background and scientific material on the risks associated with blood products?

77. Whilst we have been unable to locate the assessment of Travenol's application, the assessment of Serological Products' Kryobulin application notes that donors testing positive for hepatitis associated antigen were permanently excluded from donor panels and that donors appeared to be well screened.[45] In our submission, this demonstrates that, whilst the risk of hepatitis was in mind, insufficient consideration was given to the risk which it posed, and insufficient control mechanisms or restrictions (such as restrictions on plasma pool sizes) were put in place by the Licensing Authority to minimise and mitigate the risk posed by emerging pathogens. These issues will be considered further in Section 3.

78. The failure by the Licensing Authority to give appropriate weight to the risks posed by hepatitis can be directly contrasted with the evidence of Dr Foster,[46] who stated that fractionators and regulatory authorities alike were well aware of the risk of hepatitis because of the number of reports which had been published. In his evidence he referenced a paper which he co-authored[47] that outlined the 1953 work of Hsia et al:[48] the clinical use of Cohn Fraction IV was abandoned following the treatment of eight children, four of whom developed hepatitis. In short, the risks posed by transfusion transmitted hepatitis were considered to outweigh the benefits hoped to be obtained

[44] DHSC0003742_080
[45] MHRA0033322_060
[46] WITN6914001_0044
[47] WITN6914003_0004
[48] American Journal of Medical Sciences 1953 Vol. 226 No.3 PP261 -4 (not found on Relativity)

through the proposed treatment. It is unclear why the Licensing Authority did not conduct a similar risk-benefit analysis.

79. At the same time that the first licence applications were being granted, the leading haemophilia clinicians of the time expressed their collective opinion in the 1974 British Journal of Haematology that:

> *"….mildly affected haemophiliac patients, to whom little treatment is given, do seem to have a higher incidence of hepatitis if large pool fractions are used. Kasper and Kipsis (1972) showed this, as did also the British Survey, where female carriers of haemophilia treated with concentrate had a high incidence of hepatitis… since the majority of patients are in the multi-transfused category, the increased risk of exposure to hepatitis would not seem to be an important disadvantage to the use of concentrates from pooled material".*[49]

As this article demonstrates, there was an insufficient focus on risk, particularly for those with less severe forms of haemophilia. Further, with this clear statement in 1972, it is curious that Colette Wintle, thought to be a female carrier, would be treated with concentrates four years later.

80. The understanding of the risk which arose from the use of blood products was widely accepted across the medical profession who prescribed blood treatments by 1974. In the two-year study results report to the M.R.C. Blood Transfusion Research Committee, it was stated:

> *"Hepatitis of viral origin is a major public health concern throughout the world. It constitutes the main hazard of the transfusion of blood and the use of blood products apart from immunoglobulin and preparations pf albumin. There are no reliable biochemical or histological features to help distinguish between Type A (infectious) hepatitis and type B (serum) hepatitis. Both types of infection may be transmitted by blood transfusion and the term post transfusion hepatitis includes both types. The clinical range includes inapparent infection, anicteric illness, acute icteric disease of varying severity and chronic liver damage"*[50]

81. In our submission, the knowledge of dangerous hepatitis was so well known that it was an accepted part of a medical professional's life and a possible source of danger to clinicians, even making its way into humorous fictional works such as Colin Douglas' "The Houseman's Tale" [51][1975]:

---

[49] Biggs, Rizza, Dormandy et al. 'Factor VII Concentrates made in the UK and the Treatment of Haemophilia Based on Studies Made during 1969-72. British Journal of Haematology, 1974, 27, 391 [PRSE0002680_0001]

[50] PRSE0002988_0002

[51] Published in 1975, page 198. Born in Glasgow in 1945, Colin Douglas was schooled atHamilton Academy before graduating in medicine at theUniversity of Edinburgh in 1970.

"Mac was sitting up in his cubicle smiling and faintly jaundiced. "Welcome to the pest house. They tell me I've got the yellow peril and it'll be six months off the booze"…

"Which of the yellow perils is it?" Campbell, asked, "plain or fancy". There were two types of hepatitis, one of which killed people. Serum hepatitis did, and was less common, but more likely to occur among hospitals staff". They are running a test now. But from the way they're treating me I'd say they think it's the real fancy no-messing about nasty serum stuff. They're taking no chances. You know Ivor, the SHO here? Came at me for blood dressed like a deep sea-diver: Boots, gauntlets, a thing like a welder's mask on his face and funny paper hats like yours. It made me feel I wasn't nice to know"…

At dinner the steward put down a piece of virulently yellow coloured fish in front of Campbell and said "I heard from one of the porters Sir, that Dr MacDonald's got the serious hepatitis".

"Serum hepatitis?"

"Something like that, Sir. A shame with Christmas just coming on"

82. Between 1973 and 1975, a further three licence applications were made for FVIII Concentrates by: Abbot Laboratories (22 August 1974); Speywood Laboratories (25 July 1975); and Baxter (UK) Limited (16 October 1975). During this period, and with the advent of HBV screening, it became abundantly clear that HBV was not the only form of post-transfusion hepatitis affecting patients.

83. In August 1974, Prince published further work following a prospective study of transfusion recipients who tested negative for hepatitis A and B. He concluded:

"The fact that non-B hepatitis cases are less frequently associated with serious acute illness does not imply that such cases are of lesser importance. Long-term complications of acute hepatitis-B infection, such as chronic hepatitis, cirrhosis, and hepatoma, have been reported to follow mild anicteric infections more frequently than severe icteric cases; consideration must thus be given to the possibility that non-B hepatitis may play a role in the aetiology of some forms of chronic liver disease.

Our findings imply that a substantial proportion of post-transfusion hepatitis cases is caused neither by HB virus nor hepatitis A agent, and suggest the existence of an additional virus(es), hepatitis type C."[52]

84. Explicit warnings of the increased hepatitis risk from commercial plasma products were given to Dr Maycock by Dr J Garrott Allen in 1975, who wrote to Dr Maycock to

[52] PRSE0001431

ask him to reconsider the purchase of commercial products not only because of the increased risk, but because of the harm it did to attempts to create a volunteer donor program in the United States:

> *"…The commercial blood banks attract these kinds of donors* [lower socio-economic and prison donors]. *Until we understand this problem better, I would hope that Great Britain would give some thought to what the purchase of Factors VIII and FIX from the United States tends to do to our attempts to form a volunteer program. Commercial blood banking perpetuates the high-risk rates for hepatitis we encounter with their products, and it also tempts these same commercial firms to sell the residual products of these high risk donors (red cells, platelets, leukocytes, etc.) to non-imunized patients who tend to be more susceptible to post transfusion hepatitis than is so for the non-virgin hemophiliac."*[53]

85. As knowledge of NANB hepatitis grew, Dr Wallace, the Regional Director of Glasgow and West of Scotland Blood Transfusion Service, wrote the following in his book "*Transfusion for Clinicians*" [1977]:

> *"Several prospective studies of recipients in the USA have shown that many cases of post-transfusion hepatitis cannot be explained by known types of hepatitis. Diagnosis of type B, CMV and EBV infections has been excluded, because of an absence of serological evidence to support the diagnosis. Type A hepatitis has been excluded, because the incubation period has been too long. For the present, this unexplained and marker-less form of long incubation post-transfusion hepatitis is termed viral hepatitis type C."*[54]

84. In 1977, Professor Eric Preston was in the process of conducting liver biopsies on eight haemophilia patients, following his finding that 77% of haemophiliacs within his Sheffield Centre displayed abnormal liver function tests. He attributed the increased incidence of abnormal results to the increased use of factor concentrates. His findings confirmed that *"All eight liver-biopsy specimens showed either hepatitis or cirrhosis. HBsAG was not detected in the biopsy tissue and no specific features were identified on electron microscopy."*[55]

85. Professor Preston's article, published in the Lancet in 1978, was a seminal piece of work which ought to have stirred both the medical profession and the government into action. His findings should have eliminated any remaining notion that NANB hepatitis was a benign and inconsequential infection, and there should have been a

---

[53] CBLA0000249 and WITN1055006 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'
[54] PRSE0002052_0041
[55] HSOC0001553

complete reassessment of the circumstances under which pooled plasma products could be used. Instead, Prof. Preston was described by various clinicians in their evidence to the Inquiry as an outlier or as being ahead of his time. On 25 July 2022 in her oral evidence, Professor Aileen Keel said of Prof. Preston when asked what she knew of his work:

> *"Only insofar as I think Eric Preston's view was perhaps different from the majority of the profession. There were individuals who fairly early on said this – well, anticipated that this disease [HCV] was going to be more serious than the majority of the profession, and I think Eric Preston was one of them but, as you say, I haven't seen the article."*[56]

85. In our submission, Professor Preston's work, which showed (a) a far higher incidence of post-transfusion abnormal liver function tests than had previously been recognised; and (b) that 100% of biopsies he had examined displayed signs of significant damage, ought to have caused a sea-change in the use of pooled plasma products. His findings were not simply conjecture or a working theory, but based on empirical findings and analysis.

86. As the 1970s gave way to the 1980s, the evidence from a number of clinicians who have appeared at the Inquiry is that there was a gradual and progressive appreciation of the severity of NANB hepatitis. In our submission, the evidence of the severity of the disease had been there to observe (and indeed was observed by those such as Professor Preston), but had been ignored or given insufficient credence. This much appears to have been accepted by Dr Boulton, whose evidence was that *"..Preston's findings in the late 70's should have alerted us more strongly"*. He also went on to explain that the profession's desire to prevent bleeds in young haemophiliacs outweighed consideration of the risks of viral hepatitis.[57]

87. In contrast, Professor Christine Lee was resolute in her refusal to accept that the severity of NANB hepatitis was known or ought to have been known by the end of the 1970s. When asked whether haematologists generally should have known by the end of the 1970s that NANB was a clinically significant condition which carried a significant risk of causing liver disease, she replied:

> *"I think, I suppose what I would say in answer to that is, in an ideal world, they should have known, but what I would say is that they did not know. I don't think*

[56] Transcript 25/07/2022 Pg 48, Lines 16-22
[57] WITN3456002_0218

any of us really knew for certain what was going on. I mean that was why the study was being done: to understand it."[58]

88. Prof. Lee went on to say that the severity of NANB hepatitis emerged gradually following on from and including her paper with Professor Kernoff, "*High Risk of non-A non-B hepatitis after a first exposure to volunteer or commercial factor concentrates…*" published in 1984.[59] In light of the clear evidence and chronology traversed above, we invite the Chair to dismiss that evidence. Indeed, Professor Kernoff himself, in a letter to Dr Brian Colvin on 27 April 1979,[60] wrote:

> *"…there are clinical and moral reasons for preferring the N.H.S. material. The clinical reason is the growing awareness of the probability that commercial concentrates have a higher risk of transmitting non-A non-B hepatitis than N.H.S. material.* ***This is a serious disease with long-term consequences****, which, as far as is known, is at present much less common in the U.K. than in those parts of the world – particularly the U.S.A. – where donor blood for commercial concentrates is collected. We may, therefore, be introducing diseases which are not yet endemic in the U.K. The moral reason for preferring N.H.S. material is that it seems inappropriate to many that maintenance of adequate standards of treatment to NHS patients should be dependent on blood obtained from paid donors in foreign countries."*
>
> [Emphasis added]

89. It is worth looking more closely at the Royal Free Hospital, and the work of Kernoff and Lee which underpinned the 1984 paper, not least because the Royal Free might be viewed as an accelerated microcosm of what was going on in many other haemophilia centres. Professor Lee told the Lyndsay Tribunal that the Royal Free went on using cryoprecipitate for longer than other centres or hospitals:

> *"…this was because Catherine [sic] Dormandy had this pioneering experience, I suppose, and was very enthusiastic about cryoprecipitate. She – I am afraid our centre is full of disasters. She, in 1978, died […] just at the point the new centre had been built. And two co-directors were put in: Dr Peter Kernoff and Dr. Tudnon [sic] And they were young doctors, and they came in in 1978 and very rapidly changed everybody to concentrate. There had been some people who had had concentrate before then, but I would think that up until 1978, the majority were probably still on cryoprecipitate."*[61]

[58] Transcript 20 October 2020, Pg 129, Lines 7-17
[59] HSOC0021398
[60] BART0002487
[61] LIND0000326_0005

90. In his oral evidence, Dr Tuddenham spoke of his first year as co-director at the Royal Free in 1978. He said of Peter Kernoff:

> *"He'd been doing some research in Oxford, and he went from there to work with a Dr Hymie Nossel in New York, and I believe it was there that he became most interested in the aspect of hepatitis and treatment with Factor VIII or Factor IX products. And so he was still working on those projects when he was appointed as the clinical NHS director, and I'd been appointed as Katherine's successor to a senior lectureship, so an academic appointment. So when he eventually came to join us, we were co-directors, which I thinks is – was a unique arrangement and I'm not aware of another such arrangement in the UK or elsewhere, but we – because we had parallel but distinct interests, that worked very well. That I could focus on the academic and research and he focused – also on research, but mainly on the clinical service."*[62]

91. Professor Tuddenham went on to describe the switch from cryoprecipitate to concentrates at the Royal Free as being for reasons of convenience, ease, and patient comfort.[63] That decision was clearly made notwithstanding Professor Tuddenham's awareness of the risks associated with blood products and particularly with increased donor exposure, as set out in his witness statement:

> *"When I first began to treat people with haemophilia at Liverpool Royal Infirmary in 1969, my senior registrar told me the tragic story of a patient with severe haemophilia A who had resisted being treated with cryoprecipitate because of fear of hepatitis. He had come in with severe bleeding and my colleague convinced him to have cryoprecipitate infusions. They controlled the bleeding, but the patient developed hepatitis and died. From that time, I was well aware of the potentially fatal consequences of treating haemophilia with blood products and that the risk increased with donor exposure."*[64]

92. When asked in oral evidence whether there was a realisation in 1978 that concentrates presented a higher risk of infection, he said:

> *"That was something that those who were using the concentrates had become aware of by 1978. Certainly, Peter Kernoff was already aware of that from the research he was doing with Dr Nossel in New York. So he came in with the knowledge of that and the intention to study it in detail."*[65]

93. Whatever Professor Tuddenham's reasons for agreeing (or at least acquiescing) to a switch from cryoprecipitate to concentrates, the evidence before the Inquiry is clear: Kernoff had developed a special interest in hepatitis in haemophiliacs, had moved to

[62] Transcript 22/10/2020, Page 12 Lines 1-16
[63] Transcript 22/10/2020, Pages 19-21
[64] WITN3435002_0014
[65] Transcript 22/10/2020, Page 22

the Royal Free where there existed a cohort of patients largely untreated with concentrates, and had then immediately transferred those patients' treatment from the comparatively safer cryoprecipitate favoured by Dormandy, to large pool concentrates, with the intention of studying the known higher risk of infection.

94. Indeed, this much is, in our submission, confirmed by contemporaneous evidence, including the 1984 paper itself, which recorded that "*quantitation of the risks of currently available products is of importance because it is by comparison with these risks that the efficacy of new products of possible reduced infectivity will be assessed*".[66]

95. Patients and long-standing campaigners have long averred that Kernoff came to the Royal Free to conduct hepatitis experiments on those with bleeding disorders by treating them with factor concentrates. The evidence before the Inquiry has confirmed, beyond doubt, the accuracy of this suspicion, irrespective of any other motive that Kernoff or Professor Tuddenham may have held. It was entirely unethical, immoral, and indeed criminal to expose patients who had previously been untreated (or who had received infrequent treatments) to blood products known to carry a significant risk of hepatitis for the undisclosed purpose of monitoring infectivity of products.

96. Although Professor Lee sought to suggest during oral evidence that the study had been carried out retrospectively rather than prospectively,[67] this assertion is not supported by the study itself, which under the heading "Patients and Methods" made clear that it was the intention to carry out a prospective study, and that this was the case for 31 of the 60 first exposures which were administered: the only reason that the balancing 29 first exposures were followed retrospectively was due to lack of patient accessibility.[68]

97. The product of Kernoff's experiments, the 1984 paper with Christine Lee and Howard Thomas, is of particular significance to one of our clients, Mark Stewart who, along with his brother and father, were enrolled into the study and as a result infected with HCV.[69] They were, respectively, the anonymised patients known as 11, 19 and 18.

98. Professor Thomas, in his oral evidence, at first attempted to claim that only severe haemophiliacs were admitted to the study and that consent was obtained from them.[70] After a short break, Professor Thomas reviewed the paper again and then

[66] HSOC0021398, page 2
[67] Transcript 20 October 2020, Page 129, Line 18 onwards for example
[68] HSOC0021398_0002
[69] HSOC0021398_0007
[70] Transcript 24/03/2021, Page 137 onward

resiled from that suggestion, giving evidence that patients who presented with bleeding or who required surgery were admitted to the study: no mention was made of the severity of the patients' conditions.[71]

99. Whatever the true admission requirements, Mark Stewart and his family were treated for the first time with concentrates during the study and were all infected with HCV. It was sheer negligence that they were not assigned to the cryoprecipitate group who showed no evidence of HCV infection amongst them. Mark has told the Inquiry that neither he, his brother, nor his father consented to participation in the study or had any awareness of the risks posed by the new treatment which was administered to them.

100. There are two remarkable features to Mark's family's situation: the first is that his father's bleeding disorder was so slight that he went undiagnosed until his sons' diagnoses as children. The idea that he required factor concentrates at the very point in the time of the study, having not had them during the first 30 years of his life, defies the credibility of any suggestion that the study was restricted to severe haemophiliacs, or those who had a significant need for the treatment.

101. The second remarkable feature is that, despite follow up reports on the study cohort being published in 1993 and 2000 by Professor Lee, none of the patients were told of their infections until much later. In Mark's case, not until 2007, some 26 years later. In short, those responsible for the study and its follow up watched silently as HCV progressed in those infected. By the time Mark and his family discovered that they had been infected, it was too late for his brother and father who had already succumbed to liver failure. The delay in Mark obtaining treatment has inevitably been detrimental to his own health. All three were deliberately exposed to HCV without any consent or informed consent having been obtained. As indicated above, these actions were not only immoral and unethical, but crimes. The seriousness of the actions of Professors Kernoff, Lee and Tuddenham cannot be understated.

102. In conclusion, it is plain from the evidence before the Inquiry that the danger of transfusion transmitted hepatitis was acknowledged from at least the 1940s. It is also clear that the risk of infection with transfusion transmitted hepatitis was known to increase as plasma pool sizes increased; indeed, this was so well appreciated that there was a limit of ten donors per plasma pool for all domestic pooled plasma products prior to 1973.

103. In spite of those two well recognised principles, large-pool plasma products began to receive product licences from 1973 onwards and, as we will deal with later in these

[71] Transcript 24/03/2021, Page 155

submissions, began to be used indiscriminately by haemophilia doctors with little regard for whether the benefit of administering them outweighed the increased hepatitis risk which those products posed.

104. Moreover, insufficient regard was had for synthetic treatment options which had become available, namely tranexamic acid and desmopressin or DDAVP. Whilst little sensible could be added to the evidence of Professor Ian Roberts[72] on the role that tranexamic acid can play in reducing the requirement for transfusion therapies, more can be said of DDAVP.

105. DDAVP was licensed for use in 1976 and was in relatively widespread use by 1978. In a letter to the Lancet, published on 1 October 1977, Professor Ingram noted of DDAVP that it was *"an important new drug in the management of mild haemophilia and von Willebrand's disease because it avoids the necessity of administering blood products."*[73]

106. DDAVP works, as we understand it, by triggering an adrenal response in the patient which effectively causes them to 'dump' whatever clotting factors exist within their body into the blood stream, thus temporarily increasing the availability of clotting factors within the blood stream which, in turn, cease the patient's bleeding.

107. DDAVP was not a panacea: it did not create clotting factor or introduce it, and merely enabled the utilisation of the clotting factors that existed within the patient's body. Repeated infusions could not be given in quick succession, as a patient's body needed, in effect, to recharge what clotting factors it could before a further dose of DDAVP would have any effect.

108. What DDAVP did represent, however, was an alternative, particularly for those with mild bleeding disorders who were able to produce enough factor within themselves to make the drug effective and should, in light of the risks posed and the relative benefit, never have received factor concentrates. However, as the Inquiry's evidence has established, DDAVP was under-utilised, with tragic consequences.

109. The underutilisation of DDAVP is of particular significance to our misdiagnosed clients, each of whom was thought to have a bleeding disorder of the mildest kind. They could and should have been treated with DDAVP, instead of large-pool factor concentrates, which were used as the first option without any consideration of the risk-benefit ratio, which clearly militated against their use. Nothing illustrates the reckless failure to

[72] Transcript 10/11/2022
[73] HHFT0001431_004

consider synthetic treatment options for those with (or believed to have) mild bleeding disorders as poignantly as the circumstances of the misdiagnosed.

2. SELF SUFFICIENCY

110. Following the Licensing Authority's grant of product licences for untreated, large-pool factor concentrates from 1973 onwards, all which followed represented either a failure to mitigate the damage done by the granting of those licences or, in some cases, an exacerbation of that damage.

111. One of the primary ways in which damage could have been mitigated would have been to achieve self-sufficiency in the production of plasma products. In his written statement,[74] Lord Owen attributed his views on self-sufficiency to his reading and review of Richard Titmuss' "*The Gift Relationship*".[75] On the question of self-sufficiency, Lord Owen quoted his written answer to Parliament on 22 January 1975, where he said:

> *"…I believe it is vitally important that the National Health Service should become self-sufficient as soon as practicable in the production of Factor VIII, including AHG concentrate. This will stop us being dependent on imports and make the best-known treatment more readily available to people suffering from haemophilia. I have therefore, authorised the allocation of special finance to boost our own production with the objective of becoming self-sufficient over the next few years."*[76]

112. Whilst this was an important milestone in the story of the UK's failure to achieve self-sufficiency in the production of plasma products, it was not the first time that an ambition to achieve self-sufficiency had been expressed, nor the first time that a goal to achieve it had been set.

113. Carol Grayson set out the following in her dissertation:

> *"A meeting of the Expert Group On The Treatment of Haemophilia 1973… was held at the UK Government's own offices and identified the increased risk of hepatitis once the number of donors in the plasma pool was increased, and also the importance of screening for hepatitis B in blood and blood products. Factor concentrates were noted to be "expensive" and deemed to be in "limited supply" and that "the limiting factors are the capacity for production (and the cost) of this preparation." The minutes of the meeting emphasised the importance of "reducing and as soon as possible ending purchase from foreign sources."*[77]

---

[74] WITN0663001_0002
[75] HSOC0019917
[76] LDOW0000032
[77] WITN1055006 – Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'

114. At the first meeting of the Department of Health and Social Security's Joint Steering Committee on Blood Products Production on 20 June 1973,[78] reference was made to an earlier ad-hoc meeting which took place on 20 March 1973[79], at which a paper on the UK's AHF requirements (authored by Rosemary Biggs) had been circulated.[80] At this 20 June meeting, having considered a note of the previous meeting, the committee resolved that the UK should aim to be self-sufficient in the production of factor concentrates by 1975. This was an endorsement of a recommendation made at the 20 March meeting that the UK should become self-sufficient as soon as possible. This commitment was maintained in Parliament in 1974 when, in response to a parliamentary question, it was said by (or on behalf of) the then Secretary of State for Social Services, Barbara Castle, that *"Our policy is to make the NHS self-sufficient in the production of Factor VIII as soon as practicable…"*.[81]

115. Thus, by the time Lord Owen made his statement in January 1975, the Department of Health and Social Security ("DHSS") had already set a target to achieve self-sufficiency, and missed it. As CTI's presentation on the history of the UK's policy on self-sufficiency demonstrated,[82] this woeful cycle of commitment and failure came to epitomise the story of self-sufficiency in the UK, which was not achieved because of underinvestment, mismanagement, and neglect.

116. When it comes to the issue of self-sufficiency, the key questions that the Inquiry must answer are: how would events have unfolded in a counterfactual world where self-sufficiency was achieved? What would have happened if the UK had achieved self-sufficiency by 1975, or even 1978?

117. The answer is complicated and requires an analysis of the different manufacturing processes employed domestically and abroad in two particular areas: (a) the source of plasma; and (b) the size of plasma pools.

Comparative sources of plasma

117. Blood in the UK is, and always has been, freely given by volunteer donors for altruistic purposes. That is not to say that blood collection policies in the UK are unimpeachable but, broadly speaking, a blood donor in the UK has given their blood in return for no benefit to themselves.

---

[78] PRSE0004359_0005
[79] WITN1055006 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'
[80] PRSE0004706
[81] DHSC0100006_051
[82] INQY0000333

118. As the majority of non-domestic factor concentrates administered in the UK came from the United States of America, these submissions focus on a comparison between the sources of the UK and US plasma from which concentrates were manufactured.

119. The wealth of evidence ventilated during the course of the Inquiry's investigation and hearings demonstrated that there are three significant issues with the manner in which plasma was procured in the US:

a) Plasma centres supplying plasma to the pharmaceutical companies manufacturing factor concentrates (often owned by those pharmaceutical companies) were generally situated in poor urban areas and predominantly attracted a type of donor referred to as being a 'Skid Row donor'. The etymology of the term 'Skid Row' refers to an area of Los Angeles which is home to the US' largest stable homeless population and where problems of destitution, alcoholism and drug abuse have been prevalent since the 1930s. This gives an idea of the nature of donor attracted to commercial plasma donation, and the point was graphically illustrated in the World In Action documentary aired on 1 and 8 December 1975[83] where Professor Zuckerman described the US plasma collection practices as "*an afront to human dignity*".

The dangers of Skid Row plasma were well appreciated in the United States as well as in the UK: Dr J Garrott Allen wrote in the 1966 Annals of Surgery *"The most practical method of reducing the hazard of serum hepatitis from blood is to stop using blood from prison and Skid Row donors"*.[84] Meanwhile, in the UK, Professor Zuckerman himself had highlighted the increased risk of commercial plasma in a 1968 letter to the BMJ, where he wrote:

> *"However, the authors of this lengthy paper have completely ignored the outstanding hazard of commercially supplied blood – namely, the risk of post-transfusion hepatitis. Thus while it is easy to dismiss emotional and altruistic motives for blood donation by healthy adults, it would be a mistake to accept that purchased blood would achieve the same criteria of probable low infectivity so far as the virus of hepatitis is concerned. Experience elsewhere indicates that the risk of post-transfusion hepatitis is very much greater when commercial sources are used…"*[85]

For the avoidance of any doubt, it is not the collection of blood and plasma from lower socio-economic groups which of itself necessarily presents a risk: it is the

[83] MDIA0000113 & MDIA0000114
[84] WITN1055006_0038 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'
[85] LDOW0000210_002

practice of paying those people for their plasma, which disincentivises them to refrain from donating blood or plasma when they know or suspect they are unfit to do so.

b) Plasma was actively sought from urban homosexual communities because their plasma was rich in HBV antibodies. The Inquiry has seen a wealth of evidence concerning the collection practices of plasmapheresis centres on this issue and, particularly, the advertisements placed in publications aimed at gay men.[86] This practice evolved primarily to assist with the development and manufacture of HBV tests and vaccines, but once the plasma had served its primary purpose, it could make its way into plasma pools used for the manufacture of factor concentrates. As was seen in a Cutter memo dated 30 August 1982,[87] following a request from the FDA to exclude known gay donor donations from plasma pools, Cutter summarised that Hyland had never incorporated their residual HBV plasma into their AHF plasma pools, but had sold it to Alpha who then incorporated it into their own AHF plasma pools. Cutter also confirmed that their anti-HBs plasma had been used in the manufacture of coagulation products. In the UK, by contrast, donors with a history of jaundice had long been excluded from blood donation, and HBV screening was introduced with the development of HBV tests.

c) Finally, the way in which blood and plasma were collected within US prisons created ripe conditions for the spread of hepatitis. For example, the prototype prison plasmapheresis centre at Parchman State Penitentiary began in 1968, with a centre staffed by 15 inmates (albeit, said to be under the supervision of a clinician),[88] which created the possibility for abuse of the few safeguards that had been put in place. "*Blood on their Hands*" the account of the US group litigation brought by haemophiliacs - authored by one of the attorneys and a journalist - sets out the circumstances of US prison plasmapheresis programs explicitly:

"The plasma center operated conveniently in a tin and cement-block structure on Angola's grounds. The center contained a holding cell, rest-rooms, a bleeding area, and storage freezers. Like others of its kind, it was operated not by the local hospital or Red Cross but by a for-profit company whose owner paid the state handsomely for the right to set up shop at the prison…

At Angola, inmates helped run many of the day to day operations. It wasn't unusual for a donor to arrive at the center and have fellow inmates assist as

[86] CGRA0000204_018 being but one example of Ms Grayson's large collection
[87] BAUM0000008
[88] CGRA0000884

someone recorded his name, swabbed his arm, stuck him with a needle, drew the blood, spun it in the centrifuge to separate out the watery plasma, and then reinfused the donor with his red blood cells…

Yes, Boudreaux and the other inmates loved what they called "the bleeding" and not just because it was considered a day's work. "Donate" wasn't precisely the right word for what they did. They were paid between five and fifteen dollars per donation, as much as thirty dollars per week if they were bled twice. That compared favourably to the four cents per hour they received for working in the fields, or twenty cents for working in the laundry. So there wasn't much a man wouldn't say or do to stay on the donor list…

Under federal safety regulations, donors were supposed to be excluded permanently if they had a history of hepatitis, and the potentially dangerous liver infection was common in prisons – places, after all, where high-risk activities like homosexual sex, intravenous drug use with shared needles, and homemade tattoos all were rampant. That at least was the rule…

If you slipped two cartons of cigarettes to a worker at the plasma centre, he might look the other way about tattoos or needle tracks, even if he knew you'd just had sex on the prison bus, or in the honeymoon suite better known as the plasma centre's bathroom. Some inmates even had sex in the holding cell as they waited to give their blood…

Indeed, in all the years that Boudreaux was a donor – until the last remnants of the nation's prison plasma machine were dismantled because by then nobody, not even those gullible foreigners who trusted everything American, wanted inmate blood anymore – he estimated that he'd seen a real, honest-to-God doctor at the plasma centre maybe once. The exam, he said, went something like this:

DOCTOR: How you doing? You hurting anywhere?

BOUDREAUX: No.

End of exam."[89]

The example set out above is far from exceptional or unique: a 1970 report set out the extraordinarily high hepatitis rates amongst those involved in the plasmapheresis program at prison farms in Arkansas,[90] citing prolific homosexual contact, needle sharing, and shortcomings of the plasmapheresis program itself as causes of the spread of hepatitis, all of which were set against the backdrop

[89] RLIT0001525
[90] ARCH0002278_002

of a hepatitis epidemic having occurred at the prison farms five years previously. The report also noted that the prison supplied Cutter with plasma, and that the practice was incredibly lucrative for the prison and Cutter alike. Peter Longstaff would ultimately be infected with products manufactured from plasma sourced from Arkansas prisons and his litigation in the United States was based on this fact with the aid of evidence uncovered by investigative journalist, Kelly Duda.[91]

Again, although prison obtained blood and plasma was an issue in the UK, the collection of the blood and blood products was undertaken by trained phlebotomists in the UK, in the same way as collection involving standard donors. It was wholly unacceptable – indeed, reckless – for inmates in the US to run a clinical operation that had major safety implications for thousands of patients across the rest of the country. There is some ambiguity as to when prison collections ceased completely in the UK, but it appears to be sometime in 1982 or 1983. In the US, prison plasma programmes were not abandoned entirely until 1992.

120. These three issues highlight the difference in risk between the source materials used to manufacture domestic and imported plasma products and are set out further in the statement of Paul Cunningham,[92] the award-winning Irish journalist who conducted a detailed investigation into the practices of US commercial fractionators. Much of Mr Cunningham's findings dovetail neatly with those of Carol Grayson's own investigations into pharmaceutical practices.

121. Whereas (with the exception of prison collections) the UK generally took a risk averse approach to blood and plasma donation, the US pharmaceutical approach can be characterised as abandoning any meaningful consideration of the risk posed by their source materials in favour of procuring as much of that source material as possible, and at the most competitive price.

122. The full effect of the commercial interests of the pharmaceutical companies overriding safety considerations is set out in Chapter 4 of Carol Grayson's award-winning[93]

[91] CGRA0000204_026
[92] WITN3531001
[93] Michael Young Prize 2009, sponsored by the Economic and Social Research Council (ESRC) and The Young Foundation. Conceived in honour of the founder of the ESRC, the late Lord Michael Young of Darlington, the prize aims to reward and encourage early career researchers whose work offers genuine new insights and is likely to have an impact beyond academia. Carol won £3,000 to help her communicate her research to the wider public

dissertation[94] which, in our submission, is essential reading, particularly on the topic of United States sourced plasma.

123. A final point to note on US source plasma is that not all of it came from the US: as early as 1972, Cutter notified the FDA's Bureau of Biologics about the procurement of 14,468 litres of plasma from Mexico and Haiti under the FDA's short supply provisions; Haiti would, of course, prove to be an epicentre for the AIDS pandemic once it emerged. Plasma would ultimately be sourced from all across Latin America.[95]

124. Although US source plasma clearly carried higher rates and risks of infection for the reasons set out above, the UK was not beyond reproach in its blood collection practices, nor in its recognition of, and regard to, risk. During CTI's presentation on the Wessex Regional Blood Transfusion Centre and Dr Huw Lloyd,[96] reference was made to a letter from Dr Smith to Dr Maycock dated 28 June 1972.[97] The letter set out the incidence of Australia Antigen positivity in the general Wessex population (9 of 42,675), the Forces population (3 of 2,401) and the prison population (6 of 1,676). A rough calculation shows that the incidence of HBV in the Forces population was almost six times higher than that in the general population, and that the incidence of HBV in the prison population was greater by a factor of almost 17. As the Chair noted:

> *"**Sir Brian Langstaff:** It makes the point beautifully, doesn't it, in terms of mathematics, because there are exactly the same number of antigen positive cases if you combine forces and prisons, combined, as there are in the general public. If you combine forces and prisons in total numbers, it's just over 4,000, which, again, multiply by 10, and you get to 40,000. So it's ten times as likely, on the basis of this, very rough, to find someone who is antigen positive in the forces or in prisons compared to the public."*

123. For the avoidance of doubt, the point was understood by Dr Smith and Dr Maycock at the time: Dr Smith stated within his letter that it looked to him as though "*we shall lose our prison population of donors eventually*". However, it was a further ten years before such donations ceased, despite this clear acknowledgment of risk.

124. The differences in UK and US source plasma can also be illustrated by the comparative rates of viral positivity amongst the UK's volunteer donor panel and the US' commercial donor panels.

---

[94] WITN1055006_0038 onwards - Grayson, C. (2007) 'Blood Flows Not Just Through Our V eins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?
[95] HSOC0019915_0249 to 0259
[96] Transcript 08/02/2022 Page 11-12
[97] NHBT0108717_001

125. One would expect higher rates of infection of any bloodborne virus in intravenous drug users, particularly those in lower socio-economic demographics who may be more prone to sharing needles. We know from the raft of evidence before the Inquiry that, whether through prison donors or Skid Row donors, commercial blood products were far more likely to contain plasma from people who had used intravenous drugs. It therefore follows that one can expect higher rates of infectivity from US produced commercial products.

126. Furthermore, urban centres in the US, such as New York and San Francisco, were the epicentre of the AIDS pandemic in the early to mid-1980s. These were also the locations from which the large pharmaceutical manufacturers sourced their plasma. Again, as a matter of logic, one would expect higher rates of HIV transmission from products manufactured with source plasma from these areas.

127. The force of these logical conclusions is echoed in statistics published in Haemophilia World Journal in December 1986:[98]

    a) Page 2: *"**HIV Antibody Prevalence United Kingdom***

    The AIDS Group of the United Kingdom Haemophilia Centre Directors reported an HIV seroprevalence of 59 percent in 1,268 patients with severe hemophilia A, 23 percent in 516 patients with moderate hemophilia A, and 9 percent in 220 patients with mild hemophilia A (British Medical Journal 293: 175, 19 July 1986). For patients with hemophilia B, the antibody prevalence was 8 percent of 174 severe, 4 percent of 115 moderate, and 3 percent of 29 mildly affected patients. Eleven (5 percent) of 215 patients with von Willebrand's disease were positive.

    The prevelance of antibody was greater in patients who had received commercial factor VIII concentrates with or without other blood products. In this study, and others, it was evident that some batches of NHS factor VIII, not heat-treated, contained HIV. The overall prevelance of antibody in patients with hemophilia B (6 percent), much lower than that in patients with hemophilia A (44 percent), was closer to the prevalence in patients treated with only NHS factor VIII (10 percent). All factor IX concentrate used in the United Kingdom is supplied by the NHS."

    b) Page 5: *"**Hemophilia-Associated AIDS United States***

    As of September 15, 1986, 238 cases of hemophilia-associated AIDS had been reported to the Centers for Disease Control (MMWR 35: 669, October 17, 1986).

[98] BART0000629

Of the 238 patients, 212 (89 percent) had hemophilia A; 16 (7 percent), hemophilia B; 7 (3 percent), von Willebrand's disease; two, and acquired inhibitor to factor VIII; and one, factor V deficiency. Seven of the patients were female. Thirteen patients were known to have had other risk factors for AIDS in addition to a hematologic disease.

The first AIDS patient with underlying coagulation disorders was diagnosed in 1981. Since then the number of hemophilia-associated AIDS cases has increased each year but not at an exponential rate. However, in 1985, 92 percent of persons with hemophilia A and 52 percent of those with hemophilia B in a U.S. cohort had antibodies to the human immunodeficiency virus suggesting exposure to the virus or to virus particles."

128. These statistics demonstrate the broad difference in infectivity between domestic concentrates and US commercial concentrates, especially when one considers that the number of new HIV infections should have declined dramatically as of 1986 as a result of the advent of heat treatment.

129. Taking Haemophilia A first: in the UK, haemophiliacs treated exclusively with NHS FVIII product suffered a rate of HIV infection of 10%, but the widespread use of commercial products meant that the total HIV infection rate was 44%. In the US, where we can expect that only commercial products were used, the infection rate was 92%. Therefore, the US Haemophilia A community suffered an infection rate over nine times higher than UK Haemophilia A sufferers treated exclusively with NHS product.

130. Turning next to Haemophilia B, we are told that UK patients were treated exclusively with NHS product and suffered a HIV infection rate of 6%. In contrast, again making the reasonable assumption that all US haemophilia B sufferers were treated with commercial product, they suffered an infection rate of 52%: an 8.7 fold increase.

131. Applying a broad-brush approach, we can therefore say that imported commercial products (FVIII or FIX) were roughly nine times more likely to cause HIV infection than NHS manufactured products.

132. Turning to Hepatitis C, the seroprevalence of HCV in the US and UK from 1973 (the point at which the first commercial product licences were granted in the UK) to 1986 is a statistic which we have found impossible to find or rationally calculate, not least because it was not until the late 1980s that a test for the condition was developed. It is not empirically sound to seek to draw conclusions from HCV prevalence figures in 1991: in our submission, had earlier testing been available, it would have demonstrated lower levels of prevalence in the UK donor population.

133. Nevertheless, Professor Contreras' evidence provided the best assistance we have been able to locate. In an article in Vox Sanguinis published in 1991,[99] Professor Contreras (with John Barbara) set out that:

> *"Data have rapidly accumulated on HCV seroprevalence in blood donor populations around the world. Generally the values range from 0.2% to 1% in Europe and North America, are about 1.5% in Japan and much higher in Africa."*

134. Again, these statistics must be treated with caution because, on our reading, they relate to the seroprevalence amongst whole blood donors; whilst that may amount to one and the same thing in the UK, in the US we know that the pharmaceutical run plasmapheresis centres attracted a different demographic of donor, which does not appear to have been included within these statistics. On the question of differences in UK and US statistics, Dr Contreras wrote as follows in her written statement:

> *"I believe the quoted figures of 22,500 cases of post-transfusion non-A, non-B Hepatitis (NANBH) each year in the UK to be inaccurate and exaggerated and most likely extrapolated from US data which had a much higher prevalence of NANBH than the UK (7-17% compared with 1-2.4%) In addition, the introduction in 1983 of self-exclusion of donors at risk of transmitting HIV and anti-HIV screening of blood donations in 1985, decreased the incidence of 1-2.4% of NANBH reported prior to 1983, even further to 0.26%.*
>
> *In the context of the UK studies at the time, the prevalence of NANBH was much lower. A study in the United Kingdom by my colleagues and myself at the NLBTC, before routine donation screening for anti-HCV started, showed that the incidence of post transfusion NANBH was 0.26% […] the paper is exhibited at NHBT0000042_095. 0.26% is significantly lower than the 3% quoted by Dr Gunson."*[100]

135. Professor Contreras went on, at paragraphs 348 and 349, to set out comparative statistics for HCV prevalence in the UK and US donor populations: as at 1991, and utilising a second generation ELISA test and confirmatory RIBA test, the prevalence in the UK donor population was found to be one tenth of that found in the USA. She set prevalence in the UK at 1 in 1,000 donations, compared with prevalence in the US at 1 in 100 donors. Again, it is unclear whether Professor Contreras is referring solely to whole blood donations, or whether she includes plasmapheresis donations within her figures.

136. However, Professor Contreras' estimates are broadly supported by those generated by the Statistics Expert Group: as at September 1991, the estimated prevalence of HCV

[99] NHBT0000030_054, paragraphs 319 -320
[100] WITN5711001_0080

amongst donors in the UK was said by the Group to be 0.066%, or 1 in 1,520 donations.[101]

137. Irrespective of the differences between infection rates, HCV was (and HIV became) endemic in both the US and UK populations which included, to varying degrees, their donor populations. As such, in the absence of screening tests, the most powerful method of mitigating the risk posed by donors was to exercise some degree of control over plasma pool sizes.

The Size of Plasma Pools

138. As set out earlier in these submissions, prior to 1973 the UK operated a general prohibition on plasma pools exceeding ten donations. Travenol's 1972 product licence application included a sample package insert drafted in June 1971 which contained the following warning:

> *"This concentrate is prepared from large pools of fresh human plasma. Such plasma may contain the causative agents of viral hepatitis. There is no known laboratory test to demonstrate either the presence or absence of such agents, and the concentrate has not been subjected to any treatment known to diminish the risk of transmission of hepatitis since such treatments greatly increase the loss of AHF activity during preparation. The concentrate should, therefore, be used when its expected effect is needed in spite of the unknown hepatitis risk associated with its use. Special consideration should be given to the use of this concentrate in newborns and infants where a higher morbidity and mortality may be associated with hepatitis."*[102]

139. The question is: what constitutes a large plasma pool? For reasons set out earlier in these submissions, in the UK, although not a matter which had been defined per se, the medical profession and government departments were operating on the basis that any plasma pool exceeding ten donations was large. However, around the time of the first product licences for commercial blood products in 1973, there were signs of a shifting attitude toward the risk of exposing haemophiliacs to large pool products. For example, in a letter to Dr Rosemary Biggs dated 2 January 1973 Dr Maycock wrote:

> *"…it was suggested to me the other day that as haemophiliacs are exposed to blood from so many donors in the course of their lives that there is little point in preparing concentrates from small pools, particularly since it is now possible to eliminate Au positive blood. I would be interested at some time to hear your reaction to this.*

[101] EXPG0000049_0059
[102] SHPL0000275_013_0005

The combination of Australia antigen negative blood plus small pools for preparing concentrate would tend to protect the haemophiliac from hepatitis to a greater extent than the combination of Australia antigen negative blood and large plasma pools" [103]

140. The above is clear: Dr Maycock had reservations at the prospect of treating haemophiliacs with large pool concentrates. The timing of his letter is particularly important when one recognises that he sat on the Sub-Committee on Biologicals of the Committee on the Safety of Medicines at the time,[104] and was presumably involved in the consideration of product licence applications for Hemofil and Kryobulin between November 1972 and April 1973.

141. While we have not been able to locate a response from Dr Biggs, both she and Dr Maycock were present at the 20 March 1973 DHSS Expert Group on the Treatment of Haemophilia meeting referred to earlier in these submissions, where it was noted, inter alia:

> *"Several significant advances in the treatment of haemophilia have taken place in recent years. Various therapeutic materials are now available. The most recently developed is human freeze-dried anti-haemophilic globulin concentrate which is expensive and may be in limited supply. Nevertheless, it appears to be the therapeutic agent of choice in the majority of cases, and would be used widely if available in larger quantities…*
>
> *In practice studies in several countries have shown that the incidence of hepatitis among* ***severely affected*** *patients who have been treated with the freeze-dried preparation is not very much higher than that at centres not using freeze-dried concentrate and this suggests that the development of hepatitis in these multitransfused patients may be dose related. It was agreed that the theoretically increased risk of acquiring hepatitis (which does not seem to be borne out in practice) should not be a deterrent to using the freeze-dried preparation and in any case this complication will decrease with universal screening of donors for hepatitis antigen"* [105]
>
> [Emphasis added]

142. There are a number of important points to take from these two paragraphs of the meeting note:

    a) Despite the reservations on the part of Dr Maycock to large pool plasma products (as per his 1973 letter to Dr Biggs), Dr Maycock is not recorded as

[103] OXUH0000671
[104] MHRA0018824_0013
[105] PRSE0004706

having objected at any point during the meeting. It is not clear whether his concerns had been allayed, or whether he failed to voice them;

b) In noting that concentrates should be considered the treatment of choice in the treatment of most cases of haemophilic bleeds, the group were relying upon studies conducted in severely affected haemophiliacs, whom it is reasonable to expect were being exposed to a smaller albeit still comparatively large number of donors when treated with products other than freeze-dried concentrates;

c) Severely affected haemophiliacs account for somewhere between a third and a half of all haemophilia cases.[106] By noting that freeze-dried concentrates were the treatment of choice in most cases, the group betrayed a neglect to consider mild haemophiliacs, for whom treatment with concentrates would have vastly increased their total donor exposure;

d) The meeting neglected to consider the increased risk to non-severely affected haemophiliacs, in spite of it being recorded that the incidence of hepatitis amongst haemophiliacs appears to be dose related;

e) No regard whatsoever was recorded as to the increased risk posed by unknown or unidentified pathogens.

143. Here then, at the point at which the first two product licences were granted for large pool, freeze-dried, factor concentrates, we have a recognition that there is an increased risk of transmitting hepatitis through those products. There was, nevertheless, an opinion that such products should form the treatment of choice in most cases of haemophilia, without any regard given to the differences in severity of a patient's haemophilia, and the risk that was therefore presented by the products. A 'one size fits all' approach was adopted, in circumstances where it could not be less appropriate. Nor was it appropriate for the Expert Group to dismiss the increased risk of hepatitis as "theoretical": all risks are inherently theoretical until they materialise, and require consideration, minimisation, and mitigation.

144. We have not been able to find any document which establishes the size of the donor pools used in the manufacture of Hemofil, but it appears that as at January 1974, Kryobulin 500 iu potency was manufactured from *"a plasma pool of 1000 AU/SH/HAA*

[106] Dr Tunstall suggested a roughly even split between severe and non-severe haemophilia cases in the oral evidence of the Bleeding Disorders Expert Group– Transcript 25/09/2019 page 36, line 15, whereas a 2019 report by Allison Inserro titled *"Prevalence of Haemophilia Worldwide is Triple That of Previous Estimates, New Study Says*" in the American Journal of Managed Care identified 1,125,000 men affected by haemophilia globally of whom, 418,000 were classed as severely affected this would give a rate of 37.2%. The report goes on to note that per 100,00 men globally, there were 17.1 cases of all severities of haemophilia A and 6 cases of severe haemophilia A – this would give a slightly lower rate of 35.1%.

negative donors." [107]In addition, a report from Dr Maycock dated 4 January 1973 noted that the pool sizes used for Kryobulin were smaller than those used in the preparation of Hemofil *"but a residual risk of ictero-genicity, after the exclusion of HBAg positive donors, will remain".*[108] It therefore seems most beyond doubt that Kryobulin was manufactured from plasma pools of 1,000 donations, and Hemofil from plasma pools exceeding 1,000 donations.

145. It is extremely difficult to trace the evolution of plasma pool sizes for the various commercially available products in the UK. Minutes of a meeting on 9 February 1982 of the National Institute for Biological Standards and Control ("NIBSC") gave a flavour of the pool sizes used commercially, where it was written:

> *"In the discussion that followed, it was pointed out that the pool sizes used by the commercial fractionators ranged from 1,000 to 10,000 litres of plasma, though sometimes the pools were combined at the cryoprecipitate stage, giving a possible maximum of 20,000 litres of plasma equivalent. The average volume collected from plasmapheresis donors was 680ml, with a minimum pool size of around 1500 donors and a maximum of around 30,000 donors. The maximum pool size used by the NHS producers is 1000kg of plasma, incorporating material from about 5,000 donors."*[109]

146. Therefore, by 1982, it is estimated that the largest commercial plasma pools were greater than those used by the NHS by a factor of six. The question of how large commercial plasma pools ultimately became is very difficult to answer, but in a hearing before the Subcommittee on Human Resources of the House of Representatives in the US on 31 July 1997, Dr Zoon of the FDA was questioned by the committee on pool sizes and said as follows:

> ***"Mr. Shays**. Why don't we start in--and I'll start with you, Dr. Zoon. What is the largest pool size that has been reported to the FDA?*
>
> ***Ms. Zoon**. The interim information that we have received to date, approximately 400,000, if one includes the pooling of intermediates.*
>
> ***Mr. Shays**. And was that a surprise to you, this size?*
>
> ***Ms. Zoon**. I would say that that was larger than I had anticipated.*
>
> ***Mr. Shays**. What would explain why the FDA wasn't able to tell us the pool size? Is it just something you hadn't focused in on or----*

[107] SHPL0000071_135
[108] MHRA0033322_057
[109] PRSE0003071

***Ms. Zoon**. We had information that is available to us from a variety of sources. One initially was some information that we had received from ABRA, which is the association--let me see if I can remember--the Association of Blood Resource--American Blood Resources Association. And those estimates that we were given at that time were approximately 10,000, I believe. However, further information upon receipt of the request FDA issued to nine of the major plasma pools, there is clarification also at the BPAC advisory committee that, in fact, these reflect the primary pool sizes and did not include estimates of the intermediate pooling or consideration of adding excipients to the purified or the final product.*

***Mr. Shays**. Is it fair to say the FDA was thinking that these pool sizes were more like 10,000 and then learned it was 60,000? But wouldn't it be pretty surprising for you all to have learned that it was 400,000 in one instance? I mean, was that a surprise?*

***Ms. Zoon**. I think the number of 400,000 was high. I think at the Blood Products Advisory Committee earlier, I believe a presentation was made by one of the blood associations, that it was potentially as high as 100,000. But 400,000, I think was higher than I would have predicted.*

***Mr. Shays**. Does that give the FDA a greater interest in trying to take a look at this issue?*

***Ms. Zoon.** Well, we are committed to putting a limit on pool size."*[110]

147. In the same proceedings, Dr Edward Gomperts of Baxter/Hyland also gave evidence and said, inter alia, in response to concerns about pool sizes:

> *"Baxter will no longer re-pool – or combine – small quantities of plasma from different production runs. We have done this in the past to conserve and ensure maximum utilization of these life-saving therapeutic proteins.*
>
> *We will substantially reduce repooling of small quantities of plasma material from various production runs that had been rejected because of problems with their packaging. Note that these materials were not rejected because of concerns over safety, but because of such things as misaligned labels. Nevertheless, this change is useful in that it will allow us to maintain the identity of the plasma pool and track donors more easily."* [111]

148. Mr Gomperts' evidence was extraordinary: in 1997, after the full scale and horror of haemophiliacs' infection with HIV and HCV had become apparent, Baxter were still employing practices which saw their plasma pools grow exponentially, and at a time

[110] https://www.govinfo.gov/content/pkg/CHRG-105hhrg45902/html/CHRG-105hhrg45902.htm
[111] CGRA0000365

when the potential threat of vCJD exposure to haemophiliacs was becoming apparent in the UK.

149. To be absolutely clear, Mr Gomperts' evidence to Congress was that Baxter would stop re-pooling plasma in order to reduce their plasma pool sizes; the obvious implication being that that had been their practice. If, for example, Baxter's standard pool size was 50,000 donations, and small quantities of rejected product from five previous production runs were added to the pool, that would take the total donor size of the plasma pool to 300,000. If a batch from the same production run had labels mis-fixed to the bottles, resulting in their rejection and subsequent re-pooling, the pool size would continue to grow exponentially, exposing patients to an unacceptably high number of donors and level of risk.

150. Turning to domestically produced products, a note from Dr Bidwell to Dr Maycock on 22 January 1975 noted that the two had agreed a move away from specifying pool sizes on product labels to using a generic label which simply read that the concentrate had been produced from *"not more than 500 donations"*.[112] Subsequently, on 3 December 1975, a further note from Dr Bidwell to Dr Maycock noted a limit on FVIII and FIX pools sizes of 1,000 donations.[113]

151. CTI's presentation on pool sizes at the Blood Products Laboratory contained a table showing the progression of increases in pool sizes from March 1976 through to February 1987 at BPL: the table shows an increase from pool sizes of 1,500 donations in 1976 through to 10,000 donations by 1987.[114] This was an increase from 500 donations in January 1975.[115] From this we can deduce that the UK initially utilised plasma pools which were comprised of at least half the number of donors used in commercial equivalents,[116] however, within the space of only a few years, BPL's plasma pools matched the volume of Immuno's in their Kryobulin product.

152. Although pool sizes in domestic product may have been comparable to the smallest plasma pools used by commercial manufacturers, and never approached the enormous levels which some of the commercial manufacturers reached, they still represented a significant and unacceptably high risk to pose to bleeding disorder patients, particularly when set against the knowledge of the risks of hepatitis transmission through the products which, as set out above, were known as early as 1946.

---

[112] CBLA0000253
[113] CBLA0000325
[114] INQY0000345_0005
[115] CBLA0000253
[116] Being 500 donations in the BPL product indicated at CBLA0000253 compared with the 1000 donations indicated for Kryobulin at SHPL0000071_135

Conclusion

154. Self-sufficiency was not a panacea which would have averted the totality of HCV and HIV infections in the UK's haemophilia community. However, had the UK become self-sufficient in blood products manufacture, the scale of the contaminated blood scandal would unquestionably have been mitigated.

155. For HIV infections, we have set out above that UK haemophiliacs could have expected to suffer a much lower HIV infection rate of 10% had they been treated exclusively with NHS concentrates, rather than the 44% rate actually suffered through the combined use of NHS and commercial product. Extrapolating these rates in round figures: for every 1,000 Haemophilia A sufferers in the UK, 100 would have been infected with HIV had the UK been self-sufficient in factor concentrates, as compared to the 440 per thousand who were infected through the UK's partial reliance on commercial product.

156. In relation to HIV, it is noteworthy that the statistics presented herein are based on the actual manufacturing processes employed by NHS fractionators. There was, in our submission, scope for the NHS product infection rate to have been reduced below 10% via concomitant interventions which could have been made but were not, for example, a reduction in plasma pool sizes, more discriminating use, and a greater utilisation of synthetic treatments and cryoprecipitate.

157. The Finnish experience gives an insight as to what might have been but for the introduction of concentrates; in a memo dated 13 September 1995, Dr Rejman (the Senior Medical Officer with responsibility for Haematology at the Department of Health between March 1989 and July 1997) wrote to Ms Ann Towner (of the Department's Corporate Affairs Operational Policy Unit) in the following terms:

> *"…During the conference in Helsinki, I spoke to Professor Leikola, who is head of the Finnish Blood Transfusion Service about the incidence of HIV and hepatitis C in Finland in recipients of blood and blood products.*
>
> *He stated that there are known to be 2 HIV positive haemophiliacs in Finland and 6 HIV positive blood recipients in Finland. The number of haemophiliacs positive for HCV is probably between 50-60%. The population of Finland is 5 million compared to 56 million for the UK.*
>
> *The reason for the low incidence of HIV in Finnish haemophiliacs, is that prior to 1985 most of the patients were being given cryoprecipitate. Since this involved pooling approximately 20-30 individual donations of cryoprecipitate on any occasion, then even in severe haemophiliacs who might need to be treated 2 or 3 times each week, the overall number of donations to which a haemophiliac was*

exposed was likely to be less than in the case of Factor VIII concentrate. As you know, Factor VIII is made from 10,000-20,000 donations.

Additionally, Finland did not import Factor VIII concentrate from paid donors in the US, where HIV incidence was much higher. In the UK we did import from the US. Most UK haemophiliacs received both commercial and NHS Factor VIII concentrate, and so it is difficult to be 100% sure whether the amount of HIV positivity would have been the same in the UK even if we had not imported from the US…"[117]

158. The mitigating effect of self-sufficiency on HCV infection rates is more difficult to measure. Mitigation would have been reliant on other interventions, again including plasma pool sizes. The point is made perfectly by the Kernoff/Lee paper titled "*High Risk of non-A non-B Hepatitis after a first exposure to volunteer or commercial factor concentrates*",[118] which established that the NANBH attack rate after a first exposure to pooled plasma products (whether volunteer donor or commercial) approached 100%. The article noted that this is hardly surprising given that all clotting factor products are usually prepared from pools of at least 1,500 donor plasmas. Clearly, that situation would only deteriorate with the upward trajectory of NHS plasma pool sizes from 1974 onwards.

159. By the time of Kernoff's study, BPL manufactured concentrates were derived from plasma pools of 7,500 donations,[119] but that had not always been so: we have discussed elsewhere in this section Dr Bidwell and Dr Maycock's agreement which, prior to 1975, limited pool sizes to not more than 500 donations. In our submission, the ever-increasing size of NHS plasma pools rendered them as dangerous (in terms of HCV transmission) as commercial concentrates. Had NHS plasma pools remained in the low 100s, there was every probability that the scale of HCV infection amongst UK haemophiliacs would have been diminished significantly.

160. Finally, it must be noted that the benefit of smaller plasma pools in terms of preventing or reducing infection is two-fold. First, the smaller the pool (in terms of donor numbers), the lower the probability of incorporating an infected donation. Secondly, a smaller plasma pool results in fewer treatments which emerge from that pool, meaning that in the event of an infected donation being incorporated, there would have been fewer end products which were capable of infecting patients.

---

[117] DHSC0006795_011

[118] HSOC0021398

[119] INQY0000345_0006

3. THE LICENSING REGIME AND ITS JUSTICIABILITY

The History of Medicines Licensing

160. Licensing of medicine in the UK emerged following the Thalidomide tragedy. Thalidomide was withdrawn from the UK market on 2 December 1961, having been used as a treatment for morning sickness in pregnant women for five years. In May 1962, the UK government issued a formal warning in respect of the side effects of Thalidomide when used by pregnant women. In a House of Commons debate on 8 June 1962, the Parliamentary Secretary to the Ministry of Health told the House that the law relating to the control of medicines was being examined by government, and that "*New legislation would be needed to require the safety testing or scrutiny of all new drugs… before they were introduced*".[120]

161. The Minister of Health sought advice from his Standing Medical Advisory Committee. In August 1962 that Committee, together with the Standing Medical Advisory Committee to the Scottish Secretary of State for Health, established a Joint Sub-Committee on the Safety of Drugs to examine the issue in more detail. The Joint Sub-Committee was chaired by Lord Cohen of Birkenhead (and is hereafter referred to as "the Cohen Committee"), to examine the measures needed:

> *"(i) to secure adequate pharmacological and safety testing and clinical trials of new drugs before their release for general use;*
>
> *(ii) to secure early detection of adverse effects arising after their release for general use; and*
>
> *(iii) to keep doctors informed of the experience of such drugs in clinical practice".*[121]

162. In its final report, the Cohen Committee recommended that the Health Ministers appoint an independent expert Committee on the Safety of Drugs ("CSD"). On 4 April 1963, the day that the Cohen Committee's final report was presented to the House of Commons, the then Minister of Health (Enoch Powell) described the role of the CSD as follows:

> *"…with the assistance of three subcommittees, [the CSD] would advise, in the light of current medical and scientific knowledge, on the adequacy of toxicity*

[120] https://hansard.parliament.uk/Commons/1962-06-08/debates/291d4bde-dbe1-4c73-9b2e-1ba61b168c2c/NewDrugs(Testing)?highlight=testing%20new%20drugs#contribution-83c0f137-88b0-42d6-a864-143b099689da

[121] https://hansard.parliament.uk/lords/1962-11-06/debates/34dd9c40-9e17-44bf-9f0a-3791de55afb0/TestingOfNewDrugs

tests of a new drug before it is submitted to clinical trial and on the adequacy of clinical trials before it is released for general use, and would arrange for the collection of data about any adverse effects found subsequently".[122]

163. In the same debate, the Minister indicated that the Government accepted the Cohen Committee's recommendations, and that the "*details of the scheme will be worked out in full consultation with the industry".* Notably, the system proposed by the Cohen Committee was voluntary, and manufacturers were not obliged to submit data to the CSD for the purposes of its advice to the Ministry of Health.[123] It was noted in the House of Commons debate that two members of the Cohen Committee had signed a note of dissent, arguing that a voluntary scheme would not be sufficient, and that the law relating to drugs required more comprehensive amendment. In response to this, the Minister stated that the Government had "*in hand a review of the law relating to drugs generally, with a view to legislation. This review will be carried forward; but the preparation of legislation on this large and complex subject is bound to take time*."

164. The CSD was established in June 1963, chaired by Sir Derrick Dunlop (and, therefore, was often referred to as the Dunlop Committee). There were three sub-committees of the CSD: toxicity; clinical trials and therapeutic efficacy; and adverse reactions. The CSD's terms of reference were:

> *"1. To invite from the manufacturer or other person developing or proposing to market a drug in the United Kingdom any reports they may think fit on the toxicity tests carried out on it; to consider whether any further tests should be made, and whether the drug should be submitted to clinical trials; and to convey their advice to those who submitted reports.*
>
> *2. To obtain reports of clinical trials of drugs submitted thereto.*
>
> *3. Taking into account the safety and efficacy of each drug and the purposes for which it is to be used, to consider whether it may be released for marketing, with or without precautions or restrictions on its use; and to convey their advice to those who submitted reports.*
>
> *4. To give manufacturers and others concerned any general advice they may think fit on the matters referred to in paragraphs 1-3.*
>
> *5. To assemble and assess reports about adverse effects of drugs in use and prepare information thereon which may be brought to the notice of doctors and others concerned.*

---

[122] https://hansard.parliament.uk/Commons/1963-04-04/debates/97966bf7-502d-4ad9-a6c9-0b613c63f30a/Drugs(Sub-CommitteeSReport)

[123] The CSD's terms of reference stated (at 1) that the committee would " *invite*" manufacturers to provide "*any reports they may think fit*": https://wellcomecollection.org/works/fd896fvw/items?canvas=59

6. To advise the appointing Ministers on any of the above matters."[124]

165. In the preface to its annual report for 1964, the CSD noted the latter half of 1963 had been spent on "preparatory work" and that 1964 was the first year that the committee had focused on its substantive responsibilities, which it defined as "*to advise whether a new drug should be submitted for clinical trial; to advise whether a drug should be released for marketing; and to study adverse reactions to drugs already in use*".[125] The 1964 report also set out the system that the CSD implemented for notification of adverse reactions, known as "yellow cards". It was noted that up to 100 yellow card reports were received each week.[126]

166. Professor Bill Inman,[127] who was appointed the Senior Medical Officer and later the Principal Medical Officer to the CSD, was responsible for developing the yellow card system. In his book '*Don't Tell the Patient: Behind the Drug Safety Net*' (published in 2002), he described the importance of monitoring adverse reactions:

> *"…the small number of patients that can be assembled for most pre-marketing clinical trials will only reveal events that are so common that the hazard they present makes it unlikely that the drug company will proceed with a marketing licence application. Less common but nevertheless very important effects will often not be detected. For example, except by chance, a trial on one hundred patients could not be expected to detect a harmful reaction that only affected one patient in a thousand…"*

Thus, any comprehensive system for safe medicines necessitated a sufficient degree of monitoring of patient safety beyond the point of release to market. Clearly, that work cannot be carried out solely by a licensing body, and requires sufficient integration and co-operation as between regulators and clinicians.

167. Later in his career, Professor Inman called into question the validity of the manufacturers' post-market monitoring that had underpinned the CSD's work. Notably, in 1980 he went on to establish the Drug Surveillance Research Unit in Southampton, which monitored side effects independently of manufacturers, and also sought to test (and, if necessary, confirm) the hypotheses generated by the yellow card system.[128]

---

[124] https://wellcomecollection.org/works/fd896fvw/items?canvas=59
[125] At page 55 of https://wellcomecollection.org/works/fd896fvw/items?canvas=55
[126] Page 57 of https://wellcomecollection.org/works/fd896fvw/items?canvas=57
[127] Michael O'Donnell wrote, after reading Professor Inman's autobiography 'Feeling B etter Doctor?' (2006), the following in book's foreword: *"I suspect you will agree that the author has earned the accolade of one of those beastly people who are always bringing up awkward subjects and making respectable people feel uncomfortable".*
[128] https://www.theguardian.com/society/2005/nov/04/health.medicineandhealth

168. In a 1995 interview on the CSD and the early days of the Medicines Act 1968, Professor Inman said the following of the chair of the adverse reactions sub-committee, Professor Leslie John Witts: "*He was a specialist in blood dyscrasias and I think that was felt to be one of the target areas we might get involved in*".[129] There is no information on Relativity to shed light on why that was the case, but in our submission this demonstrated the growing importance and understanding in the 1960s (building upon earlier knowledge, as already outlined in these submissions) of the role of blood, blood products, and the way in which medicine and blood interacted.

An Overview of the Product Licensing Regime in the Medicine Act 1968

169. Following the introduction of the CSD, there were repeated calls for comprehensive legislation on the safety and approval of modern medicine, and for the CSD to be placed on a statutory footing to make it a mandatory process for pharmaceutical manufacturers. On the question of voluntary or mandatory co-operation by industry, during a House of Lords debate on 3 March 1964 Lord Cohen, the architect of the CSD, noted that:

> *"the pharmaceutical manufacturers, as represented by the Association of British Pharmaceutical industry and the Proprietary Association of Great Britain, who together are responsible for about 90 per cent. of all the drugs which are manufactured and marketed in this country, have agreed that they will accept the advice of the Dunlop Committee and will act upon it. That leaves 5 to 10 per cent. of drugs produced by the "black sheep" of the pharmaceutical industry, and of course it takes no account of the drugs which are imported, say, from North America or from Europe. That is why the Safety of Drugs Committee said there must be legislation, that legislation on the whole subject is urgently required, and they emphasised that its proposed interim measures should not be regarded as a justification for delaying this essential measure."*

Lord Cohen went on to note that there was an inter-departmental working party considering this and other, related matters.[130]

170. On 2 February 1968, the Medicines Bill had its first reading in Parliament, following the publication of a White Paper (Command Paper 3395) on the Bill in September 1967. The Bill also followed the 1967 report of the Sainsbury Committee, which had investigated the relationship between the NHS and the pharmaceutical industry. That

[129] https://wellcomecollection.org/works/bgj5xxbq at 4:20and see the transcript at p.2 of www.histmodbiomed.org/sites/default/files/Inman%20Professor%20Bill_-%20The%20Committee%20on%20the%20Safety%20of%20Drugs%20a%20personal%20account.pdf

[130] https://hansard.parliament.uk/Lords/1964-03-03/debates/1c5da8fc-134e-472c-b332-bb811eeea318/TestingOfNewDrugs?highlight=safety%20drugs#main-content

committee made a number of recommendations on the pricing and profits of pharmaceutical companies, but also recommended that the quality control and testing of medicines should be undertaken by an independent, official body.

171. The Bill's second reading took place on 15 February 1968. The then Minister of Health, Kenneth Robinson, said the following of the CSD and the intention to place the CSD on a statutory footing via the Bill:

> *"The voluntary system has had the full support of the pharmaceutical industry and the medical and pharmaceutical professions, but the Government is convinced that the provision of statutory backing for the safeguards should not be further delayed. Indeed the Committee on Safety of Drugs itself in its annual report for 1965 said that whilst the Committee had not been hampered by lack of statutory powers, thanks to the co-operation of manufacturers, it believed that the arrangements should be given permanence within the framework of legislation. It welcomed an assurance that I gave in Parliament that my aim would be to maintain under future legislation the scope for flexibility and the exercise of professional responsibility which the Committee's experience had shown to be necessary."* [131]

172. Similarly, in a second reading of the Bill in the House of Lords on 4 July 1968, Lord Kennet said:

> *"For four years we have had the Safety of Drugs Committee under Sir Derrick Dunlop, and on the animal side we have had the Voluntary Veterinary Products Safety Precautions Scheme. This Bill, which follows a White Paper published late last year, now moves the whole thing over on to a statutory basis. I do not think anybody has doubted that it would be right to go statutory as soon as we had enough experience of the voluntary arrangements to know we were on the right track. The voluntary arrangements have worked well, but we cannot leave it at that, for two particular reasons. First, although the great bulk of the British pharmaceutical industry has conducted itself responsibly and has been amenable to this voluntary system of control, yet there have been one or two fringe firms which make the Government feel that it would be safer to have a Statute up their sleeves; and secondly, we are among the few technically advanced countries in the world which have no statutory controls, and this poses certain problems in talking to other countries about this whole field of medical safety."*[132]

173. As to how the new system would assess medicinal products, the Minister of Health Kenneth Robinson also said the following of the Bill in the second House of Commons reading:

---

[131] https://hansard.parliament.uk/Commons/1968-02-15/debates/88cbc856-a6a2-46d4-ab9e-c7ef7c9e7a02/MedicinesBill

[132] https://hansard.parliament.uk/Lords/1968-07-04/debates/ea092605-066d-4bae-a00f-562d417b1d17/MedicinesBill

"It is not intended that efficacy by comparison with other products intended for the same purpose should be a factor affecting the issue of a licence, but efficacy must be taken into account in relation to the product's toxicity and to the question of whether the evidence supports the purposes for which the product is intended. Thus, a product which might carry with it the risk of serious side effects might nevertheless be licensed if it were a very valuable drug for treating a disease which carried a higher risk to the patient. But a product which might be very effective in treating a relatively trivial condition could be refused a licence, if the side effects were disproportionately serious."[133]

We return to this balancing act in our analysis of the mechanics of the legislation below, but this introductory speech demonstrates that the legislation was intended to place an evidence-based understanding of 'toxicity versus efficacy' or, put another way, the risk-benefit ratio, at the heart of the licensing system. That, as has and will be seen, was not an approach which characterised the treatment of haemophilia patients.

174. The Bill was given royal assent on 25 October 1968, and on the same date the majority of its provisions came into force. As the first comprehensive piece of post-war legislation on the topic, the Medicines Act 1968 (hereafter referred to as 'the 1968 Act') was lengthy and complex. Specific sections of the 1968 Act are examined in further detail below but, by way of overview of its product licensing provisions, the 1968 Act created the following:

a) A Medicines Commission, which would be supported by expert committees to advise the Health Ministers in England, Scotland, and Wales (both in their capacity as Licensing Authority, and also on broader matters relating to the 1968 Act and to medicinal products);

b) A scheme of product licences (to be held before a particular product was marketed, imported, or distributed) and manufacturer and wholesale dealer's licences (to be held generally, rather than in relation to particular products);

c) A system for applications to the Licensing Authority, including how such applications should be made and determined;

d) So-called 'licences of right', through which existing medicinal products were to be brought into the licensing scheme;

e) A system for the suspension, revocation, or variation of licenses; and

[133] https://hansard.parliament.uk/Commons/1968-02-15/debates/88cbc856-a6a2-46d4-ab9e-c7ef7c9e7a02/MedicinesBill

f) Criminal offences for the production and distribution of medicines other than in accordance with the provisions of the 1968 Act.

175. The 1968 Act remained in force throughout the time period of interest to the Inquiry, and remained mostly unchanged until the early 2000s. Where amendments are of relevance to the Inquiry's work, those amendments are set out within these submissions.

The Medicine Act 1968: The Medicines Commission and the s.4 Committees

176. Section 2 of the 1968 Act established the Medicines Commission ("the Commission"), which was to consist of not less than eight members (s.2(2)), to be appointed by Ministers after consultation with "*such organisations as they consider appropriate*". Section 2(3) of the 1968 Act stipulated that the Commission should include at least one person who, in the view of the Ministers, had "*wide and recent experience of, and to have shown capacity in*" each of the following areas: the practice of medicine; the practice of veterinary medicine; the practice of pharmacy; chemistry, other than pharmaceutical chemistry; and the pharmaceutical industry.

177. The statutory function of the Commission was to give Ministers "*advice on matters relating to the execution of this Act or the exercise of any power conferred by it, or otherwise relating to medicinal products, where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question, to do so*" (s.3(1)). In addition to this broad advisory function, s.3(2) of the Act specified the following additional functions of the Commission:

a) To make recommendations as to the number of expert committees required under the 1968 Act, their functions, and any members of those committees;

b) To review those committees from time to time and to make any recommendations considered to be appropriate;

c) To advise the Licensing Authority in accordance with the provisions of Part II of the 1968 Act (set out below), or in circumstances where the Licensing Authority was not required by virtue of the 1968 Act to consult with the Commission but elected to do so; and

d) To undertake the functions of the committees insofar as they had not been assigned to a committee.

178. Section 4 of the Act gave the Ministers the power to establish committees of the Commission as considered appropriate, "*for any purpose, or combination of purposes,*

connected with the execution of this Act or the exercise of any power conferred by it" having regard to any recommendations made by the Commission. In particular, and without prejudice to that general power, s.4(3) specified that committees could be established for either or both of the following purposes:

> *"(a) giving advice with respect to safety, quality or efficacy, or with respect to all or any two of those matters;*
>
> *(b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given."*

179. Both the Committee on Safety of Medicines ("CSM") and the Committee on the Review of Medicines ("CRM") were established under orders made under s.4 of the Act (and, accordingly, will be referred to collectively as the "s.4 Committees"):

    a) The Medicines (Committee on Safety of Medicines) Order 1970, which was commenced on 7 September 1970 and established for two purposes, which broadly reflected the language of s.4 of the 1968 Act (above) insofar as it related to human medicine:

    > *"(a) giving advice with respect to safety, quality and efficacy, in relation to human use, of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Act is applicable; and*
    >
    > *(b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given"*

    b) The Medicines (Committee on the Review of Medicines) Order 1975, which commenced on 7 July 1975 and was charged with reviewing medicines which were already on the market (and therefore likely to receive, if applied for, licences of right):

    > *"…there shall be established a committee to be called the Committee on the Review of Medicines for the purpose of considering and giving advice with respect to the safety, quality and efficacy, in relation to human use, of any substance or article to which any provision of the Act is applicable."*

180. In turn, the CSM created a number of sub-committees on: toxicity, clinical trials and therapeutic efficacy; chemistry, pharmacy and standards; standards of herbal products; adverse reactions; anti-microbial substances; and biologicals. The biologicals sub-committee (referred to within these submissions as the CSM(B)) has been the focus of the Inquiry's work. In turn, the CRM created the following sub-committees:

anti-rheumatic agents; analgesics; psychotropics; immunologicals. The members of the CSM(B) were members of the CRM immunologicals sub-committee.[134]

181. The Commission and its Committees were governed by Schedule 1 to the 1968 Act, and by the regulations made under that schedule, the Medicines Commission and Committees Regulations 1970. By and large, Schedule 1 and the 1970 Regulations are not relevant to the work of the Inquiry, save for paragraph 7 of Schedule 1 which stipulates that "*Neither the Commission nor any such committee or sub-committee shall be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown*".

182. As far as we are aware, there are no materials on Relativity which capture the advice given by the Commission to the Ministers in relation to the need for, or the setting up of, the Committees and the Sub-Committees.

183. By virtue of s.5 of the 1968 Act, the Commission and the s.4 Committees were directed to provide annual reports on their functions to the Ministers (and, in relation to the s.4 Committees, to the Commission). Only a handful of those reports can be found on Relativity, all of which were authored by the CSM and contained, inter alia: a summary of key issues considered by the CSM; action taken by the CSM; adverse reaction reporting and the 'yellow card' scheme; discussions on particular medicines; discussion of national and international events; and a summary of licences granted.[135]

184. At the time of the 1968 Act's passage through Parliament, there were calls to make the Commission an independent body with responsibility for licensing. However, it was the Government's view that Ministers should retain the ultimate decision-making powers under the 1968 Act, in order to remain accountable to Parliament. In the Bill's second reading, it was said by the Health Minister that:

> *"The Commission will have complete professional independence, and will be expected to offer the Ministers advice which has regard solely to the professional and technical considerations concerned. What I might call departmental considerations are not to colour its advice at all... The same considerations apply to the appointment of the special committees provided for in Clause 4."*[136]

185. Professor Inman, in the same 1995 interview about the CSD and its successor system under the 1968 Act, was asked what he considered to be the main lessons to be learned from that time. On independence and transparency, he said:

---

[134] {MHRA0004773/8}, paragraph 17

[135] We have identified the following reports: 1972 {MHRA0018824}; 1979 {MHRA0018816}; 1987 {MHRA0012978}; 1988 {MHRA0014826}; 1990 {WITN6406003}; 2002 {MHRA0009363}

[136] https://hansard.parliament.uk/Commons/1968-02-15/debates/88cbc856-a6a2-46d4-ab9e-c7ef7c9e7a02/MedicinesBill

"As far as the independence is concerned, I always felt that it was a great mistake to expect doctors and other scientists working in the Department to be loyal to a scientifically independent committee on one hand and to the minister of the day on the other hand. There may be perfectly good reasons why ministerial decisions clash apparently with the scientific decisions, and if they were separate these problems wouldn't arise. I think that the doctors now working at the Department find themselves more as medical advocates rather than being free to communicate scientifically." [137]

186. In addition to the sub-committees, the s.4 Committees were assisted by the work of the NIBSC. Senior NIBSC members were members of the CSM(B). Lord Fowler described the purpose of the NIBSC as follows:

"…to secure high standards of quality, safety, efficacy and consistency of biological substances used in medicines. In fulfilling this role it devised standards for the quality, purity and potency of biological substances, tested batches of biological products on behalf of DHSS, carried out research and advised a number of bodies, including Medicines Division of DHSS and its Section 4 committees. NIBSC staff were members of the BSC/CSM."[138]

187. As explained by Sir Joseph Smith, director of the NIBSC between 1976 and 1985, the NIBSC had five scientific divisions, one of which was blood products.[139] The blood product division had three workstreams: standardisation, control and research. The control workstream advised the CSM and Licensing Authority on applications for product licences, and also assisted in the review of products which were subject to a batch release order, discussed below.[140]

The Medicine Act 1968: Overview of the Licensing Regime

188. The 1968 Act introduced the following system of restrictions on the distribution of medicinal products[141] covered by the Act:

a) Section 7: a product licence was required for the sale, supply, export, import, procurement of sale, or procurement of manufacture or assembly of any medicinal product;

---

[137] https://wellcomecollection.org/works/bgj5xxbq and see the transcript at www.histmodbiomed.org/sites/default/files/Inman%20Professor%20Bill_-%20The%20Committee%20on%20the%20Safety%20of%20Drugs%20a%20personal%20account.pdf

[138] [WITN0771001_37] paragraph 3.6(12)

[139] Until October 1976 the division was known as the Division of Hormones and Blood Products, but subsequently split into two separate divisions

[140] [WITN5281001_008] paragraphs 2.9-2.15

[141] Medicinal products are defined in s.130 of the Medicines Act 1968. It is not controversial that that definition encompasses the blood products which have been examined by the Inquiry

b) Section 8: a manufacturer's licence was required to manufacture or assemble any medicinal product. Although a manufacturer's licence gave a manufacturer the right to manufacture generally (i.e. there was no need for a manufacturer to obtain a manufacturer's licence in respect of each product), by virtue of s.23 the manufacturer could not manufacture products for sale or supply to another unless the manufacturer also held the product licence, or unless the product had been manufactured at the order of the person who was the product licence holder;

c) Section 8(3): wholesale distribution of medicinal products required a wholesale dealer's licence;

d) Sections 9-11: exemptions for medical professionals including doctors, dentists, vets, pharmacists, registered nurses and midwives, who created or supplied medicinal products in the course of their treatment of patients;

e) Section 13: an exemption on imports where imported by a person for treatment of him/herself and household, or to the order of a doctor or dentist for administration to a particular patient;

f) Section 12: exemptions for herbal remedies; and

g) Section 14: exemptions for imported medicinal products which were to be exported in the same form as they were imported.

189. Section 15 of the Act gave Ministers the power to make further exemptions by order. Several orders were made under this section such as, for example, an exemption for clinical trials, which supplemented the exemptions in the Act in relation to clinical trials. In summary, the regime laid down in the Act required that products used in clinical trials had either a product licence authorising the clinical trial in question, or a clinical trial certificate.

190. The 1968 Act prescribed a number of criminal offences for breaches of the licensing regime.

The Statutory Framework for the Grant or Refusal of Licences

191. As alluded to above, the Licensing Authority ("LA") for the 1968 Act consisted of the British Health and Agricultural Ministers. Any function conferred on the LA could be taken by one Minister alone, or by a combination of Ministers: see s.6 read with s.1 of the 1968 Act. In practice, however, the Ministers typically delegated their licensing

functions to officials within the Medicines Division of the Department of Health, which subsequently became the Medicines Control Agency ("MCA") in 1989.[142]

192. The LA enjoyed a wide discretion when considering applications for licences under the 1968 Act. Section 19 stipulated factors that the LA "*shall in particular take into consideration*" when considering an application for a product licence, namely:

> *"(a) the safety of medicinal products of each description to which the application relates;*
>
> *(b) the efficacy of medicinal products of each such description for the purposes for which the products are proposed to be administered; and*
>
> *(c) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality."*

193. On the question of a medicinal product's efficacy, s.19(2) directed that the LA "*shall leave out of account any question whether medicinal products of another description would or might be equally or more efficacious for that purpose*", but also clarified that that provision did not require the LA to leave out of account "*any question whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose*", i.e. the LA was to discount any argument that other medicines were equally or more efficacious, unless it could be shown that equally or more efficacious medicines might be safer for the particular purpose or administration being considered, in which case that would be relevant for the LA to consider. In addition, s.20(2) was unequivocal that a licence should not be refused "*on any grounds relating to the price of any product*", and that the LA should not insert provisions into a product licence relating to pricing.

194. Where the LA was considering an application for a product licence relating to medicinal products which had been imported or were due to be imported, s.19(3) stipulated that the LA should also take into consideration in particular "*the methods, standards and conditions of manufacture of those products*". The same subsection also gave the LA the power to require an applicant to provide: an undertaking by the manufacturer to permit the premises of manufacture to be inspected; an undertaking by the manufacture to comply with conditions; and/or a declaration by the manufacturer that the law of the country in which the products were manufactured had been, or would be, complied with. There was an implicit recognition in this section of the Act that standards around the world could vary, and may have been lower than

[142] WITN0771001_0034 at paragraph 3.6; MHRA0004770_008 at paragraph 22.

those of the United Kingdom. Where applicable, those variances in international practices should therefore have formed part of the LA's consideration of a medicinal product's safety, and any conditions or undertakings in respect of a product's licence.

195. Although the s.19 stipulated factors of safety, efficacy and quality reflected the statutory ambit of the CSM and the CRM, there was no requirement in the 1968 Act that the LA consult with either of these committees in advance of approving a licence. Whilst s.20(3) of the Act stipulated that the LA "*shall not refuse to grant such a licence on any grounds relating to the safety, quality or efficacy of medicinal products of any description, except after consultation with the appropriate committee or, if for the time being there is no such committee, with the Commission*", there was no equivalent provision for the granting of a licence.

196. The evidence heard by the Inquiry suggested that this statutory anomaly was somewhat ameliorated by the practices of the Department of Health: typically, a doctor and pharmacist within the Medicines Division (and later MCA) would jointly evaluate each application, and then submit the application along with their initial evaluation to the appropriate s.4 Committee (which, in turn, directed the initial evaluation to the relevant sub-committee for a first review). Once the relevant sub-committee had considered the application, it would make a recommendation to the CSM or CRM which, in turn, would consider the application and then advise the LA.[143] Although Sir Michael Rawlins (a former member, vice-chair and chair of the CSM) stressed that the CSM did not "rubber stamp" the decisions of the sub-committees,[144] the CSM generally agreed with the recommendations of the CSM(B).[145]

197. Although the evidence is not clear on the point, the above approach appears to have been adopted as the usual practice.[146] However, it is important to recognise three sub-standard features of the legislative regime:

    a) First, notwithstanding any amelioration by practice, the fact that the statutory framework did not mandate consultation of the s.4 Committees in anticipation of the grant of a licence was a significant oversight. It had the potential (and indeed, in some circumstances, may have) exposed the general public to risk;

    b) Second, the Inquiry heard evidence of the LA retaining decisions on important safety matters, rather than consulting the relevant s.4 Committees: for

[143] [MHRA0004773_9] paragraph 25; [WITN6406001_0022] paragraph 6.5
[144] [WITN6406001_0022] paragraph 6.7
[145] [WITN5281001_0040] paragraph 3.54
[146] [MHRA0004773_13] paragraph 32

example, the issue of differences in heat treatment processes for viral inactivation, which the LA "*decided to deal with… 'in house' and not refer to the Committee for advice*";[147] and

c) Third, the statutory framework gave Ministers the ability to, in effect, overrule the scientific ruling of the s.4 Committees. Although the evidence heard by the Inquiry suggested that the LA "*invariably accepted*" the CSM's recommendations,[148] there was evidence of Lord Owen as Minister of Health involving himself in the licensing of Armour's Factorate, and of the Department of Health expressing a view on the desirability of Factorate being licensed because of the beneficial cost implications that this would have for the NHS.[149] The statute left a dangerous loophole by which licensing decisions could be taken on an impartial, political basis, or at least influenced by impartial and political considerations.

198. Despite the CSM being, for the most part, the s.4 Committee which gave advice to the LA,[150] there was little direct contact between the CSM and the LA, or between the CSM and the Commission (unless the Commission had conduct of an appeal to a licence application, which we return to below). The relaying of advice from the CSM to the LA was conducted via the secretariat and staff of the Medicines Division/MCA.[151] This system was justified in the following way during the Bill's second reading in the House of Commons:

> *"The secretariat of the expert committees will be integrated with the licensing staff so as to enable applications, though technically made to the licensing authority, to be handled by staff serving the expert committees and knowing their views. Under the voluntary scheme there has been easy communication between the staff handling the submission and the staff of applicant firms. This has produced a situation in which applications can be handled without the delay that so easily arises where precise stages of procedure are laid down, and I am sure that mutual respect has been built up in this way. There is no reason why this situation need change or why applications should be handled any less expeditiously than are submissions at present."*[152]
>
> [Emphasis added]

[147] [MHRA0019502]
[148] [WITN6406001_0014] paragraph 5.3; [WITN7067001_4] paragraph 7.1
[149] [MHRA0004180]; [DHSC0003742_076]
[150] Although the hierarchy of the relevant bodies established by the 1968 Act suggests that the CSM and CRM reported to the Commission, the evidence suggested that, in fact, the CSM reported directly to the LA (or the officials to whom the LA's functions were delegated)
[151] [WITN6406001_0011-13] paragraphs 4.4 and 4.12
[152] https://hansard.parliament.uk/Commons/1968-02-15/debates/88cbc856-a6a2-46d4-ab9e-c7ef7c9e7a02/MedicinesBill

199. In instances where the LA was considering the refusal of a licence application on the grounds of safety, quality, or efficacy, and the consulted s.4 Committee (i.e. the CSM or CRM) "*[had] reason to think that they may be unable to advise the licensing authority to grant the licence, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application"*, an applicant was entitled to be notified, and to be given the opportunity of being heard in person or making representations in writing (s.21(1)). Only once that opportunity had been afforded (whether or not the applicant elected to take it) would the CSM or CRM report to the LA its "*findings and advice and the reasons for their advice*". The LA was directed by the same subsection that it "*shall take that report into account in determining the application*".

200. In addition, where the LA was ultimately advised by a s.4 Committee that a licence ought to be refused or contain additional provisions, the LA was required to notify the applicant of that advice, and of the reasons given by the s.4 Committee: s.21(3). At that stage, if the applicant had not taken the opportunity to be heard or make written representations to the s.4 Committee, the applicant would have an additional opportunity to be heard by, or make representations in writing to, the Commission. If an applicant chose to do so, the Commission would hear from the applicant before reporting "*their findings and advice and the reasons for their advice*" to the LA, which was again required to take that report into account in determining the application: s.21(4).

201. If, following the receipt of advice from the s.4 Committees and/or Commission, the LA proposed to determine the application in a way that differed from the advice given to it, the LA was obliged to notify the applicant, and to provide it with a further opportunity of being heard by a person appointed by the LA (whether in person or by making representations in writing): s.21(5).

202. Where licences were granted, by operation of s.24 of the 1968 Act they expired five years after the date on which they were granted. An applicant could apply to the LA to renew the licence prior to its expiry, which the LA could do with or without modifications or additional provisions. The process for an application to renew a licence was, for the purposes of the Inquiry's investigations, identical to that of the initial application for a licence.

203. Prior to a licence's expiry, the LA had a power to revoke, suspend, or vary a product licence under s.28, though those powers could only be exercised on grounds prescribed by that section, which included: an application having been false or incomplete in a material particular (s.28(3)(a)); the provisions of the licence having been contravened in a material way (s.28(3)(b)); and, importantly for the Inquiry's

work, where the products specified in the licence "*can no longer be regarded as products which can be safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes*" (s.28(3)(g)). The evidence of Sir Michael Rawlins suggested that revocation would only take place in the event of a "*major safety hazard*",[153] which was an unjustifiably high threshold when set against the statutory language, which was concerned only with a lack of safety.

204. Where the LA sought to revoke, suspend or vary a product licence in accordance with the provisions of s.28, depending on the grounds for doing so it may have been obliged to consult with the appropriate s.4 Committee: s.29 read with Schedule 2 to the 1968 Act. As with a decision to refuse a licence, a decision under s.28 required, by virtue of the provisions in Schedule 2 to the Act, the licence holder to be notified and to be given an opportunity to make representations, subject to the powers of the LA to suspend a licence with immediate effect "*in the interests of safety*" (see paragraphs 10-15 of Schedule 2 to the Act).

205. By virtue of ss.44(1), (2), and (3), where the LA was in receipt of a licence application and was considering (whether of its own volition or as a result of representations by the Commission or the s.4 Committees) whether a licence should be varied, suspended or revoked, the LA had a power to request that the applicant furnish it with information considered by the LA to be "*requisite*" for considering that question. If that power was exercised, the LA was not required to determine the application until the information had been furnished, or it had been shown to the LA's reasonable satisfaction that the applicant was unable to furnish the information requested. There was no requirement that the LA should consult the Commission or s.4 Committees on whether it ought to be reasonably satisfied that information could not be furnished, for example, where the information sought related to the safety of the product, or the status of scientific knowledge relating to the product, its components, and its risks.

206. The LA could also vary a licence on the application of a licence holder, provided the LA was "*satisfied that the variation will not adversely affect the safety, quality or efficacy or medical products*" (s.30). Again, there was no statutory obligation to consult either the Commission or the s.4 Committees upon receiving such an application, but it would seem reasonable that the LA would be required to do so (as the evidence demonstrated it did in relation to applications for variations due to heat treatment) in order to satisfy itself that there was no such adverse effect, save for in the most straightforward of cases. The evidence of Sir Michael was that there was no material

[153] [WITN6406001_0048] paragraph 13.19

difference in the level of scrutiny applied to applications for variations, as compared to applications for new product licences.[154]

Safety, Efficacy and Quality: The Realities of the Decision Making of the CSM

207. Sir Michael's witness statement also set out how, in his view, the CSM approached its recommendations (which, for the purpose of the remainder of these submissions should be taken to include recommendations on the grant, variation and revocation of licences) to the LA:

> *"7.2. Safety, efficacy and quality were therefore at the heart of our work. Very broadly, 'safety' in this context would look at the issue of contamination. This might be assessed by batch testing and screening and of course, later, post-release surveillance in the form of the yellow card reports. Batch testing would confirm potency but could not test efficacy. `Efficacy' meant looking at how effective a product was and to assess this, it would involve considering the clinical trials. `Quality' assessment was carried out by the pharmacists who would look at the molecular breakdown of the product to assess how pure the product was, whether it contained the correct chemicals and how stable it was.*
>
> *7.3. We did not consider whether there was another product on the market that was or might be equally or more efficacious for the same purpose (and indeed, such considerations were prohibited by s19(2) of the Medicines Act 1968). We could take into account, however, that a safer product was just as or more effective. We did not consider any other criteria.*
>
> *7.4. I vaguely recall that it took a while before international standards for potency were universally used by pharmaceutical companies but I cannot recall when these standards were adopted."* [155]

208. Although the legislation and Sir Michael's explanation is clear that the LA (and therefore CSM) could "*take into account*" the fact that a safer product was just as or more effective, it is unclear whether (and, if so, how) this was taken into account by the CSM in its consideration of applications for blood products: in our submission, this was the pivotal prism through which the CSM should have considered the first applications for products using larger plasma pools[156] and, subsequently, applications

[154] [WITN6406001_0023] paragraph 6.9
[155] [WITN6406001_0026]
[156] For instance, during the consideration of the applicationfor a product licence for Hemofil, when it was noted (at DHSC0105593_006, page 14, under paragraph 26 'Medical Comment') that *"The major disadvantage of currently available commercial preparations, such as Hemofil, is that they are prepared from very large plasma pools, and carry the risk of transmitting hepatitis virus".* Although the medical comment went on to state that clinicals could balance the potential hazard against the anticipated therapeutic benefit to the patient, this was not a factor which translated into any product information or warnings at the request of the LA/CSM.

which sought to vary the sources of plasma from European to American, which was known to have a significantly higher hepatitis risk. The fact that those applications resulted in licences demonstrates that the relative safety of the products was not considered, or was not given sufficient weight. We invite the Chair to find that the CSM should have recommended that the LA insist on safer plasma pool sizes and sources, in line with products which were already on the market and just as efficacious: had it done so, the evolution of commercial blood products on the UK market could have been very different.

209. Furthermore, although Sir Michael describes safety, efficacy and quality as being at the heart of the CSM's work, the Inquiry has seen evidence of:

a) Licences being granted with insufficient regard to safety, for example: the decision to licence Kryobulin in 1985 notwithstanding inadequate information on viral inactivation, due to a desire to move to heat treated products,[157] in circumstances where a licence revocation or safety notice in respect of non-heat treated Kryobulin would likely have had the same effect. A safety notice could have emphasised that, in light of the risks posed by non-heat treated blood products, they should be used sparingly and only in patients for whom the risk of not receiving blood products was severe;

b) Licences being granted without appropriate conditions or qualifications which reflected the CSM's, or CSM(B)'s, evaluation of the product, for example: the CSM's reflection, when considering an application for the licence of Prothromplex in 1973, that it saw a justification of some risk of hepatitis in treating a haemophiliac who would otherwise die from a haemorrhage, but failing to translate that qualified justification into conditions, product labelling, or warnings which indicated that the risk may not be justified for all haemophiliac patients, and that the product required a risk/benefit analysis by clinicians.[158] This was not in accordance with the 'toxicity versus efficacy' risk analysis that had been commended in the Bill's introduction, referred to earlier in these submissions, and which should have been at the heart of the licensing system; and

c) A failure to revoke or otherwise act swiftly in relation to safety concerns, for example, concerns raised in relation to Travenol's Factor VIII production in both

[157] SHPL0000048_026, which was referred to in the Inquiry's presentations, NOT RELEVANT
[158] SHPL0000665_142, referred to in the Inquiry's presentation NOT RELEVANT

a Department of Health inspection report, as well as the World in Action 'Blood Money' documentary.[159]

210. As Sir Michael went on to explain, assessing the 'quality' of blood products required special arrangements as compared to other medicines. As part of the grant of a licence, an applicant could be required to submit full details of the control tests applied to a product, or to even provide samples of each batch of a product to the NIBSC prior to its release for sale, alongside an undertaking that the batch would not be released for sale until the NIBSC gave a batch release certificate.[160] Although discussed under the heading of 'quality', in the context of blood products those licence conditions, if applied, operated as a stringent control on the safety of blood products. We invite the Chair to find that such restrictions should have been maintained on all blood products over the time period of interest to the Inquiry, given the uncertainties, developing knowledge, and evolving testing in relation to blood-borne diseases.

211. Turning to the question of efficacy, Professor Inman, in the same 1995 interview referenced earlier in these submissions, opined that "*the need for more information about the efficacy of drugs*" was one of the three main lessons to be learned from his experience of the CSD and the early days of the 1968 Act. He said:

> *"I think there was a serious defect in the Act probably initiated by pressure from the industry but many other countries now insist that a new drug has to have a margin of superiority or to be very considerably safer so that in other words you've got to have the complete equation: relative safety and relative efficacy and the Medicines Act prohibits this, really, these considerations".*[161]

Such a system would have ensured that the producers and manufacturers of medicinal products were constantly looking to progress and improve their medicines, rather than relying on a floor, standard, or precedent preparation that may have been set by another company. The race to the top that such a system creates could foreseeably have resulted in the earlier development of treated and safer blood products. While the Inquiry has not heard evidence on why this approach was adopted, it appears that the system favoured equity of profits among producers and manufacturers. The Parliamentary debates surrounding the Bill demonstrated that there was anxiety about causing the pharmaceutical industry undue hardship as a result of the new licensing regime.

---

[159] [MHRA0004180]
[160] [WITN6406001_0029] paragraph 7.16; [MHRA0004773_0015] paragraphs 4445
[161] https://wellcomecollection.org/works/bgj5xxbq and see the transcript at www.histmodbiomed.org/sites/default/files/Inman%20Professor%20Bill_-%20The%20Committee%20on%20the%20Safety%20of%20Drugs%20a%20personal%20account.pdf

The Medicine Act 1968: The Named Patient Exemption

212. As set out earlier in these submissions, the Act contained exemptions for medical professionals who supplied medicinal products in the course of their treatment of particular patients. In summary, doctors were able to order medicinal products which had not received a licence from the LA, provided that such an order was for "a particular patient". Prior to November 1978, there were no safety or regulatory restrictions on professionals importing blood products on this basis which, as the Inquiry heard, operated to permit the importation and use of vast quantities of commercial blood products created from large plasma pools.

213. Although this regulatory omission was justified by reference to a 'doctor knows best' dogma, the evidence heard by the Inquiry demonstrated that doctors repeatedly failed to conduct an appropriate and bespoke risk-benefit analysis which considered: the safety of that particular product; the risk posed to the patient; and whether, in light of the severity of the patient's haemophilia, the proposed benefit could reasonably justify the risks which had crystallised in medical knowledge at that point in time. The evidence also demonstrated that there was a gross failure by the professionals using these unlicenced products to inform patients adequately (if at all) of the risks that they posed so as to enable them to give informed consent.

214. Furthermore, although a doctor could be said to know the needs of their patient best, it does not follow that a doctor's knowledge is superior to that of the industry regulator: the Inquiry heard evidence about the vast volumes of evidence and technical information submitted alongside every product licence application. It is unclear how it could ever be considered that swathes of busy, treating doctors could, in the absence of the vast majority of the relevant information, make an appropriately informed decision as to the risks posed by particular products to their patients.

215. In our submission, this was a reckless exemption which encouraged complacent and reckless behaviour. We therefore invite the Chair to find that the statutory scheme should never have permitted unlicensed products to be used in the absence of satisfactory restrictions or safety mechanisms which, in our submission, was no earlier than May 1984, with the arrival of the additional restrictions imposed by the Medicines (Exemption from Licences) (Importation) Order 1984. Although restrictions were introduced by the same-named order of 1978, those restrictions did little more than notify the LA and were inadequate for controlling the quantity of imports and ensuring that the LA was kept apprised of any safety information or ramifications.

4. CHALLENGES TO, AND THE JUSTICIABILITY OF, LICENSING DECISIONS

216. When considering its final recommendations, the Inquiry is likely to be assisted by consideration of the legal remedies available to the infected and affected, both currently and as a matter of history. Although the Inquiry is not constricted by those remedies, and has the flexibility to make recommendations that courts could not, in our submission those remedies represent a starting point or a baseline for what the Inquiry should find to be due to victims of the infected blood scandal.

Tortious Liability - Breach of Statutory Duty

217. As the Inquiry is aware, a number of the victims of the scandal sought to sue the Department of Health, the Licensing Authority and the CSM (among other parties) in what became known as the 1990s HIV litigation. As was explained in the oral and written evidence of Justin Fenwick KC,[162] who was a junior member of the legal team advising the three aforementioned bodies at the time, the victims' claims were ultimately settled. As a result, the legal basis for these claims was not tested in court.

218. The claims settled (at least in part) due to two interventions; the first was Mr Justice Ognall's intervention,[163] and the second was Virginia Bottomley's recognition of the special status of haemophiliacs infected with HIV and their families. Ms Bottomley said:

> *"…I pointed out that haemophiliacs are a group of people who by virtue of their haemophilia are already disadvantaged in respect of their employment prospects and their ability to obtain mortgages and life insurance. We have no evidence to suggest that those people who have become infected with HIV via blood transfusion were similarly disadvantaged before the illness or accident leading to the need for transfusion."*[164]

The government would use the special status to justify the ex-gratia payments made in settlement of the HIV litigation.

219. However, the case came before the Court of Appeal in September 1990, following an appeal to an interim judgment on the defendants' disclosure obligations. As part of the Court of Appeal's judgment on the appeal, the court expressed doubts as to whether the victims would be able to make out claims for breach of statutory duty against the three aforementioned bodies in reliance on the National Health Service Act 1977 but did, as we return to below, suggest that a claim founded in negligence

[162] WITN7067001 and transcript of Justin Fenwick KC's oral evidence, 9 June 2022
[163] DHSC0046964_024
[164] DHSC0003328_001

was strongly arguable.[165] A claim brought on the basis of the then in force provisions of the Medicines Act 1968, and the duties that that Act imposed on the LA, the Commission, and the Sub-Committees was never tested in Court.

220. Although Section 107(1) of the 1968 Act provided that the validity of licences, certificates or an LA decision "*shall not be questioned in any legal proceedings*" other than the narrow proceedings provided for within s.107 (which were, in their nature, a public law challenge and to which we return below), the impact of this provision was narrow:

    a) First, s.133(2)(c) of the 1968 Act was explicit that the provisions of the Act "*shall not be construed as… (c) derogating from any right of action or other remedy (whether civil or criminal) in proceedings instituted otherwise than under this Act*". Thus, civil proceedings founded in tort were not excluded by the operation of s.107 (or any other section);

    b) Second, the terms of s.107 were that the validity of licences, certificates or an LA decision could not be questioned in legal proceedings. For the purposes of civil proceedings, a licensing decision could be negligent and/or in breach of statutory duty whilst remaining valid. Section 107 was aimed at limiting public law *vires* challenges, a subject which we return to below.

220. Furthermore, while s.133(a) of the Act stated that the provisions of the Act "*shall not be construed as… (a) conferring a right of action in any civil proceedings (other than proceedings for the recovery of a fine) in respect of any contravention of this Act or of any regulations or order made under this Act*", that prohibition related only to contraventions of the Act. That wording cannot encompass acts or decisions made pursuant to the Act which the victims nonetheless allege to be contrary to duties owed to the victims of the scandal.

221. Finally, although s.133(3) of the Act stated that the provisions of the Act were not to be construed as derogating from any exemption or immunity of the Crown, that was a provision which had no bearing on tortious claims, given that the Crown's immunity from suit in tort was removed by s.2(1) of the Crown Proceedings Act 1947. Although the Crown's immunity may have resulted in NHS-produced blood products being exempt from the licensing regime, the relevant arms of the NHS still had a tortious obligation to take reasonable care in their production and administration of products, which would be determined by reference to the standards prevailing at the time.

[165] See the Court of Appeal judgment at {RLIT0000657}. The judgment was given on 20 September 1990, but was reported in the 1996 Personal Injuries and Quantum Reports.

222. As a result, any restrictions within the provisions of the 1968 Act did not prevent the victims from mounting tortious claims, including a claim for a breach of statutory duty, brought as a distinct class of the public that the licensing regime was intended, post-Thalidomide, to protect. As set out earlier in these submissions, the licensing regime was intended to: identify risks associated with medicines, ensure that those risks were considered as part of a measured and evidence-based licensing process, and to ensure that only safe or sufficiently low-risk medicines were approved for use, or that higher-risk medicines were only used in circumstances where the risk-benefit analysis supported their use (typically severely ill patients). The failure by the LA, the Commission and its s.4 Committees to adequately control the use of commercial blood products made from unsafe plasma pools and sources, in light of the known risk of viral infections associated with such products, was a clear and serious breach of the purpose and intent of the licensing regime as created by the 1968 Act.

Tortious Liability - Negligence

223. In addition to a claim for breach of the statutory duties created by the 1968 Act, the victims also hold a claim for negligent performance of the duties under that statute. The leading case on negligence claims based on statutory duties was and remains X v Bedfordshire County Council [1995] 2 AC 633, which was decided after the settlement of the 1990s HIV litigation.

224. Giving the leading speech in X, with which all other Law Lords agreed, Lord Browne-Wilkinson[166] drew on a line of previous authorities in concluding that a distinction must be drawn between cases which allege that there has a been a failure to take care in the exercise of a statutory discretion, and those where there has been an alleged failure to take care in the execution of that discretion. Decisions which fall in the former category (amounting to the exercise of a statutory discretion) are unlikely to be actionable in negligence as:

> *"It is clear both in principle and from the decided cases that the local authority cannot be liable in damages for doing that which Parliament has authorised. Therefore if the decisions complained of fall within the ambit of such statutory discretion they cannot be actionable in common law…"*

Lord Browne-Wilkinson did, however, go on to identify a caveat to this general rule:

> *"…if the decision complained of is so unreasonable that it falls outside the ambit of the discretion conferred upon the local authority, there is no a priori reason for excluding all common law liability… It follows that in seeking to establish that a*

[166] This section of closing submissions draws on the entirety of Lord Browne-Wilkinson's analysis at 735 -739

local authority is liable at common law for negligence in the exercise of a discretion conferred by statute, the first requirement is to show that the decision was outside the ambit of the discretion altogether: if it was not, a local authority cannot itself be in breach of any duty of care owed to the plaintiff."

225. However, he also added that decisions reached on the grounds of policy matters cannot be subject to the court's adjudication, and that it is not possible for a decision reached on the grounds of policy to fall outside the ambit of the discretion (and to therefore qualify as being unreasonable):

> *"If the decision complained of falls outside the statutory discretion, it can (but not necessarily will) give rise to common law liability. However, if the factors relevant to the exercise of the discretion include matters of policy, the court cannot adjudicate on such policy matters and therefore cannot reach the conclusion that the decision was outside the ambit of the statutory discretion. Therefore a common law duty of care in relation to the taking of decisions involving policy matters cannot exist"*
>
> [Original emphasis]

226. Thus, in summary, the victims are able to bring a common law negligence claim based on a statutory duty where:

    a) The victims can demonstrate that the challenge is to the execution of a decision; and/or

    b) The exercise of the statutory discretion was unreasonable and related to operational matters, rather than policy matters.

227. In our submission, both criteria are satisfied. Following a broad policy decision (or exercise of discretion) to permit and licence commercial blood products (whether created in the UK or abroad) for the treatment of haemophilia, there was a duty on the relevant bodies to examine the particulars of each licensing application and, having regard to the known risks of viral contamination, to ensure that there were adequate safeguards in place (either of the producer's own volition, or imposed by ss.19-20 of the 1968 Act), including but not limited to: a restriction on plasma pool sizes, a restriction on the sources of the plasma, heat treatment, a requirement that the patients to whom the products were administered be provided with detailed information and warnings, and/or a requirement that the products be 'rolled out' with scrutiny for a defined period of time.

228. These were technical, operational decisions that should have been taken based on the risk profile of each application presented to the LA, but on which there were woeful

failings. These were not questions of over-arching policy, as Bingham LJ (as he then was) was inclined to accept ahead of detailed examination of the facts in the 1990s HIV litigation.[167] On this point, we rely on the New Zealand Court of Appeal authority of Attorney-General v Strathboss Kiwifruit Ltd [2020] NZCA 98, in which a decision as to the grant or refusal of an import permit on the grounds of the biosecurity risk was (at paragraph 118) held to be "*purely a technical decision… one determined by reference to the organism's profile and potential effects, unrelated to economic or political considerations*".

229. To the extent that it may be argued that the aforementioned failings involved the exercise of a statutory discretion rather than its execution (which is firmly contested, for the reasons set out above), this would nonetheless be actionable as having been unreasonable. The LA's operational decisions to grant and vary licences in the absence of appropriate restrictions, as well as its decisions not to revoke licences, set against the risks of viral infection that were known to the relevant bodies and known to be particularly associated with the larger plasma pools, would clearly satisfy the *Wednesbury* unreasonable threshold, being so unreasonable that no reasonable decision maker could have reached that decision. Even in circumstances where the CSM may have wished to facilitate treatment for those with blood disorders, it was incumbent on the CSM to ensure (by advising the LA) that product licences contained appropriate safety mechanisms; a failure to impose restrictions which reflected the known risks and concerns which were discussed and debated by the CSM was clearly unreasonable.

230. On the question of the relevant tests that would apply to these decisions, Justin Fenwick KC said in his oral evidence:[168]

> *"…it's got to be a decision, not that no reasonable minister – that's the Wednesbury test – but that no reasonably competent professional in that profession would do or no opinion they would hold. When you've got 20 or 25 or 30 eminent people and they all collectively decide to do something then the legal standard for "no reasonably competent practitioner would do it" could only be met in the most extreme circumstances. They all went out to dinner and got drunk and had a licensing day the next day and passed the papers through without reading it. There would probably be a cause of action then because that would be an operational action. But when they all get together and they think and read the papers and they debate and they decide, then it must follow, in my view, that you cannot say that no reasonably competent person would have done it. So even if there was a duty of care, then you would fail on negligence on that test because they've considered it. Again, you have to have the position, if*

[167] See {RLIT0000657} at p.249 under (3)
[168] 9 June 2022, page 27, line 2 – page 28, line 2

there's something they haven't considered, a piece of information which has been missed, then that's probably something which the Department failed to provide to them, and that would be an operational duty of the Department, for which there would be a cause of action in negligence…"

231. On this evidence we offer three observations:

a) We agree that the applicable test for a negligence claim founded on the basis of operational decisions is that of a reasonably competent professional in that profession, as opposed to the higher *Wednesbury* unreasonable test. The failings did not, for the reasons we have set out above, involve a statutory discretion;

b) We agree that the making of a licensing decision without having regard to the relevant papers would be negligent in an operational sense. Clearly, there is no evidential basis for suggesting that a negligent licensing decision was taken because of intoxication or its aftermath. However, given what the Inquiry has established as to the then known risks of viral infection, it must follow that either the LA (as informed by the CSM) did not have proper regard to the known risks of these products or, in the alternative and as alluded to in the evidence of Justin Fenwick KC set out above, was not provided with the relevant information on the known risks of contamination. In our submission that was an operational failing and would be negligent;

c) We also agree that had the LA and/or CSM not been provided with relevant information on the risks associated with blood products, that would amount to breach of an operational duty founding a cause of action in negligence.

232. In our submission, the recognition by the CSM in December 1972/January 1973 that larger plasma pools were a disadvantage and carried the risk of transmitting hepatitis[169] reveals that the CSM and LA were aware of the relevant risks and therefore, on the balance of probabilities, failed to have proper regard to the known risks of blood products when reaching licensing decisions (including decisions as to restrictions on any product licences). We invite the Chair to make that finding.

233. In support of the above, we adopt the words of Gibson LJ (with whom Sir John Megaw and Lord Justice Bingham, as he then was, agreed) in the 1990s HIV litigation disclosure decision, in relation to the negligence claim brought by some of the victims:

"I have also reached the conclusion that the plaintiffs appear, on their allegations of fact, to have at least a good arguable claim in law based upon

[169] In the context of its consideration of the produce licence application for Hemofil: [DHSC0105593_006], page 14, paragraph 26

common law negligence… P.242 The plaintiffs have set out, in my judgment, a prima facie case to the effect that the Department knew or should have known of the risk to the plaintiffs from the use of concentrate obtained from suppliers in the United States; that practicable steps could have been taken by the Department to eliminate or to reduce that risk; and that if those steps had been taken the injury suffered by all or some of the plaintiffs would not have been caused to them. By "prima facie case" I mean no more than that the plaintiffs have alleged facts, which, if proved, could justify those conclusions. The plaintiffs have supported their allegations, and in particular the allegation that the central defendants knew or ought to have known of the nature and gravity of the risk to which the plaintiffs were exposed by the use of infected blood products and of the steps which could be taken to eliminate or reduce that risk, by reference to publications and proceedings which appear to give substance to the allegations…"[170]

As this Inquiry has established, the victims' allegations were well founded and capable of being proven beyond reasonable doubt, let alone to the civil standard of the balance of probabilities.

234. Finally, we would add that, in addition to a claim for negligence founded on the relevant statutory duties, the victims had and will have 'ordinary' claims in negligence against those who administered contaminated blood products with knowledge of the risks that those products presented, in circumstances where those risks (which were plainly material in the sense that "*a reasonable person in the patient's position would be likely to attach significance to the risk*") were not explained and consented to by the victim. It is more likely than not that either the Department for Health or the appropriate NHS body would be vicarious liable for the acts of any such individuals. Such claims will clearly be of significance in respect of the use of unlicensed products in clinical trials and on a named-patient basis, given the evidence the Inquiry heard on the failings to advise patients appropriately ahead of the administration of unlicensed products.

235. It follows from the above that the victims of these tragic events do not accept the unnecessarily bleak characterisation of their prospects as presented in advice given to the central defendants in the 1990s HIV litigation, and submit that their strong claims (which, at an early stage, were recognised by a heavyweight Court of Appeal panel) should be recognised by this Inquiry and, subject to the actions of the government in response to the Inquiry's findings, are likely to be recognised in the courts. No disrespect is meant to Justin Fenwick KC or his contemporaries by the making of these submissions, and we note that the Inquiry has been presented with an incomplete picture of advices and conferences on the litigation. The way in which the law has

[170] {RLIT0000657} at p.234 and p.242-243

evolved in the circa 30 years since the 1990s litigation is also relevant to one's assessment of the victims' prospects: not only was this particular issue clarified in the X v Bedfordshire decision, there has been, more generally, an expansion in pertinent areas or ambits of tort law, including the number of successful tortious actions against the state, and the doctrine of vicarious liability.

236. Following a successful action founded in tort, the primary victims of the infected blood scandal would have been, and going forward would be, entitled to financial compensation for: their pain, suffering and loss of amenity; the costs of their care; the cost of any treatment or equipment that they reasonably required by virtue of their viral infections; their lost earnings; and any other financial outlay reasonably required by virtue of their infections. In addition, an infected victim could claim for the financial equivalent of his or her 'lost years' or, in the alternative, his or her dependants could bring claims for their financial and service dependency on the deceased. While such claims would require calculation on an individual basis, they are likely to be significant.

The Impact of the European Convention on Human Rights ("ECHR") and Human Rights Act 1998 ("HRA")

237. The obligations imposed on the state by the ECHR and HRA are relevant both to a court's assessment and interpretation of the state's tortious duties (statutory and at common law) and in their own, actionable right.

238. Article 2 to the ECHR provides:

> *"1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.*
>
> *2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary:*
>
> *(a) in defence of any person from unlawful violence;*
>
> *(b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained;*
>
> *(c) in action lawfully taken for the purpose of quelling a riot or insurrection."*

239. As the Inquiry will be aware, the case law of the European Court of Human Rights ("ECtHR") has identified three distinct obligations which make up the right to life under Article 2:

a) The negative obligation not to take life intentionally and unlawfully:

b) The positive obligation to take steps to safeguard the lives of those within the state's jurisdiction; and

c) The investigative or procedural obligation to initiate an effective public investigation by an independent official body into any death occurring in circumstances in which it appears that either the negative or positive obligation may have been violated.

240. A state's healthcare policy and healthcare provision is capable of founding a claim that the state has breached its positive Article 2 obligation: see Powell v United Kingdom (Admissibility, 45305/99), and Calvelli and Ciglio v Italy (32967/96) at paragraphs 48-50. Healthcare is inextricably and inevitably bound up with the loss of life, resulting in much debate in both domestic courts and the ECtHR as to which actions are capable of engaging the state's Article 2 positive obligation. The leading case of Lopes de Sousa Fernandes v Portugal (56080/13), concerned with a deceased's contraction of meningitis at hospital, clarified the dividing line in this area:

> *"187. Even in cases where medical negligence was established, the Court would normally find a substantive violation of Article 2 only if the relevant regulatory framework failed to ensure proper protection of the patient's life. The Court reaffirms that where a Contracting State has made adequate provision for securing high professional standards among health professionals and the protection of the lives of patients, matters such as an error of judgment on the part of a health professional or negligent coordination among health professionals in the treatment of a particular patient cannot be considered sufficient of themselves to call a Contracting State to account from the standpoint of its positive obligations under Article 2 of the Convention to protect life (see, among many other authorities, Powell and Sevim Güngör, both cited above).*
>
> *188. For the Court's examination of a particular case, the question whether there has been a failure by the State in its regulatory duties calls for a concrete assessment of the alleged deficiencies rather than an abstract one. In this regard, the Court reiterates that its task is not normally to review the relevant law and practice in abstracto, but to determine whether the manner in which they were applied to, or affected, the applicant gave rise to a violation of the Convention (see Roman Zakharov v. Russia [GC], no. 47143/06, § 164, ECHR 2015 and the cases cited therein). Therefore, the mere fact that the regulatory framework may be deficient in some respect is not sufficient in itself to raise an issue under Article 2 of the Convention. It must be shown to have operated to the patient's detriment (compare and contrast Z v. Poland, cited above, §§ 110-12, and Arskaya, cited above, §§ 84-91).*

189. It must, moreover, be emphasised that the States' obligation to regulate must be understood in a broader sense which includes the duty to ensure the effective functioning of that regulatory framework. The regulatory duties thus encompass necessary measures to ensure implementation, including supervision and enforcement."

241. In short, this distinction boils down to, on the one hand, one-off incidents of medical negligence (which will not engage the state's Article 2 duties) and, on the other hand, incidents of wholesale or regulatory framework such that it is the state, rather than one or more individual medical practitioners, that is called into question. There can be no doubt that the administration of infected blood products to the victims of this scandal emanate from the failures associated with the licensing of those products, as well as the general failings of, and omissions in, the licensing system, which enabled those flawed decisions to be made. In our submission, that regulatory dysfunction was directly causative of the death and personal injury of the victims who were treated with contaminated blood products.

242. Specifically on the question of viral infections, the ECtHR has determined in case law that:

a) Delay and "*serious deficiencies*" in the diagnosis and treatment of HIV and concomitant illnesses of a detainee amounted to a violation of the state's Article 2 obligations (Karpylenko v Ukraine, 15509/12);

b) That, in cases of medical negligence (which, on their own, would not necessarily engage Article 2 for the aforementioned reasons) the state's positive obligations may be satisfied "*if the legal system affords victims a remedy in the civil courts, either alone or in conjunction with a remedy in the criminal courts, enabling any liability of the physicians concerned to be established…*" (Colak and Tsakiridis v Germany 77144/01 and 35493/05, at paragraph 30); and

c) That the court may, in exceptional circumstances, find a violation of Article 2 where the events complained of do not result in death. In a case concerning the transmission of HIV to a living complainant, the ECtHR proceeded on the assumption that the case raised an Article 2 issue, although, ultimately, that case was dismissed, and thus the court did not need to determine the point (Colak, paragraph 29). In our submission, the transmission of a viral infection such as HIV, which impacts one's life expectancy and life quality so significantly and represents a serious endangerment to life, does engage Article 2; and

d) In another case concerning the transmission of HIV to a living complainant, that "*where lives have been lost or seriously endangered in circumstances potentially engaging the responsibility of the State*", there was a duty on the state to investigate the circumstances in which the applicant contracted HIV (Gorelov v Russia (49072/11).

243. We therefore submit that it is clear that the victims are able to establish that the state's involvement in the infected blood scandal amounts to breaches of the state's positive Article 2 duties. Furthermore, although the establishment and thorough work of this Inquiry will now satisfy the procedural limb of Article 2, the repeated way in which the state has prevented and explicitly declined an effective public investigation by an independent official body has, over a number of years, amounted to an ongoing breach of the state's procedural Article 2 obligation.

244. Those findings impact the victims' legal entitlements in two significant ways:

a) Following the coming into force of the HRA, the victims have had the right to bring standalone claims in domestic courts pursuant to ss.6-7 HRA for the unlawful acts of a public authorities, in reliance on the state's Article 2 breaches as outlined above. Those claims can continue to be brought although, in the case of historic deaths, they will require the courts to adjudicate on applications to disapply limitation periods. Although our clients are confident that the courts would recognise the justice in disapplying those limitation periods, particularly given the information that has been concealed for a number of years and only exposed as a result of the Inquiry's work, we invite the Inquiry when making its recommendations to recognise its flexibility to go above and beyond legal entitlements, and to have regard to the many claims that could have been brought by victims over the years; and

b) Prior to the HRA, domestic courts would have been required to interpret legislation in accordance with the presumption that Parliament intended to legislate so as to ensure the state's compliance with its obligations under the ECHR, following its accession to the ECHR in 1951. Therefore, as the Court of Appeal recognised in its disclosure judgment,[171] if the victims could not have gone on to establish a common law negligence claim (which is not a contention that we accept for reasons set out earlier in this section), the state's ECHR obligations would have required the relevant statutes, and the question of whether they enabled civil claims for breach of statutory duty, to be interpreted in accordance with the presumption that the state intended to provide for an

[171] At {RLIT0000657}, pp.237 -239

effective remedy for ECHR breaches. In light of the courts' strong interpretative approach under s.3 HRA 1998,[172] we submit that it is highly likely that the courts would have interpreted the relevant statutes as permitting claims for breach of statutory duty. Had the courts not done so, the victims would have exhausted their domestic remedies and would have had a clear remedy in bringing ECtHR proceedings for breach of the state's Article 2 obligations.

245. In summary, we submit that there were, and are, a number of clear paths for the victims to obtain financial compensation by way of civil claims. We therefore invite the Inquiry to build upon its interim report on interim payments and make recommendations which ensure that the victims of this horrendous tragedy receive further financial compensation. At the bare minimum, that financial compensation should reflect that which could be obtained in breach of statutory duty or negligence proceedings. However, we also invite the Inquiry to go further, recognising (a) its flexibility to award that which is not obtainable as a matter of strict legal remedy; and (b) the extraordinary amount of delay and obfuscation that the victims have experienced in their continuous and tiring quest for answers and justice over several decades.

Public Law Challenges

246. We also invite the Inquiry to have regard to the potential public law challenges that may have been available to the victims historically.

247. Section 107 of the 1968 Act, which prohibited the questioning of the decisions of the LA (as well as the validity of any licence granted or other thing done in pursuance of such a decision), provided a narrow avenue of challenge under s.107(2):

> *"(2) If the person to whom such a decision relates desires to question the validity of the decision on the grounds—*
>
> *(a) that it is not within the powers of this Act, or*
>
> *(b) that any of the requirements of this Act or of any regulations made under this Act, which are applicable to the matter to which the decision relates, have not been complied with,*

[172] Including, by way of example, the well known cases of Gilham v Ministry of Justice [2019] UKSC 44 (in which the Supreme Court interpreted legislation which required a contractual relationship between a worker and employer as, by virtue of s.3 HRA, as including district judges, who the court found were not engaged under any contract) and Ghaidan v Godin-Mendoza [2004] UKHL 30 (in which the words "as his or her wife or husband" were interpreted as including as including same-sex couples who, at that time, were not able to marry one another)

that person may, at any time within the period of three months from the date on which notice of the decision is served on him, make an application to the High Court under this section."

248. The narrowness of statutory s.107 challenges are clear on the face of the statute:

a) It is likely that only licence applicants could bring the challenge as "*the person to whom such a decision relates*". Such challenges would inevitably be to the refusal or variation of a licence application, given that applicants would not challenge their own application or licence on the grounds of public safety;

b) The two grounds available were, in summary, that the decision fell outside the statutory powers and provisions. It was not open to an applicant to challenge the merits of a decision, or the extent to which it took account of the merits; and

c) A challenge was required to be brought within three months of the decision.

249. Thus, any judicial review challenges to the legality and validity of LA decisions and/or Commission or s.4 Committee recommendations would be contrary to the restriction in s.107. However, in our submission it is clear that judicial reviews which related to decisions taken under the 1968 Act would have been possible on Anisminic grounds:[173] in summary, and as is likely to be known to the Inquiry, if the victims could establish that the statute did not intend to exclude or oust the High Court's supervisory jurisdiction in respect of errors of law which render a decision a nullity.

250. In our submission, the courts were unlikely to find that a clear intention had been expressed in s.107 of the 1968 Act, which stated simply that licences and related actions "*shall not be questioned in any legal proceedings*". This is less explicit than other statutory language which has been held to be insufficient to oust the High Court's supervisory jurisdiction, including the language in the recent case of R. (on the application of Privacy International) v Investigatory Powers Tribunal [2019] UKSC 22: *"…determinations, awards and other decisions of the Tribunal (including decisions as to whether they have jurisdiction) shall not be subject to appeal or be liable to be questioned in any court shall not be subject to appeal or be liable to be questioned in any court*".

251. It follows that if the victims were able to bring judicial review proceedings to licensing decisions and associated recommendations, they could have challenged any failure by the LA, the Commission or the s.4 Committees to take the known, high risk of viral infection from larger plasma pools into account as a relevant consideration when

[173] Taken from the well known case of the same name:Anisminic Ltd v Foreign Compensation Commission [1969] 2 A.C. 147

reaching a view as to whether to recommend, and ultimately licence, the relevant blood products, including any licence conditions to be applied in the interests of safety. In our submission, it is likely that a *Wednesbury* unreasonable ground founded on the same facts would also have good prospects of success. Furthermore, the limited evidence the Inquiry has on how the CSM reached its decisions demonstrates that the CSM adopted internal policies on how it approached questions of efficacy[174] and, therefore, presumably safety and quality. Judicial review proceedings could also have been brought in respect of an unreasonable policy, or a failure to follow a written policy.

252. It is important to observe that judicial review challenges to the relevant licensing decisions are only of historic relevance, given the requirement that judicial review challenges must be brought promptly and, in any event, no later than three months from the date of the decision. Although a haemophiliac patient was unlikely to be treated with an infected blood product and develop adverse symptoms of a viral infection within three months of a product being licensed, had information on the risks associated with blood products created from larger plasma pools been communicated to those being provided with the treatment, there would have been a window of opportunity to challenge licensing decisions which flew in the face of that risk. The state's failure to be transparent with those it was treating was the very reason that those challenges could not be, and were not, brought. However, we invite the Inquiry to have regard to the fact that those challenges were, at least in theory, open to those who would in due course come to be affected by this treatment, and to the fact that those challenges, had they been facilitated, could have played a role in stopping, minimising, and/or publicising this tragedy at an earlier date.

Concluding Observations on Product Licensing and Associated Challenges

253. This section of our closing submissions, in reliance on the evidence exposed by the Inquiry, has demonstrated that those who have been deeply affected and injured by the infected blood scandal did (and do) have strong legal foundations for holding the government to account for what went wrong. It is a matter of deep regret that a number of successive governments have fought victims' attempts to have justice done at every twist and turn. A great number of those victims were tired, some dying. It is no surprise that, in light of the governments' stance, some victims felt that their only realistic option was to accept ex gratia payments in settlement of litigation. Much can and should be learned from how the government handled the 1990s HIV litigation.

[174] [MHRA0018824_0006] paragraph 3.2

254. Looking beyond legal claims, political accountability for licensing decision making also appears to have been non-existent. Despite the 1968 Act making provision for annual reports to be sent by the Commission and s.4 Committees up the chain, the reports could not have been (and the evidence has not demonstrated to the contrary) an effective form of accountability given their internal and inherently biased starting point. Those reports would have been one means, but far from the only means, of sharing information on the known risks of viral infection with those who were receiving treatment through blood products. The state (which includes the arms of the licensing system, the Department of Health, the NHS, and clinicians) failed to share knowledge of those risks with those who would be deeply impacted and affected by them. Adding insult to injury, this Inquiry has shown a series of shocking failures by Government to listen to, never mind act upon, the concerns and dreadful experiences of those affected by poor licensing decisions.

255. We therefore invite the Chair to find that:

a) The licensing system enacted by the Medicines Act 1968 favoured the interests and concerns of producers and manufacturers ahead of those of the general public, whose health and lives were to be impacted by the system's decision making. Although the intention behind the licensing framework in the Act was clearly one of public safety, for reasons set out in these submissions, the Act failed to prioritise questions of safety adequately, afforded too much weight to the voices of industry, and gave too little opportunity for the voices of those affected to be heard;

b) There should have been some form of effective political accountability for those making decisions on medicinal licensing and the levels of risk to which members of the general public would be exposed. In that sense, the mechanisms of the 1968 Act failed to strike an appropriate balance between efficacy and business continuity on one hand, and public information and safety on the other; and

c) That victims of the infected blood scandal are entitled to financial compensation on a basis which is at least as generous as that which would be established in a tortious claim.

256. We add a final note on the importance of accountability. Although the eviden ce in this Inquiry has demonstrated, as set out earlier in these submissions, that there was sufficient knowledge of the risks associated with larger plasma pools as early as 1946, for the purposes of lessons to be learned from this scandal it is important to recognise

that, in some instances, risks and side effects of medicines are not known or fully understood at the time of a licensing decision.

257. In those instances, it is a culture of constructive accountability which ensures that action can be taken speedily when new information comes to light, including revising earlier decisions which have been thrown into doubt, thereby preserving the health and wellbeing of as many people as possible, and taking quick and effective steps to help those for whom the risks have already materialised.

258. Such a culture requires a paradigm shift from the culture that sadly has dominated both the private and public sectors of the UK for decades, which centres around denial and preservation of reputations. Going forward, transparency and a desire to raise standards must come ahead of defensiveness, profit and personal interests. The fact that this is a central takeaway from a number of ongoing public inquiries demonstrates the seriousness and scale of this challenge, which requires more than lip service to see meaningful change.

5. KNOWLEDGE AND SPREAD OF HIV

The Establishment of the Connection between HIV and Blood Products

259. For many UK haemophilia patients (including the misdiagnosed), their HIV infections came to them from the US. By 1982, many haemophiliacs would have already been infected with HIV through the use of imported blood products for reasons already set out in these submissions. Furthermore, as AIDS was already present in the UK community, blood products sourced from UK plasma alone would have continued to infect some haemophiliacs. However, the immediate cessation of imported blood products, particularly when combined with appropriate restrictions on donors and pool sizes, would in our submission (and as set out previously) have resulted in far fewer HIV infections.

260. In January 1982 Bruce Evatt, an expert on haemophilia at the Centres for Disease Control in Atlanta, received a call from a Miami physician who was convinced that Factor VIII had killed his patient, an elderly haemophiliac who had recently died of pneumocystis. The physician asked Dr Evatt whether the pneumocystis protozoa could have been transmitted in the clotting factor that his patient injected. Dr Evatt sought to persuade the physician that the Pneumocystis protozoa would be caught by the filtering process.

261. However, this was not accurate, as the filters could not catch microbes or viruses (such as Hepatitis B). The case was a worrying one, and it was reported that the patient's death was subsequently considered by Harold Jaffe of the Kaposi's Sarcoma and Opportunistic Infections Taskforce, in discussion with the US Centre for Disease Control ("CDC") Director Bill Foege, both of whom understood that a connection between the patient's death and blood products could represent the beginning of an explanation of the cause of the growing epidemic.[175] Although the conclusion was that

[175] Five cases of *Pneumocystis carinii* pneumonia (PCP) were reported in what turned out to be the first reporting of AIDS in the medical literature (June 5, 1981). Los Angeles-based general practitioner Joel Weisman and immunologist Michael S. Gottlieb of the UCLA Medical Center had encountered a series of gay male patients with symptoms that appeared to be immune system disorders including significant loss of weight and swollen lymph nodes, accompanied by fever and rashes, in addition to two patients with chronic diarrhoea, depressed white blood cell counts and fungal infections. Gottlieb diagnosed these and a number of his other patients as having pneumocystis pneumonia. A report they jointly wrote and published in the June 5, 1981, issue (30(21:1-3) of *Morbidity and Mortality Weekly Report* , described their patients as "*5 young men, all active homosexuals, [who] were treated for biopsy-confirmed Pneumocystis carinii pneumonia at 3 different hospitals in Los Angeles, Californid*" and that "*[t]wo of the patients died*" by the time of the original report. This notice has been recognized as the first published report marking the official start of the AIDS pandemic.

the patient's death could not be conclusive evidence of a link, Foege reportedly said *"if it's real there'll be another one"*.[176]

262. On 11 June 1982, Sandy Ford (the CDC technician who highlighted the unusual prescribing of pentamidine to treat PCP pneumonia) called Dr Evatt, having identified a haemophiliac patient who had contracted pneumocystis. One of Dr Evatt's associates, Dr Dale Lawrence, flew to see the patient that day. Dr Lawrence rapidly eliminated other possible factors, and also investigated and then eliminated the possibility of a 'bad lot' of FVIII. The sicks man's wife explained to Dr Lawrence that her husband had worked as a janitor, that his joints had been affected by his haemophilia, and that Factor VIII had been "a godsend", but that he was now wheezing his life out on a ventilator. Dr Lawrence was convinced that Gay Related Immune Deficiency ("GRID"), as AIDS was then known, was being spread via Factor VIII. Dr Evatt had suspected the same for months. For both, the second pneumocystis haemophiliac patient confirmed that GRID was caused by a virus: bacteria, protozoa, and one-celled microbes were easily weeded out of Factor VIII during its preparation process, meaning that GRID had to be caused by the only organism that was small enough to pass through the filters, a virus.[177]

263. On 16 July 1982, the CDC published these two cases and a subsequent case in its report '*Epidemiologic Notes and Reports Pneumocystis carinii Pneumonia among Persons with Haemophilia'*:[178]

> *"A CDC recently received reports of three cases of Pneumocystis carinii pneumonia among patients with haemophilia A and without other underlying disease.* ***Two have died; one remains critically ill. All three were heterosexual males; none had a history of intravenous (IV) drug abuse. All had lymphopenia, and the two patients who were specifically tested have had in vitro laboratory evidence of cellular immune deficiency.*** *The case reports follow.*
>
> *Patient 1: A 62-year-old resident of Westchester County, New York, with a history of chronic hepatitis had received frequent injections of Factor VIII concentrate for severe haemophilia for many years. In February 1981, he began to experience weight loss and vague right upper quadrant abdominal discomfort associated with laboratory evidence of increasing hepatic dysfunction. In December 1981, while hospitalized in Miami, Florida, for elective knee surgery, he complained of cough and fever. He was lymphogenic, and chest X-ray revealed interstitial*

[176] p.116 '*And the Band Played On, Politics People and the AIDS Epidemic*' - 1987 Randy Shilts. The remainder of this section draws on Shilts' book.
[177] CBLA0000015_0186
[178] PRSE0000523: Pneumocystis Carinii Pneumonia among Persons with Haemophilia A "Morbidity and Mortality Weekly Report 31 (16th July 1982): 366

infiltrates compatible with viral pneumonia[179]*. He was discharged in late December after a brief course of corticosteroids associated with overall clinical improvement. He returned in severe respiratory distress a few days later. Open lung biopsy on* GRO-A *5 revealed P. carinii, for which he received sulfamethoxazoleltrimethoprim (SMZ/TMP) during the 2 weeks before death. P. carinii pneumonia and micronodular cirrhosis were documented at post-mortem examination.*

Patient 2: A 59-year-old lifelong resident of Denver, Colorado, noted the onset of gradual weight loss, dysphagia associated with pharyngitis, aphthous-like ulcers, and anterior cervical adenopathy beginning in October 1980. As a patient with severe haemophilia, he had received frequent injections of Factor VIII concentrate for several years. Weight loss continued over a period of months. Oropharyngeal candidiasis was diagnosed in February 1982. He was hospitalized in May 1982 with symptoms including nausea, vomiting, and recurrent fever. Pneumonia was diagnosed, and P. carinii and cytomegalovirus (CMV) were repeatedly identified from lung tissue or bronchial secretions using histopathologic and culture techniques. Therapy with SMZ/TMP and pentamidine isethionate continued until death on GRO-A *1982. Laboratory evidence for cellular immune dysfunction included absent mitogen responses and depletion of the T-helper lymphocyte cell population, relative increase in T-suppressor cells, and resultant inverted T-helper/T-suppressor ratio.*

Patient 3: A previously healthy 27-year-old lifelong resident of north-eastern Ohio developed fever, urinary frequency and urgency, and extreme lassitude in July 1981. He had frequently received parenteral Factor VIII concentrate for severe haemophilia. Bilateral pneumonia was diagnosed in October 1981, and open lung biopsy revealed P. carinii. He responded successfully to a 3-week course of SMZ/TMP. In February 1982, he received ketoconazole to suppress repeated episodes of oral candidiasis. I-le was hospitalized again in April with fever, splenomegaly, anaemia, and lymphopenia. An extensive tumour work-up (including laparotomy) did not uncover an underlying malignancy. Cultures of bone marrow, liver, mesenteric lymph nodes, and blood grew Mycobacterium avium. In vitro immunological testing in March indicated a reduction in absolute number of circulating T-cells. Subsequent, more extensive testing documented the lack of lymphocyte responsiveness to mitogens, absolute and relative decrease in T-helper cells, relative increase in T-suppressor cells, and resultant inverted T-helper/T-suppressor ratio. For each patient, records of the

[179] Sandra Ford a technician at the Centres for Disease Control in Atlanta had first noticed the increased demand for pentamidine in April 1981. She was surprised by the request as it related to two patients being treated by one doctor, an unheard of event and queried this with the treating doctor, asking 'what was the underlying cause of the immune suppression that had brought on the pneumonia? At this time Ms Ford believed that the Doctor was either 'incompetent or lazy' and had perhaps confused charts for two patients. But this was not the only unusual request for this medication as in the last eight weeks she had filled in five orders for the drug for adult male patients with unexplained Pneumocystis: p.61 And the Band Played On, Politics People and the AIDS Epidemic 1987 Randy Shilts.

administration of Factor VIII concentrate were reviewed to determine manufacturer and lot numbers.

No two of the patients are known to have received concentrate from the same lots.

Editorial Note: Pneumocystis carinii pneumonia has not been previously reported among haemophilia patients who have had no other underlying diseases and have not had therapy commonly associated with immunosuppression. A review of the Parasitic Disease Drug Service's records of requests for pentamidine isethionate for 1980-1982 failed to identify haemophilia among the underlying disorders of patients for whom pentamidine was requested for Pneumocystis carinii therapy. The clinical and immunologic features these three patients share are strikingly similar to those recently observed among certain individuals from the following groups: homosexual males, heterosexuals who abuse IV drugs, and Haitians who recently entered the United States. ***Although the cause of the severe immune dysfunction is unknown, the occurrence among the three haemophiliac cases suggests the possible transmission of an agent through blood products.***

CDC has notified directors of haemophilia centres about these cases and, with the National Haemophilia Foundation, has initiated collaborative surveillance. A Public Health Service advisory committee is being formed to consider the implication of these findings. Physicians diagnosing opportunistic infections in haemophilia patients who have not received antecedent immunosuppressive therapy are encouraged to report them to the CDC through local and state health departments."

[Emphasis added]

264. The salient features of the CDC report are:

a) The identification of three haemophiliacs with no risk markers for acquiring AIDS;

b) Two of the three patients died within a year and a half of symptoms developing;

c) The third haemophiliac patient, who was still alive at the time of the report, was extremely ill

d) All three patients had had long term use of FVIII concentrate; and

e) No two of the patients had received blood products from the same lots.

265. The CDC's working hypothesis seemed to be that AIDS could be caused by a virus. The report was – and should have been taken as – notice that there was a virus in blood

products which: had an unknown incubation period; once symptomatic, killed within 18 months or less; and had no treatment nor cure.

266. Despite the lack of any other explanation, a memorandum from Charles J. Carman of The National Haemophilia Foundation ("NHF") to the NHF Chapter Presidents, forewarning the recipients about the potential risk to haemophiliacs due to be published in the Morbidity and Morbidity Weekly Report by the CDC, recommended no change in treatment stating "*…even if the preliminary speculation is confirmed, CDC does not recommend any changes in treatment regimen at this time*".[180]

267. In his statement dated 29 September 2000, Dr Snape (former member of the CSM(B) and, at the time of his statement, employed as a technical director for BPL and appointed as a member of the advisory commitment on microbiological safety of blood and tissues) said the following of the CDC report:

> *"in July 1982 the first report of AIDS related symptoms associated with a haemophiliac was published and of course fractionators, like haemophilia treaters were very concerned about whether the causative agent of AIDS could be transmitted through factor concentrates. Of course until the causative agent had been identified and characterised, it was not possible to conclude that heat treatment would help to prevent the transmission of AIDS to haemophiliacs".*[181]

267. By December 1982, the numbers of haemophiliac patients diagnosed with AIDS was going up amongst 'no risk' adult and child groups. In most cases, these patients were the first AIDs patient in their "respective city, region or state", as noted by an NHF chapter advisory publication dated 9 December 1982, which aimed to provide an update since the July 1982 report. By this stage, the CDC had changed its advice:

> *"It is important to note, that while there is insufficient data to directly link the spread of AIDS to concentrates, there is an increased concern that AIDS may be transmitted through blood products. It is NHF's point of view that patients and parents should be aware of the potential risks."*[182]

268. In a letter sent from Alpha Therapeutic UK Ltd to Professor Bloom (in the Department of Haematology at the University Hospital of Wales) on 16th March 1983, in which Alpha sought to relay precautionary steps taken by its parent company to minimise the risk of AIDS being transmitted via donor pools, the following was noted:

> *"Surveys now being conducted by NHF are producing other disquieting findings:*

[180] BAYP0004186_007
[181] WITN3431002_0010, paragraph 176
[182] BAYP0000018_119

- *AIDS has jumped from the seventh to the second most common cause of death in haemophiliacs within a year.*

- *The case rate appears to be rising."*[183]

269. In the wider medical journals and press at the time, the following developments (by way of examples) were being reported:

a) Dr Jay E Menitove et al reported that persistent generalised lymphadenopathy was considered to be part of AIDS. Their studies showed abnormal T4/T8 cells in 36% of all treated haemophiliacs and 57% of haemophiliacs using FVIII concentrates;[184]

b) Peter Jones et al reported that 11 out of 16 patients, all of whom had been exposed to US commercial concentrates, had altered T cell subsets similar to AIDS, and that a New York study had made similar findings;[185]

c) The Lancet's editorial reported that there were 788 cases of AIDS in the US, that haemophiliacs were a major risk group, and a link with FVIII administration was suggested;[186]

d) RV Ragni et al reported on the occurrence of an AIDS-like syndrome in two haemophiliacs. They suggested that transmission by blood products seemed likely, and that haemophiliacs could be at an increased risk of AIDS;[187]

e) An Observer article on 16 January 1983 stated that commercial blood products from the US used by haemophiliacs to improve clotting could be infected, and that there was an apparent risk of infection with AIDS;[188]

f) Susan Douglas' article "*Hospitals' using killer blood*" in The Mail on Sunday[189] which, as the Inquiry heard, led to a Press Council complaint[190]and, in turn, a response from the editor[191] which carefully refuted the complaint. As Susan Douglas said in evidence to the Inquiry, no one was looking at the risk nor taking it seriously, thus the Mail on Sunday campaign aimed to ask relevant questions

[183] CBLA0000060_067
[184] PRSE0001320
[185] ibid
[186] ibid
[187] ibid
[188] DHSC0002223_085
[189] PRSE0000199_001 dated 1st May 1983
[190] PJON0000001_100
[191] PJON0000001_104

and try to provoke answers to the question 'What should the doctors say to the patients?'.[192] (evidence 15th September 2022).

270. The Inquiry has not been presented with evidence of any other possible explanation as to why children or 'no-risk' adults could possibly be contracting AIDS. Despite this, there was a failure to convey adequately the risk to haemophiliac patients receiving potentially infected blood products: phrases which conveyed, for example, an *"increased concern that AIDS may be transmitted through blood products"* failed to grasp the nettle and convey the clear risks and dangers involved in these continued practices. The medical advice that was continuing to be dispensed to haemophiliac patients was the equivalent of 'there is a good possibility that the brakes on this car do not work, but you can continue to drive it for the time being'. Instead, there should have been a clear direction that the significant risks of death to which haemophiliacs were going to be exposed warranted a restriction on the continued use of blood products, save for in certain, life threatening circumstances when the risk-benefit ratio was tolerable.

271. At this juncture, it is important to understand the question of how ethics and the acknowledgement of risk are intertwined, particularly in the context of decisions to be taken on treatment options or the continuation of treatment. For the purpose of this Inquiry's investigation, the question to be asked is: what would the reasonable patient, who was not already infected with HIV (or at least not known to have been infected with HIV), likely have decided if fully informed of the risks of continued treatment using blood products?

272. The following statement from 1968 describes the then thinking on the interplay between risks and consent:

> *"'[The patient] will be entitled to demand a bona fide statement in broad terms of the risks to life or future health or of pain and discomfort involved in the contemplated procedure or to a frank admission that in the given circumstances these cannot be assessed with any accuracy. He must also be given a fair appreciation of the probable value of his sacrifice, to the recipient if he is to be a donor, and to medicine in general if he is to enter a clinical trial. The greater the risk the greater will be the obligation on the doctor to ensure that the patient understands. The lesser the risk the lesser will be the onus on the doctor. It is merely pedantic to insist that the patient be fully informed of a mass of facts which he cannot assimilate or assess."*[193]

[192] Transcript 15/09/2022

[193] Referred to at page 23 of the Expert Report to the IBI: Ethics; Ormrod Sir R. Medical ethics. BMJ 1968; 19(2): 7-10. https://www.bmj.com/content/bmj/2/5596/7. fullpdf

273. The Inquiry's expert report on ethics analysed the position around that time and into the 1970s:[194]

> *"Notwithstanding the limited remedy in negligence for non-disclosure in the mid-to-late 20th century, we consider there was nonetheless recognition of the need to inform patients about important risks associated with medical interventions. The BMA's pamphlets[195], Medical Ethics, 1970 and 1974 focused on etiquette designed to protect the reputation of the profession, and replicated the Declaration of Geneva and Declaration of Helsinki. The BMA guidance referred readers to Medical Defence Union (MDU) pamphlets on Consent to Treatment. The MDU's 1971 edition opened with a quote from an American case: "No amount of professional skill can justify the substitution of the will of the surgeon for that of his patient"[196]. It made clear that treatment without authorisation would constitute a battery and that: 'The patient should ... be told, in non-technical language, of the nature and purpose of the operation' and `If the operation contemplated carries special risks which are probably unknown to the patient he should, as a general rule, be informed of these risks."*[197]

274. The same expert report then went on to set out the relevant position in the late 70's and the 80's:

> *"The Medical Act 1978 gave the GMC additional powers to advise doctors on medical ethics[198]and a brief `medical ethics' section was duly added to GMC guidance in 1980, focusing on the importance of maintaining trust between doctors and patients. In 1980, Professor (now Sir) Ian Kennedy's Reith Lectures[199] prompted critical reflection of the traditional role and power of doctors and hastened further development of a `patient centred' approach to health-related decision-making. The BMA's 1980 guidance included two paragraphs on adult 'consent',[200] which speaks to consent's growing importance and also recognition that it is potentially contentious. In this guideline, focus on patient understanding moved beyond the basic legal requirement of battery, and the doctor was required to adapt information to meet the needs of the patient and situation. The BMA 1980 guidance put the onus on the doctor to give an explanation adequate for the patient to understand 'the nature and consequences of what is proposed'. The doctor's duty, then, was to decide which option was preferable, and to furnish the patient with information sufficient that they could accept or refuse it. The degree of information required depended on the patient's education and intelligence and the seriousness of the condition. The BMA guidance was revised in 1981, adding that: `Doctors offer advice but it is the*

[194] INQY0000241_0027

[196] Bennan v Parsonnet 83 A 948 (1912)
[197] Medical Defence Union, Consent to Treatment. 1971, p.3
[198] GMC. Professional Conduct and Discipline: Fitness to Practise 1980
[199] Published in Kennedy I. The Unmasking of Medicine. London: Allen and Unwin, 1981
[200] BMA. Handbook of Medical Ethics. London: 1980, para 1.8 and 1.9

patient who decides whether or not to accept the advice' (para 2.6). In 1988, the GMC released specific guidance on HIV Infection and AIDS: The Ethical Considerations which incorporated two earlier statements and new guidance on issues of confidentiality and consent. Based on the broader 1980 GMC guidance, it (somewhat defensively) reminded doctors that guidance cannot be comprehensive and will often be responsive: In all areas of medical practice doctors need to make judgements which they may later have to justify. This is true both of clinical matters and of the complex ethical problems which arise regularly in the course of providing patient care, because it is not possible to set out a code of practice which provides solutions to every such problem which may arise (para 4). Consent is dealt with in paragraphs 12-14. Paragraph 12 begins: It has long been accepted, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent." [201]

275. In our submission, the combined effect of (a) the knowledge of the seriousness of the risk to haemophiliacs, and (b) the ethical considerations which should have provided a benchmark for any consideration as to the continuation of treatment, results in the inevitable conclusion that, following the publication and promulgation of the CDC's July 1982 report, the only safe and sensible course for the vast majority of haemophilia patients would have been to cease treatment with any imported blood product whatsoever and immediately revert to any other possible treatment option which, at that time, would have been known to carry no risk of infection with HIV, including synthetic products, or any domestic products which carried a much lower risk as a result of having been made from small pools (which, for reasons set out earlier in this submission, should not have exceeded 10 donors). To carry on treatment with imported blood products and prescribing their use in the UK at that stage was morally, ethically, and criminally wrong.

The Government's Response to the Spread of HIV through Blood Products

276. Lord Patten's witness statement[202] referred to his understanding of the briefing papers he received around this time from Dr Walford (which had been sent to his PPS on the 28th June 1983). He said:

> *"reading it now, it suggests that needles, and blood and transfusion of blood and plasma were a likely route of infection for drug abusers and haemophiliacs/blood transfusion recipients respectively… Dr Walford stated that the cause of AIDS was unknown but the evidence was suggestive that it may be a virus and that it also seemed likely that some additional predisposing factors may determine an individual's susceptibility".*

[201] INQY0000241_0028
[202] WITN5297001_0014

It is likely that the Government's mantra of *"no conclusive proof"* came from Dr Walford's briefings, where she used the phrase "*there is no conclusive evidence*".[203]

277. This interpretation of Dr Walford's briefing notes by Lord Patten – and no doubt by others – tends to suggest that the connection between blood products and infection was still a matter under discussion. Had Dr Walford given an emphatic and unequivocal statement that imported US blood products were, on the evidence available at that time, the most likely cause of the spread of a very serious and probably fatal disease with a long incubation period for which there was no treatment, this may have (and certainly should have) altered the urgency of government handling of these issue.

278. Lord Patten's statement also referred[204] to the difference in views between, on the one hand, Dr Galbraith (the founder of the Public Health Laboratory Service), who considered that in light of the literature that all blood products from 1978 onwards should be withdrawn[205] and, on the other hand, the view expressed by Dr Walford in her minute of 13 May 1983 that:

> *"Perhaps the situation is best put in perspective by a statement which was drafted to appear in the minutes of the meeting of the Directors of Haemophilia Reference Centers which I attended today:*
>
> *"Many Directors have until now restricted their use of FVIII in young children (under the age of 4 years) and in mild haemophiliacs to NHS materials and we consider that it would be circumspect to continue with that policy. <u>There is not sufficient evidence to restrict the use of imported FVIII concentrates in other patients in view of the benefits of the treatment</u> but the situation will be kept continuously under review by means of a surveillance system which has been instituted and by means of regular meetings of the Reference Centre Directors.""*[206]
>
> [Emphasis added]

279. It seems Dr Walford was (at least in part) led to this view by her attendance that same day (13 May 1983) as an observer at a special meeting of the Haemophilia Reference Centre Directors, where it was recorded in the minutes: *"…It was agreed that there was, as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy…".*[207]

---

[203] DHSC0002309_121 & DHSC0002309_124
[204] WITN5297001_0014 at paragraph 3.41
[205] CBLA0000043_040
[206] DHSC0002227_047
[207] HCDO0000003_008

280. In our submission, that viewpoint was the maintenance of the status quo without any proper regarded to the risks, or to an actual, empirically-founded risk benefit analysis. Dr Walford should have provided, and Lord Patten and other ministerial colleagues should have requested, a more detailed briefing as to the relative risks versus benefits. It was not enough, without more, to blindly perpetuate the statement that imported FVIII concentrates and other blood products were clearly of such benefit to outweigh the risks of a prolonged and likely fatal disease. One cannot help but query whether the ministers would have reached a different decision had the pertinent materials set out in the earlier paragraphs of this section (specifically, but not restricted to, the CDC reports in 1982 and Dr Galbraith's recommendation in May 1983, only a matter of days earlier) been made available to them, rather than the deceivingly straightforward analysis that Dr Walford presented.

281. When viewed as a whole, the materials available at the time presented a very clear picture: that haemophiliac patients were being infected with a lethal disease through blood products. Dr Walford's advice and briefings failed to alert ministers to the very clear picture that had emerged on the international stage, nor did it relay adequately the clear and present danger that blood products presented to haemophiliac patients. Having regard to the background of the Medicines Act 1968 and the Thalidomide scandal, in our submission if the material had been properly drawn to the attention of the ministers, the likely and only appropriate government response would have been that proposed by Dr Galbraith: to withdraw US blood products and other large pool blood products from use within the UK which, in turn, would have required a reversion to alternative products and a bigger drive for self-sufficiency (which despite a number of promises still lacked the requisite political power and drive for any meaningful change to occur). In addition, greater urgency should have been given to the development of the "*new BPL facility at Elstree*".[208]

282. Lord Patten was asked by the Inquiry about the tension between the statement that there was "*no conclusive evidence*" or "*no conclusive proof*" that AIDS was being transmitted by blood or blood products, and various examples of literature which suggested otherwise.[209] Lord Patten's response acknowledged that there was a tension, but went on to say that the "*statements were unqualified*" and that in the "*fuller citations of the documents set out above there is, in each case, contextual reference to the steps that the Department was taking to deal with the risk and/or covert reference to the possible risks*". For example, Lord Patten relied on a sentence within the September 1983 press statement[210] (which accompanied a September 1983

[208] WITN5297001_0014 at paragraph 3.46
[209] WITN5297001_0031 at paragraph 3.37
[210] DHSC0006401_006

donor leaflet[211]) which stated: "*We must continue to minimise any possible risk of transmission of the disease by blood donation but it is not possible to test a person's blood for the presence of AIDS*".

283. With respect to Lord Patten, this argument fails to withstand scrutiny and appears to be a continued defence of the Government's position, which we now know to be misguided. The line "*We must continue to minimise any possible risk…"* failed to convey to haemophiliac patients how risks would be minimised, nor did it adequately convey the true scale of the risk that haemophiliacs were being exposed to. Further, the statement in the donor leaflet that there was "*only the most remote chance of* [AIDS transmission by blood or blood products] *happening with ordinary blood transfusions in hospital*"[212] was not substantiated by evidence and was, in fact, contradicted by the emerging evidence, which has already been set out in these submissions. After all, why would longitudinal studies on relative risk/benefit ratios by "*urgently needed*"[213] if the risk was so remote?

284. Therefore, the information being relayed to the public, upon which Lord Patten sought to rely, was not a fair representation of the risk exposure and was a total failure in transparency. The supplied information (or lack thereof) deprived patients of the opportunity to understand the potentially fatal risks to their health, and to make an informed decision about their treatment.

The Response of Manufacturers and Clinicians to the Emerging Risk

284. In his witness statement, Dr Peter Foster gave evidence[214] that fractionators would have been aware of the risk of HIV from 16 July 1982, following the CDC reports of three haemophiliacs suffering from PCP, two of whom had died. Despite that knowledge of a connection between blood products and AIDS, fractionator companies in the US continued to champion the use of their products without appropriate qualifications or warnings. See, for example, Alpha's promotion of December 1982:[215]

[211] BPLL0007247
[212] BPLL0007247
[213] PRSE0001351
[214] WITN6914001, page 46
[215] p.278 The Bleeding Disease, Stephen Pemberton, John Hopkins University Press 2011

GRO-A

FIGURE 7.2. "It Takes a Team" Clotting Factor Advertisement, December 1982.

285. It appears that Alpha's commercial response was to advertise the safety of their products by explaining that their products had been tested "*twice*" for Hepatitis and that "*the end product are tested and found to be non-reactive to HBsAg*". However, tellingly, at the same time in December 1982 Alpha, of its own volition, began to exclude donors who were "*male homosexuals*", "*drug abusers*" or "*persons who had been in Haiti*".[216]

286. In December 1982, further to the two CDC reports mentioned earlier, the Morbidity and Mortality Weekly Report ("MMWR") added to the knowledge of risk in reporting the story of a 20 month old child who had developed immunodeficiency and infection following transfusion from, inter alia, a man who was subsequently found to have had AIDS. The publication warned:

> *"This report and continuing reports of AIDS among persons with hemophilia A (7) raise serious questions about the possible transmissions of AIDS through blood and blood products. The Assistant Secretary for Health is convening an advisory committee to address these questions.".*[217]

287. In light of that and all the other reports set out above, it is inconceivable to suggest that fractionators were not aware of the connections and risks associated with the creation of blood products. Yet the Inquiry was told by Dr Snape that *"In January 1982, the donation number limit for BPL and PFL pools was further increased to 7500 donations"*[218], and there was no evidence to suggest that this number was reduced in or after 1982, when he and others must have been (or, at the very least should have been) aware of the risk of infecting haemophiliac patients with AIDS. These reactions to – or, perhaps more fittingly, the failures to act in relation to – the risk posed by HIV/AIDS is impossible to reconcile and, put frankly, beggars belief.

288. At paragraph 195 of his witness statement, Dr Snape also stated:

> *"In June 1985 Dr John Craske indicated that a small number of NHS Factor IX treated patients were HIV antibody positive and one or two had developed symptoms of AIDS but there had been no transmission in the haemophilia B patients in Edinburgh although they had been exposed to Factor IX produced from the same starting plasma pool as that implicated in the transmission of HIV to haemophilia A patients. He recommended changing to heat treated NHS*

---

[216] The Bleeding Disease, Haemophilia and the Unintended Consequences of Medical Progress, Stephen Pemberton, John Hopkins University Press 2011, pages 355-6 refer to David J Gury, vice President, Plasma Supply, Alpha Therapeutic Corpn., letter to all source affiliates, December 17th 1982, in Leveton et al., HIV and the Blood Supply, pages 269 and 272

[217] "Possible Transfusion-Associated Acquired Immune Deficiency Syndrome (AIDS) – California" MMWR 31 (10th December 1982) 652-654

[218] WITN3431001 paragraph 217

Factor IX concentrates as soon as possible but made no recommendation about the use of heated US products."

289. The article "*Blood borne infections and haemophilia: the worst of times*"[219] referred to the first Royal Free Hospital patient who had seroconverted, noting that he was the first documented patient to seroconvert in the UK. He had severe von Willebrand's disease and, following abdominal bleeding in the summer of 1979, was given commercial concentrate. The article went on to state that the haemophilia centre at the Royal Free Hospital *"was at the forefront of research into the natural history of both diseases* [AIDS and HCV]" and that "*in 1982 we were able to determine whether or not patients had a problem based on the clinical manifestations of immunodeficiency.... We established that there was a steady decline in the CD4 count and that this was associated with the development of AIDS.*"

290. From this it is clear that the likelihood of haemophiliac patients becoming infected with HIV was on the minds of those treating them in 1982, and that indirect testing could indicate that a patient was likely to be suffering from the disease before an HIV test was available. Despite this, the evidence from surviving haemophiliacs and their family members demonstrated that this risk was not discussed with them.

291. At a meeting of the Scottish National Blood Transfusion Service ("SNBTS") and the Haemophilia Directors on 21 January 1983,[220] Dr Cash drew attention to recent articles about AIDS:

> *"6. (a) Acquired Immune Deficiency Syndrome (AIDS) Dr Cash drew members attention to recent articles in the United States, and also in the Observer and the Lancet, about this problem. A 1070 extract (CDC, Atlanta) had been circulated with his paper. Dr Ludlam informed members that in the UK a letter and questionnaire had been sent out to haemophilia directors."*

292. The article "*Acquired Immunodeficiency-like Syndrome in Haemophiliacs*" appeared in the Lancet on 29 January 1983.[221] It identified an AIDS like syndrome in two haemophiliacs in the USA and highlighted the need for careful observation in other haemophiliacs for the appearance of symptoms.

293. Dr RS Gordon (Chairman of National Institutes of Health AIDS Working Group, USA) subsequently wrote a letter in the Lancet dated 30 April 1983, entitled "*Factor VIII Products and Disordered Immune Regulation*".[222] Dr Gordon discussed the altered distribution of T-lymphocyte subpopulations in young haemophiliacs under treatment

[219] RLIT0000196
[220] PRSE0001736, paragraph 6
[221] RLIT0000201
[222] CBLA0000059_031

with factor VIII concentrate, mentioning that, by 3 March 1983, eleven cases of AIDS in haemophiliacs had been reported to the CDC, all of whom had received factor VIII concentrate. This was consistent with the likelihood that AIDS was caused by a virus in blood products. He went on to say that the findings were:

> *"…also compatible, however, with the possibility that repeated administration of factor VIII concentrate from many varied donors induces a mild disorder of immune regulation by purely immunochemical means, without the intervention of an infection. Such a mild immunosuppression could predispose a subsequent infection with a biological agent… these alternative hypotheses might be distinguished through a study of T-lymphocyte subpopulations among similarly treated haemophiliacs in a geographical area to which AIDS has not yet been introduced".*

295. Dr Gordon suggested that the resolution of this question by a timely investigation in countries where AIDS had not yet been reported would be an immense help to public health workers worldwide. He said that in this situation "*negative results*" would be of "*great significance*". The same suggestion was put to Sir James Gowans (Secretary of the Medical Research Council) by Dr Gordon in March 1983.[223]

296. In the letter, NIH Directors discussed a study that could readily be carried out which could be of real importance to the understanding of AIDS. The study would consider haemophiliacs in the UK who had received only factor VIII concentrates prepared in the UK, to which AIDS seemed not to have spread at that point in time.[224] This correspondence was in the month that the `AIDS Studies' began on haemophiliacs in Edinburgh but before it is likely that haemophiliacs in Edinburgh became infected.

297. In May 1983, Dr Ludlam published a reply to Dr Gordon's letter in the Lancet, entitled "*Disordered immune regulation in haemophiliacs not exposed to commercial Factor Viii*".[225] He said that he had studied 23 patients who had received exclusively SNBTS products in the past five years and had found that two-thirds had helper/suppressor ratios below the lower limit of their normal range. Dr Ludlam concluded:

> *"Our results confirm other reports of low helper/suppressor ratios in haemophiliacs. Since there are no known cases of AIDS in our blood donor population it seems likely that the immunosuppression observed in haemophiliacs, as reflected by reduced T lymphocyte helper/suppressor ratios, results from infusion of foreign protein or a ubiquitous virus rather than a specific AIDS virus in the factor VIII concentrates."*

---

[223] MRCO0000439_177
[224] WITN2189063
[225] PRSE0001303

298. Also in May 1983, Dr Galbraith of Public Health Laboratory Services ("PHLS") wrote to Dr Ian Field of DHSS, stating that all blood products made from blood donated in the USA after 1976 should be withdrawn until the risk of AIDS transmission by these products had been understood and evaluated.[226] Dr Galbraith's sage advice was ultimately ignored. Had his warnings been heeded, the infection of many haemophiliacs with HIV might have been avoided.

299. In May 1983 at a "Special Meeting of Haemophilia Reference Centre Directors", the directors discussed recent publicity in the press, radio and television about AIDS. They debated whether to change the type of concentrate used in patients who developed the features of the full-blown condition. Their ultimate conclusion was that the condition was likely to be irreversible "*so that there would seem to be no clinical benefit to be gained by changing to another type of factor VIII*". More broadly:

> *"With regard to general policy to be followed in the use of factor VIII concentrates, it was noted that many directors have up until now reserved a supply of National Health Service concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy. It was also agreed that there was, as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy. The situation shall be kept under constant review"*[227]

300. At the same meeting, there was a discussion about donors and the exclusion of high-risk donors, and it was noted that "*Directors were adamant that there would be no direct questioning of donors about their sexual habits nor about the presence of symptoms such as night sweats etc.*"[228] This suggests that the feelings of the donors were more important than the lives of the recipients who would ultimately receive the blood donations and, but for adequate mitigation and prevention measures, a life threatening virus. It is relevant to note that, at this time in the UK and the USA, there was a heighted discussion about the rights of gay men to give blood; for example, an article published by the Scottish Homosexual Rights Group in May 1983 opposed the ban on gay blood donors.[229]

---

[226] CBLA0000043_040 and WITN1055006 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'
[227] WITN2189027
[228] BPLL0001351_024
[229] PRSE0003057

301. A report in the September 1983 publication of Gay News, entitled "*AIDS in Scotland — Mystery Virus Claims Two*", proclaimed that AIDS had arrived in Scotland,[230] It follows that, by Autumn of 1983, AIDS was most likely in the UK donor population.

302. By June 1983, Coventry and Warwickshire Hospital wrote to its haemophilia patients in respect of AIDS. The letter advised that the hospital wanted to monitor all haemophiliacs and asked for a blood test.[231] In the same month, a document entitled "Acquired Immune Deficiency Syndrome" from the CDSC in June 1983 referred to AIDS as "*A serious, and often fatal illness (39% mortality)*" and stated that *"[o]ther groups thought to be at risk are intravenous drug abusers, consorts of bisexuals, and recipients of infected blood and blood products*".[232]

303. Further, on 15 June 1983, a meeting of the FVIII Safety Sub-committee referred to the "*putative AIDS virus… as a potential hazard in FVIII concentrates*".[233] Subsequently, at a meeting of UK Haemophilia Centre Directors which took place on 17 October 1983, Dr Craske outlined his proposals to investigate cases of AIDS in UK Haemophiliacs and proposed following up on patients who had received suspect batches for a period of three years.[234] Even at this advanced stage, too little was being done to prevent or stem the spread of AIDS through blood products. Had the warning signs been heeded at an earlier stage, the spread of the virus in haemophiliac patients could have been either prevented or, at the very least, significantly stemmed. However, with AIDS in the donor population and with inadequate screening of donors, it was inevitable that AIDS would spread rapidly among haemophilia patients.

304. In March 1984, haemophiliacs at the Edinburgh Haemophilia Centre received an infected batch of Factor VIII. Approximately 50% of those who received the batch were on the road to seroconversion to HTLV III. A SNBTS Directors Meeting on 11 December 1984 referred to the batch as having been presumed to be from a 'homosexual' who had given a donation that was positive for venereal diseases.[235]

305. The Inquiry paper "*The History of the Blood Transfusion Services: an Overview*"[236] refers to the more general lack of structure and cohesion within the umbrella organisation behind BPL which explains, in our submission, a lot about the reasons for the failures in achieving self-sufficiency. Those failures, in turn, ultimately contributed

[230] PRSE0003358
[231] WITN1369002
[232] MACK0001938_002
[233] MACK0001263_004
[234] ARCH0002566
[235] PRSE0001767
[236] INQY0000307_0018

to the mass importation of blood products which infected many haemophiliac patients with HIV.

306. The continuing chaos into the 1990s is made clear by the following excerpt from Inquiry's paper:

> *"Examples of the National Directorate having to work by persuasion can be seen as follows:*
>
> *• In the July 1990 letter to Dr Donald in the Quality Department at BPL Dr Gunson noted that there were different criteria at different RTCs for the repeating of anti-HIV tests. Dr Gunson stated that he was "trying to establish a uniform system through the Service, but… still [has/ some work to do." (BPLL0001702)*
>
> *• In relation to the timing of the introduction of anti-HCV screening, Dr Gunson stated, in a letter on 25 September 1990, that a universal approach across RTCs should be adopted. (NHBT0000190_013) He did not achieve this as Dr Lloyd of the Newcastle RTC implemented HCV testing before other RTCs.*
>
> *• Similarly, Dr Gunson wrote to the Senior Medical Officer at the Department of Health in October 1990, asking for a uniform policy for anti-HBc testing, which had been implemented by some (but not all) RTCs. He noted that this would prevent criticism for "piecemeal" introduction of testing, divergent standards of testing for HBV and reduce the of legal action. He further recorded that the issue had been addressed several years prior by an advisory group but that the group had not met now for several years (NHBT0003601)."*[237]

309. As with the UK's broader handling of the spread of hepatitis and HIV within blood products, important actions were delayed in circumstances where they ought to have been expedited. The UK's response was, in summary, too little, too late, resulting in the unnecessary and avoidable spread of HIV. The impact on haemophilia patients was not restricted to the devastating effects of the virus alone: as haemophilia patients were among the first cohort of people to contract HIV, many were treated with AZT, which had horrific, toxic side effects. Those side effects are still being felt by some of the infected community to date.

[237] INQY0000307, paragraph 62

6. THE ROLE OF THE UK HAEMOPHILIA CENTRES DOCTORS' ORGANISATION ("UKHCDO")

Contemporaneous Minutes of the Haemophilia Centre Directors

310. In essence, our submission in relation to haemophilia treaters in the 1970s and 1980s is simply that they were (with notable exceptions) the wrong people, dealing with the wrong problems, at the wrong time.

311. In his evidence to the Inquiry, Dr Mark Winter discussed being of a generation of later doctors who were both physicians and pathologists.[238] The following week, Dr Brian Colvin gave evidence and, in reference to Dr Winter's evidence, said:

> *"A. I began my training in '69/'70 with the absolute intention of being a physician as well as a pathologist. So although Mark was saying that he was the first generation of people who were physicians and pathologists, I'd like to claim four years earlier. That's exactly what I wanted to do and he was quite right to emphasise it.*
>
> *Q. So would you accept, whatever the precise timing, the broad point he was making, that there may be a difference between those whose path to specialising in the care of patients with haemophilia was a laboratory-based path, science path, and those whose path was through general medicine?*
>
> *A. Yes, if you look at the content of the so-called Reference Directors in the time that I was about to qualify in haematology, some were physicians, not haematologists; some were haematologists who were laboratory haematologists, and we had one paediatrician. There was a number of different ways of being a Haemophilia Centre Director. I think the fact that juniors like myself or like Mark became members of the Royal College of Physicians and of the Royal College of Pathologists was key in our desire to be physicians and pathologists…"*[239]

312. Whosever evidence is most accurate, the late 1960s and early 1970s saw a generational shift from those who were pathologists to those emerging into the specialty who were physician pathologists. In tandem, the focus of haemophilia treatment moved from the laboratory and into treatment centres where the skills of a physician were just as important as those of a scientist. We submit that this change was prompted by the development of increasing numbers of treatment options, from cryoprecipitate to concentrates.

---

[238] Transcript 01/10/2020 – page 34, line 19+
[239] Transcript 06/10/2020 – page 2, line 15 – page 3, line 15

313. However, the older generation of those treating haemophiliac patients – who, generally speaking, had a focus on science rather than engagement with patients – were the dominant force in setting the treatment guidelines for haemophilia care. This was, in the 1970s, at a critical time in the evolution of treatments for haemophilia. This is the foundation of our submission that the wrong people were primarily responsible for a problem that they were ill equipped to address.

314. By the beginning of the 1970s at the latest, Haemophilia Centre Directors had begun to coordinate. The earliest document recording a meeting of Haemophilia Centre Directors that we have located is a letter dated 8 March 1971, which opens:

> *"There has been a favourable response to my suggestion that we should have another meeting and many items have been proposed for the agenda. The date which is convenient for the largest number of Directors is MONDAY, 5th APRIL, so I am arranging for the meeting to be held here* [Oxford Haemophilia Centre] *on that day and I hope that it will be possible for you to come."* [240]

315. The meeting which pre-dated 8 March 1971 is, therefore, likely to have been the first formal meeting of Haemophilia Centre Directors. The letter also enclosed an agenda for the proposed second meeting on 5 April 1971 which included, at item three, a *"Report on the progress of the MRC Cryoprecipitate Working Party Survey of the Incidence of Transfusion Jaundice and the Incidence of Inhibitors in Haemophilic and Christmas Disease Patients"*. This appears to be the report appended to the agenda and letter though it is difficult to be clear given that the first page of the report is missing.

316. The report appended to the agenda recorded, inter-alia:

a) There were 29 cases of clinical jaundice arising amongst the 1,066 patients upon whom reports were made (2.7% though stated in the report as 2.8%). All of the patients who developed jaundice were severely affected patients and 3 of the 29 (10.3%) died. One of those who died was nine years old. All three patients who died had been treated exclusively with very large amounts of cryoprecipitate;

b) *"From a detailed study of the 7 Oxford patients who developed jaundice, we have calculated that they had a total risk from exposure to at least 4,482 donors during the 2-6 months prior to becoming jaundiced, the average risk per patient therefore being 640 donor exposures, which is not greater than that of the average patient…"*;

[240] HSOC0011682

c) *"The data on hepatitis suggests that patients with coagulation defects are very resistant to clinical hepatitis. Hepatitis transmission must be related to the number of 'donor exposures' of the patients. This number will increase with the use of dried concentrates made from large pools of donors. These concentrates have advantages in treatment in that the potency is known and they are convenient to make up and administer. The problem in recommending an increased manufacture of these lies in the possible increase in hepatitis and antibodies. From the point of view of clinical hepatitis this danger seems to be small though the high incidence of Australian antigen and antibody in haemophiliacs suggests that they do become infected. We feel that the increased risk of clinical illness is not so great as to overbalance the advantages of the use of concentrates."*; and

d) *"The choice between different available concentrates is a difficult one. The incidence of jaundice in treated patients must increase with the number of donor exposures and the number of donor exposures must increase using concentrates derived from large pools. However the greater reliability, ease of administration and economy of manufacture are in favour of concentrated materials. Perhaps now that the virus associated with Australian antigen can be studied a method will be found to remove the antigen from concentrated materials, though of course its removal may not necessarily remove the virus."*

317. Within this report then, presented at the near genesis of the UKHCDO, we have a recognition that the risk of hepatitis increases in correlation with the number of donor exposures, as well as a recognition that a 10.3% death rate has been recorded amongst recognised cases of hepatitis in haemophiliacs. Despite those findings, the UKHCDO still expressed the view that the benefit of a much larger donor exposure (through dried concentrates) outweighed the risk posed by the inevitably greater incidence of hepatitis in haemophiliacs.

318. This is one of the earliest points in the chronology at which we can see haemophilia treaters taking the decision to expose their patients to a greater number of donors and therefore, by their own recognition, to a greater risk of infectious disease), and without any apparent consultation with patients and with no intention to have any such consultation expressed.

319. This decision in or around April 1971 must be set in the relevant historical context, as set out at length in Section 1 of these closing submissions, when there was a large body of evidence warning of the danger of hepatitis associated with transfusion, blood products, and plasma pools of more than ten donors. When set alongside that evidence, it is difficult to understand and justify the UKHCDO's decision to justify

concentrates which exposed patients to a significant number of donors. The hope expressed by the HCDO, namely that a method of removing HBV from concentrates might be discovered, entirely failed to recognise that if one virus can be carried in plasma products, so can others. As has been demonstrated at length, that sadly became true of the transmission of AIDS.

320. By 1972, the meetings of the Haemophilia Centre Directors appear to have formalised. On 27 October 1972 a meeting took place where it was decided that a trial should be conducted at LMTC on the efficacy of prophylaxis treatment in 10-15 boys.[241] It was decided that commercial, freeze-dried concentrates ought to be used (despite none holding a licence from the Licensing Authority at that point) and that the boys would be treated prophylactically, once per week. It was noted that *"Co-operation of the Haemophilia Centre Directors would be required wherever possible to obtain parents' consent for the boys in the trial and to supervise boys in the holiday."*

321. This 'call to arms' via the UKHCDO certainly appears to have been taken to heart by Dr Peter Jones at the Newcastle Haemophilia Centre: once the trial at LMTC was up and running, he wrote to the parents of Peter Longstaff on 12 April 1973[242] in the following, absolutely unqualified terms:

> *"…You will have received a letter from Lord Mayor Treloar asking for your permission for Peter to participate in the special trial of regular factor VIII injections.* GRO-A *'s parents have also been asked for their permission. I saw the* GRO-A *'s last week and explained that* ***I was in complete agreement with the trial and that it could do nothing but good for the boys and other patients****…."*
>
> [Emphasis added]

322. As is well known to the Inquiry from the evidence of Carol Grayson, Peter would ultimately go on to die from the infections he acquired whilst a subject of the trials at LMTC. In our submission, Dr Jones' careless explanation (or, more accurately, lack thereof) of the risk/benefit calculation in employing large pool concentrates is typical of that given by the vast majority of haemophilia clinicians throughout the 70s and 80s: this much has been borne out by the wealth of evidence the Inquiry heard throughout 2019 from the infected and affected witnesses, and by the even greater volume of written evidence received from them. Although Dr Jones averred, in his first written statement,[243] that he told all of his patients of the risk of hepatitis posed by concentrates, Pete's case demonstrates that this was clearly inaccurate, and we invite the Chair to dismiss that evidence.

---

[241] HCDO0001015
[242] WITN1055172
[243] WITN0841005_0010

323. The decision to hold a trial at LMTC, while knowledge of the risks associated with large-pool, freeze-dried concentrates was still developing and emerging, was curious. It is our understanding that Baxter's Hemofil was used for the trial.[244] The package insert for that product, submitted to the Licensing Authority in November 1972 as part of the product licence application, warns:

> *"…The concentrate should, therefore, be used when its expected effect is needed in spite of the unknown hepatitis risk associated with its use. Special consideration should be given to the use of this concentrate in newborns and infants where a higher morbidity and mortality may be associated with hepatitis."* [245]

324. It is difficult to envisage a trial which could have been designed with less regard for the express warnings given by the manufacturers of the product to be trialled. Not only was the product used in a trial upon children, in spite of the highlighted increased risk of morbidity and mortality, but it was also trialled to test the efficacy of prophylaxis: as such, the expected effect was entirely unknown and could not be counterbalanced against the unknown hepatitis risk.

325. Why, then, was the trial conducted at LMTC? The answer is contained at page 7 of the 27 October 1972 UKHCDO meeting minute: *"About the organisation of the trial, questions were asked about the treatment of boys during holidays. The trial treatment would have to lapse during holidays and this was a pity."*[246] In summary, the trial was conducted at LMTC because there lay a captive cohort of haemophiliacs upon whom the security of the trial's methodology and organisation could be best assured. No regard whatsoever was given to the increased risk of hepatitis which the boys would be exposed to, nor to the greater risk hepatitis posed to them by virtue of their age.

326. The minute went on to record:

> *It was agreed that the Chairman [Professor Blackburn] should ask the Ministry of Health and Social Security to set up an Expert Committee to consider and advise on the supply of factor VIII in this country, taking into consideration the fact that Directors prefer freeze dried factor VIII to cryoprecipitate."*[247]

327. This indication of preference came a month before the first product licence application for freeze-dried concentrates was made to the Licensing Authority. Considering the amount of freeze-dried concentrates that had been used at this point, and the timeframe over which they had been used, this preference could not possibly

[244] INQY0000281_0016 with reference to TREL0000244_042
[245] SHPL0000275_013
[246] HCDO0001015
[247] HCDO0001015, page 10

have been born of extensive experience of clinical use. In light of the evidence the Inquiry has heard about patient engagement and consent, nor could this preference have stemmed from, or even had regard for, the preferences and choices of patients, most if not all of whom would have (at that point) no experience of concentrates.

328. It follows, in our submission, that the Haemophilia Centre Directors had decided that the comparative ease of use and certainty of potency in concentrates were more important factors than the increased risk of transmissible disease. It follows that, where they did discuss the comparative risks of treatment options with patients, they emphasised the benefits and trivialised the risks: *"Nothing worse than a mild flu"* is a phrase that has been repeated throughout the written and oral evidence of the infected and affected witnesses and which, for reasons already set out, could not have survived scrutiny at the time.

329. Finally, the same minute recorded under the heading "Any Other Business":

> *"There was a short discussion about laboratory precautions to be taken to protect the staff against infection with hepatitis…"*

330. What was good for the goose was, in fact, not good for the gander. The risk of hepatitis was sufficient to warrant precautions for the protection of staff who may be handling concentrates, but yet the minute failed to record a single instance of discussion on the precautions to be taken for patients, who would come to have concentrates (and any hepatitis) directly injected into their circulation. This is far from the only instance in the evidence collected by the Inquiry where a stark juxtaposition appears in the precautions taken to protect clinicians and laboratory workers from hepatitis, as opposed to those taken to protect patients.

Dr Peter Jones

331. In 1974, the Director of the Newcastle Haemophilia Centre, Dr Peter Jones, published the book "Living with Haemophilia",[248] which was intended as a layman's guide to (as the title suggests) living with haemophilia. It was written primarily for patients as a guide on how their condition should be treated and with what therapeutic materials.

332. Dr Jones began chapter five of the book, on therapeutic materials, with a description of the manner in which blood and plasma donations are procured. He wrote:

> *"Most of the materials used in the treatment of bleeding disorders are derived from human blood. This is provided by voluntary donors and is collected by a*

[248] RLIT0000041

transfusion service which may be local or national; in the United Kingdom the donors receive no payment for their generosity."[249]

333. The book omitted any mention of commercial plasma, collected from paid donors. On concentrates, Dr Jones said:

> *"The starting-point for the preparation of concentrates is pooled plasma from several donors. With care to prevent contamination with infection the pool is treated with various chemicals which separate it into a number of fractions, a procedure known as fractionation. The end product is freeze dried and just before use water must be added to make up a solution for injection. The advantages of the fractionation process are that because the factors are stable in their dry form the final product does not have to be stored in a deep freeze, and that a lot of activity is concentrated in a small volume. The disadvantages are that many many more blood donors are required as some activity is lost in processing. Processing is also more expensive, and there is a greater chance of serum hepatitis. This last disadvantage has lessened recently with the availability of laboratory tests for hepatitis virus; all blood is now routinely screened before use."*

334. A reader would be forgiven for understanding this chapter to say that factor concentrates used in the UK were sourced from British, volunteer donors, whose blood had been screened to all but exclude the risk of hepatitis. In fact, at the point of publication in 1974, two commercial products (Baxter's Hemofil and Immuno's Kryobulin) had been licensed, both sourced from foreign, paid donors and both manufactured from pools well in excess of "several donors": even NHS pools were several hundred (rather than several) donations in size by the time of publication.

335. Dr Jones went on (at page 78) to describe serum hepatitis as a rare but important side-effect of blood transfusion. He concluded by saying

> *"With all the precautions serum hepatitis is nowadays a rare cause of jaundice and it is far more likely that the patient presenting with jaundice has infectious hepatitis which is spread by contact like influenza. Anyone with either type of hepatitis in hospital will find themselves being barrier nursed to prevent spread to other patients and members of staff."*

Again, a reader would be excused for understanding serum hepatitis to be an unlikely side-effect to treatment for their haemophilia rather than an inevitability.

336. The second edition of Dr Jones book was not published until July 1984, by which point the AIDS crisis would be well underway. This book was likely to have been the most comprehensive, single source of information available to haemophiliacs and their

[249] RLIT0000041_0079

families. The fact that the book, until 1984, attributed serum hepatitis to a single virus which was screened for amongst blood donors, and which was said to pose a rare risk of jaundice to haemophiliacs, was one example (though by far the sole example) of the extensive misinformation that haemophilia patients were supplied with.

337. The second edition of Jones' book,[250] published in 1984, finally noted the inclusion of paid, foreign donor plasma in treatment products, and recognised that NANB hepatitis is important because it can lead to chronic liver disease. The second edition is perhaps most notable for its brief comment on AIDS, where Jones explains that the syndrome is an unknown in haemophilia but, against this unknown threat, his advice is clear and straightforward: patients should *"continue to treat their bleeds as quickly and as effectively as possible"*. We consider this a surprisingly bold statement given that, for the reasons set out earlier in these submissions, it should have been apparent to Jones and his colleagues by no later than 16 July 1982 that AIDS posed a very real threat to haemophiliacs, as indeed was recognised by many other writers. On any analysis, Jones' nugget of advice did not age well.

Dr Craske and the Hepatitis Working Group

338. Elsewhere in 1974, Dr Craske became substantively involved with the Haemophilia Centre Directors. It appears that Dr Craske was approached - or took an interest - following an outbreak of HBV caused by a batch of Hemofil. The epicentre of the outbreak was Bournemouth. Dr Craske issued a report on the outbreak in 1975 or shortly thereafter.[251] Dr Craske's report was made available to the UKHCDO at their July 1975 meeting,[252] and it was here that Craske *"undertook to draw up a plan to study the incidence of various types of hepatitis at different Centres and the relationship of infection to the various types of materials used."*

339. By December 1977, Dr Craske had been installed as the Chair of the UKHCDO's Hepatitis Working Group.[253] In 1979, the Working Group issued a report to the UKHCDO[254] which set out, inter alia, that two overt cases of NANB had been detected from 1,329 infusions of cryoprecipitate, as compared with 31 cases from 2,544 treatments with concentrates. The respective rates of icteric NANB hepatitis arising from the treatments were 0.15% and 1.22%: in short, concentrates were, on the Group's findings, 8.1 times more likely to lead to an overt case of NANB hepatitis.

---

[250] PRSE0004552
[251] CBLA0000566
[252] HCDO0001017
[253] HCDO0000544
[254] HCDO0000270_090 and WITN1055006 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'

340. Significantly, the Hepatitis Working Group noted in their report that a symptomatic acute phase of HCV infection was associated with a substantially reduced risk of progression to chronic infection.[255] However, in only analysing overt cases of NANB hepatitis, the Working Group could never hope to appreciate the long-term morbidity and mortality of HCV infection, because the people in whom they invested their interest were the most likely to self-clear within six months and, therefore, were less likely to display long-term sequalae.

341. Shortly prior to the publication of this report, on 8 February 1978 Dr Craske proposed a retrospective study of haemophiliacs infected with NANB hepatitis, utilising haemophiliacs maintained on cryoprecipitate and those not in receipt of implicated batches as controls. The study was ultimately funded by the DHSC and extended to run for three years[256].

342. At this juncture in the chronology (although not related to Dr Craske's study), a remarkable coincidence in timing occurred for one of our clients. WITN1103 had a family history of mild haemophilia and, on no apparent other basis, he was considered to be a mildly affected haemophiliac under the care of the Birmingham Children's Hospital.[257] This would ultimately (and perhaps unsurprisingly) turn out to be a misdiagnosis. Born in 1979, as a very young baby, on 28 November 1979, WITN1103 required an operation for which it was initially recommended that cryoprecipitate cover be maintained for seven days. Ultimately, it is recorded that Dr Hill arranged FVIII concentrate cover instead and it is from this decision that WITN1103's infection with HCV occurred.

343. What is particularly remarkable about Dr Hill's decision to administer FVIII was his knowledge of chronic liver disease caused by hepatitis from commercial concentrates. Dr Hill had attended a UKHCDO meeting just a matter of days before WITN1103 was admitted to his care. At this UKHCDO meeting,[258] Dr Craske reported:

> *"The Working Party felt that it was important for the incidence of chronic hepatitis in haemophilic patients to be assessed. There was much discussion regarding the incidence of chronic hepatitis in haemophilic patients, the possible value of liver biopsies and the type of information which directors would be willing to give to the working party…"*

344. Underlying Dr Craske's comments were the findings of the Hepatitis Working Party, that preliminary results from an Oxford study had found evidence of chronic liver

[255] EXPG0000001_0026
[256] CBLA0000727
[257] WITN1103011
[258] HCDO0000015_068_0015

disease.[259] Armed with this information, and mere days later, Dr Hill still infused WITN1103 with commercial concentrates.

345. Further to this, Dr Hill had long been aware (and indeed preached himself) the hepatitis risk posed by freeze dried concentrates. At a meeting of the West Midlands Regional Health Authority on 22 November 1976,[260] the following minute was recorded:

> *"Dr Hill referred to the hepatitis risk in respect of freeze dried Factor VIII concentrate obtained from commercial sources, and with this in mind he asked whether it might not be advantageous to reserve the supplies of concentrate obtained from the Lister Institute for children, leaving the concentrate obtained from commercial sources, largely of foreign origin, for adults. Dr Stuart agreed with Dr Hill as to the hepatitis risk, and said that in case of doubt he would prefer to use cryoprecipitate for children rather than commercially obtained freeze dried Factor VIII concentrate."*

344. During the course of the Inquiry's presentation on the Birmingham hospitals, the juxtaposition between Dr Hill and Dr Stuart's 1976 conversation and WITN1103's subsequent treatment was not lost, the following exchange took place between the Chair and Counsel to the Inquiry:

> *"**SIR BRIAN LANGSTAFF**: So it would be open to the inference that cryoprecipitate was perfectly acceptable as cover?*
>
> ***MS RICHARDS**: Yes, and for reasons that we do not know, Factor VIII concentrates were used instead, commercial Factor VIII concentrates, in this very young baby with mild haemophilia.*
>
> ***SIR BRIAN LANGSTAFF**: Who didn't actually have it, but they didn't know that at the time?*
>
> ***MS RICHARDS**: No. Who did contract hepatitis C, probably as a result of this infusion.*
>
> ***SIR BRIAN LANGSTAFF**: Yes.*
>
> ***MS RICHARDS**: You'll see how that -- you'll see the coincidence of timing, if I can put it that way, in terms of that treatment following on from the discussions at the UKHCDO meeting."*[261]

[259] HCDO0000135_023_0005
[260] SHIN0000043
[261] Transcript 27/10/2020, Pg 50, Line11

345. Whilst the Chair and Counsel to the Inquiry were referring to the coincidence of timing in Dr Hill's acknowledgment of the risk of concentrates and then subsequent treatment of a baby with such concentrates, another coincidence of timing occurs in this context: on 10 May 1979, Dr Craske wrote to Dr Aronstam at Lord Mayor Treloar College ("LMTC") encouraging the use of concentrates in mild haemophiliacs.[262] Dr Aronstam replied on 14 May 1979 in what appear to be angry tones:

> *"We have not had any cases of hepatitis following N.H.S. Factor VIII. As far as your suggestion about transfusing mild haemophiliacs with this material is concerned, I totally disagree with this concept. I do not wish any of my mild haemophiliacs to develop hepatitis in any form and therefore adopt the policy of either using D.D.A.V.P. or Cryoprecipitate."* [263]

346. This exchange illustrates Dr Craske's developing interest in studying previously untreated patients. It is reasonable to assume that he similarly encouraged other centre directors to extend their use of concentrates to those in whom the clinical need was not absolute. The question which WITN1103 has is whether Dr Hill's apparent volte-face in acknowledging the risks of concentrates and then transfusing them to a misdiagnosed baby was influenced by Dr Craske's research ambitions?

347. Following the conclusion of his retrospective concentrates study, Dr Craske reported to the UKHCDO on 24 September 1981, noting:

a) A 4-20% greater incidence of overt NANB hepatitis in those treated with commercial concentrates rather than NHS concentrates;

b) 70-80% of overt cases of NANB hepatitis were associated with a first exposure to concentrates; and

c) Donor screening appears to have eliminated any difference between commercial and NHS concentrates in relation to HBV infectivity.

346. Prior to the conclusion of this study on 2 July 1980, Dr Craske had submitted proposals for a prospective study to assess the risk of transmission of HBV and NANB hepatitis in newly diagnosed haemophiliacs.[264] In our submission, Dr Craske was seeking to establish the infectivity of the blood products by testing them on previously untreated patients who, by that point, were in such short supply that the severity of their condition (and, therefore, their need for replacement therapy) had become a secondary consideration after their status as a virgin patient.

---

[262] HHFT0000916_003
[263] HHFT0000916_002
[264] CBLA0001466

347. This was confirmed in 1982 when Dr Craske forwarded his proposals for a prospective study on the incidence of acute and chronic hepatitis in haemophilia as a result of first exposure to concentrates or cryoprecipitate to Dr Rizza. In his proposals, Dr Craske wrote:

> *"The only way of determining whether any of these methods [of viral inactivation] is effective in activating hepatitis viruses in these products is by chimpanzee inoculation or a prospective study in haemophiliacs who have had no previous exposure to concentrate. Chimpanzees are in short supply, so in the absence of laboratory tests for non-A, non-B, hepatitis trials in patients likely to be susceptible to non-A, non-B, hepatitis present the only possible way of evaluating this risk."* [265]

348. Here, Dr Craske was echoing the sentiment of Dr Bloom and Dr Rizza in the now infamous 'cheaper than chimps' letter of 11 January 1982[266] and showing how, by the second half of 1982, the prevailing attitude across the UKHCDO was that it was perfectly acceptable to test the infectivity of plasma products on patients in the absence of animal subjects.

The Advent of Aids

349. The development of knowledge about HIV/AIDS and the risk it posed to haemophiliacs has already been traversed at length and need not be repeated here. However, it is worth recalling that by July 1982 the threat of AIDS to haemophiliacs should have been appreciated as a result of the CDC's publications. Nevertheless, by January 1983 the issue of AIDS remained a footnote or afterthought in the minute of the meeting of the UKHCDO which took place on 8 January that year: the Directors noted that AIDS was similar in its epidemiology to HBV, and that the working party ought to enquire about the likelihood of transmission of the disease through blood and blood products.[267] In our submission, this lack of recognition of the severity of risk posed is characteristic of the UKHCDO's lethargic approach to addressing emerging threats.

350. Just over a month later, on 14 February 1983, at a further meeting of the UKHCDO, it was recognised that reports from the US suggested that the incidence of AIDS might be higher than previously thought, and there was concern that UK haemophiliacs who had received American concentrates might be at greater risk.[268] The Directors asked Dr

---

[265] OXUH0001617_002

[266] ARCH0001640 and WITN1055006 - Grayson, C. (2007) 'Blood Flows Not Just Through Our Veins But Through Our Minds. How Has The Global Politics of Blood Impacted On The UK Haemophilia Community?'

[267] HCDO0000003_058

[268] HCDO0000411

Craske to prepare a reporting form and suggested that an epidemiologist be added to the Working Group. Two important points arise from this meeting:

a) There was no suggestion whatsoever that AIDS in haemophiliacs was caused by the cumulative effect of repeat transfusions, or that there was anything innate about replacement therapy which could cause immune compromise. In fact, to the contrary (and in apparent recognition of AIDS being caused by a transmissible agent), it was recommended that an epidemiologist be added to the Working Group tasked with addressing the problem; and

b) Despite the Working Group recognising that the incidence of AIDS was higher than previously thought, and that UK haemophiliacs might be at an increased risk, there was no proposal to re-evaluate the suitability of different types of treatments, no suggestion that concentrates should be confined to use in certain emergency situations, nor any proposal to implement a system of batch dedication in order to minimise risk. There was, in short, no meaningful response to the risk.

351. At a special meeting of the UKHCDO on 13 May 1983, the Directors bemoaned press reports about the threat of AIDS from imported blood products, which had caused anxiety to haemophiliacs. Despite acknowledging those reports, the group still failed to take any substantive action to minimise or reduce the risk to haemophiliac patients. As set out in the previous section of these submissions, the Directors agreed that in relation to the use of factor VIII concentrates:

a) In patients displaying signs of HIV/AIDS, since the condition was thought to be irreversible there was no clinical benefit in changing treatment;

b) More generally, it was considered circumspect to continue with the policy of reserving NHS concentrates for children and mildly affected haemophiliacs, but that there was insufficient evidence to restrict the use of imported concentrates for other patients.

352. This policy only applied to factor VIII concentrates, because the UK was largely self-sufficient in FIX concentrates and so there was little, if any, cause for concern about the enhanced risk of imported products in the case of Haemophilia B. The decision by the Directors to continue in their use of FVIII concentrates notwithstanding the known, increased risks showed a complete disregard for patients who may have previously been treated with commercial concentrates yet escaped infection thus far: by continuing to expose those patients to concentrates, the Directors were allowing them to face an ever increasing risk of acquiring infection.

353. For this to be overlooked by a group of professionals indicates either the scant regard held for the safety of haemophiliacs, and/or the deficient manner in which the group approached their responsibilities toward patients and the identification of safe treatments: the conclusion that the immense benefits of therapy outweighed the risk of infection was made flippantly and without any proper analysis or risk assessment. In any event, the balance of risk versus reward should only ever have been conducted by a patient, in receipt of advice on both the risks and the rewards in the case of treatment or abstention.

354. The UKHCDO met again on 13 February 1984. Despite the passage of time and the ever-pressing concerns and knowledge in relation to the transmission of AIDS through blood products (as set out earlier in this submission), the Directors still failed to seek out or consider any practical measure to reduce the risk posed to those under their care. Despite noting that a third of European respondents to a survey launched by Professor Bloom had indicated that they had altered their treatment practices in response to AIDS, there was still no discussion amongst the UKHCDO about making similar changes, or otherwise substantively responding to the risk.[269] Although Dr Craske did seek an amendment to previous minutes to record that the use of non-heat-treated products in previously untreated patients should be avoided, there was still a glaring omission in the failure to consider the exposure of those who had previously been treated with commercial products without contracting infection, and for whom continued exposure to commercial products was, therefore, exceedingly risky.

355. The UKHCDO's actions from this point in the chronology onwards were well ventilated at the Inquiry's hearings and, in short, can be characterised as a shocking failure to change or adapt course, despite the wealth of information and knowledge that was emerging. In our submission, it is evident that the Centre Directors had, at an early stage, become entrenched in a position from which they could not extricate themselves; they had committed to maintaining the use of concentrates (whether foreign or domestic) and had missed the opportunity to lobby for a reversion to cryoprecipitate.

356. The Centre Directors could not change course or openly reverse their position because to do so would have necessitated finally explaining to patients the true magnitude of the risks that were posed by factor concentrates and that, in fact, HBV, HCV and HIV were the primary (and significant) risks of treatment with concentrates. Even worse, the Inquiry has seen evidence that the Directors made no attempt to remove concentrates, known to be contaminated, from their shelves; in her first written

[269] HCDO0000415

statement, Colette Wintle described being treated with unheated Alpha FVIII concentrates in preference to the DDAVP which her mild condition warranted[270] equally, each and every one of our misdiagnosed clients ought to have been treated with DDAVP, if at all.

357. As the 1980s progressed, the Centre Directors came slowly to the realisation that the scale of infection inflicted upon the bleeding disorder community was terrible. However, they were torn between trying to find support for their patients and trying to protect their own positions. This much was demonstrated in minutes of subsequent UKHCDO meetings; for example, in the minute of the meeting on 29 September 1988,[271] reports of the Macfarlane Trust being put in funds were accompanied by notes of the threat of litigation from patients.

358. Whilst supporting calls for some form of no-fault compensation to be paid to HIV-infected haemophiliacs, the UKHCDO were also arranging meetings with the Medical Defence Union,[272] who advised them on the unlikelihood that they would be found liable providing that they had acted in accordance with an established body of medical opinion.

359. It is a shame that many of those at the head of the UKHCDO throughout the 1970s and 80s were unable to give evidence to the Inquiry, but we commend CTI for the presentations that were produced and endorse and adopt their content.

360. As a final note, we submit that the dysfunction and disconnect between haemophilia patients and those treating them grew over the decades, negatively impacting the standard of care that was given to those with bleeding disorders. The attitude of some in the UKHCDO was nothing short of hostile and offensive towards their patients, as was is typified in Dr Gerry Dolan's email to other members of the UKHCDO on 12 July 2004, where he wrote:-

> *"I agree with Charlie's suggestions. My first impression of this letter was that he clearly did not know the background to this or the dismay of the haemophilia treater community who are f*****g sick of being the first route of attack for many patients who have been warped by their experiences.*
>
> *I would suggest you take him aside, point out that this is a hornet's nest and that any suggestion of including it in an audit process would not be well received…"*[273]

[270] WITN1056001
[271] BART0002329
[272] HCDO0000430
[273] HCDO0000254_558

361. Attitudes of some involved in the treatment of patients with factor concentrates have remained shocking even through the currency of the Inquiry; the Chair will recall the shocking response of Dr Nalini Naik[274] to the written statement of Stuart McLean.

362. The way in which the infected community were dismissed demonstrates the desire, at that time, for haemophilia care to forget about the past and focus on the new generation of patients who had not yet been infected. Irrespective of the emotions and context behind the e-mail, the fact that it was sent to other UKHCDO members demonstrates a level of comfort in making the comments to UKHCDO colleagues which, in turn, suggests that there was an expectation that those comments would be welcomed, understood, or, at the very least, not received with hostility. This speaks to the attitude of the UKHCDO, taken as a whole.

[274] WITN3802001

7. CRIMINAL LAW

362. In the oral opening we described the criminal consequences which flow from the supply of blood products to individuals in the knowledge that they carry a high risk of causing a serious illness:

a) If that supply caused the contraction of Hepatitis B, C or HIV, it amounted to grievous bodily harm ("GBH"), even if the person supplied did not die immediately;

b) If the supplied person died as a consequence of that supply and subsequent infection, this amounted to murder; and

c) If the person supplying the blood product supplied it in the knowledge that it may cause some harm, but not necessarily serious harm, then that would be an assault and, if death flowed, manslaughter.

363. This section of these closing submissions will define the criminal offences that may have been contravened, and also consider what evidence, including evidence about consent and medical ethics, may have a bearing on the application of the criminal law to treatment with infected blood.

Murder

364. The crime of murder is committed, where a person:

a) Of sound mind and discretion (i.e., sane);

b) Unlawfully kills (i.e., not self-defence or other justified killing);

c) Any reasonable creature (human being);

d) In being (born alive and breathing through its own lungs;[275]

e) Under the Sovereign's Peace;

f) With intent to kill or cause GBH.

365. Section 1 of the Law Reform (Year and a Day Rule) Act 1996 abolished the conclusive presumption at common law that a death was not murder (or any other form of homicide) if it occurred more than a year and a day since the act (or omission) that

[275] *Rance v Mid-Downs Health Authority* (1991) 1 All ER 801 and *AG Ref No 3 of 1994* (1997) 3 All ER 936

was alleged to have been its cause (known as the 'year and a day rule'). The remaining provisions of the Act state that where a death occurs more than three years after an injury, or where the accused was previously convicted of an offence committed in circumstances connected with the death (for example, a previous conviction for GBH), criminal proceedings can only be instituted with the consent of the Attorney General.

366. The 1996 Act does not have retrospective effect. As such, the vast majority of those who have died (and who will die) as a result of the infected blood scandal will have received their treatment long before the abolition of the year and a day rule. The effect of this is that, unless the law were to be changed, no prosecution for criminal acts with the consequence of death will be possible.

367. For the purposes of a murder charge, the Prosecution must show an intention to kill or cause GBH. However, a jury may draw an adverse inference of intent from foresight.[276]

368. Attempted murder requires the existence of an intention to kill, not merely to cause grievous bodily harm.[277] The requisite intention to kill can be inferred by the circumstances.[278] It is possible that an allegation of attempted murder could be laid even though the victim died, i.e. in circumstances which would normally amount to murder save for the operation of the year and a day rule.

The prosecution must always show a causal link between the act or omission and the death. The act or omission must be a substantial cause of death, but it need not be the sole or main cause of death. It must have "*more than minimally negligibly or trivially contributed to the death*"., as per Lord Woolf MR in *R v HM Coroner for Inner London ex p Douglas-Williams* [1999] 1 All ER 344. Furthermore, it does not matter that a defendant's act or omission merely "*hastened*" the victim's death, as the defendant must take his victim as he finds him under the 'egg-shell skull' rule.[279]

Manslaughter

369. Involuntary manslaughter occurs where a person kills another, but does so without the intent to kill or cause GBH. Apart from the absence of the requisite intent, all other elements of the offence are the same as for murder. There are two types of involuntary manslaughter, namely:

    a) That caused by a defendant's unlawful and dangerous act

[276] *R v Woollin* [1999] 1 Cr App R 8 (HOL)
[277] *R v Grimwood* (1962) 3 All ER 285
[278] *R v Walker and Hayles* (1990) 90 Cr App R 226
[279] *R v Dyson* (1908) 1 Cr App R 13; *R v LeBrun* (1991) 4 All ER 673

b) That caused by a defendant's gross negligence.

Unlawful Act Manslaughter

370. Unlawful act manslaughter occurs where the killing:

a) Is the result of the defendant's unlawful act (not omission);

b) Where the unlawful act is one which all sober and reasonable people would realise would subject the victim to the risk of some physical harm;

c) Whether or not the defendant realised the risk of physical harm.

371. On the question of knowledge of harm, the unlawful act need not be directed against a particular person.[280] The accused's state of mind is relevant only to establish that the act was committed intentionally and that it was an unlawful act. Once these points are established, the question whether the act was dangerous is to be judged not by the appellant's appreciation but that of the sober and reasonable person, and it is impossible to impute the mistaken belief of the defendant that what he was doing was not dangerous.[281] Furthermore, the knowledge attributed to the sober and reasonable person is that which such a person would acquire as an observer of the whole course of the defendant's conduct throughout the unlawful act.[282]

Gross Negligence Manslaughter

372. This is where the death is a result of a grossly negligent (though otherwise lawful) act or omission on the part of the defendant. The law in respect of this offence was clarified in the case of R v Adomako (1994) 3 All ER 79, where a four-stage test for establishing gross negligence manslaughter (now known as the Adomako Test) was outlined by the House of Lords:

a) The existence of a duty of care to the deceased;

b) A breach of that duty of care;

c) Which causes (or significantly contributes) to the death of the victim; and

d) The negligence should be characterised as gross and criminal in nature.

---

[280] *R v Willoughby* (2005) 1 WLR 1880

[281] *R v Ball* 1989 CLR 730.

[282] *R v Watson* (1989) 2 All ER 865; *R v Dawson* (1985) 81 Cr App R 150; *R v Carey* and others (2006) EWCA Crim 17.

373. It is for the judge to decide whether or not there is evidence capable of establishing a duty. Thereafter, the question of whether a duty of care existed is a matter for the jury.[283] In our submission, it is very unlikely that a jury would find that a medical practitioner who was treating a patient would be outside the definition of a duty of care, particularly in light of civil case law on the topic,

374. Breach of a duty of care is, by and large, a question of fact. Allegations of gross negligence manslaughter can be (and often are) based upon an alleged omission to act.

375. Reasonable foreseeability is judged by reference to the knowledge that a reasonable person in the defendant's position would be expected to possess and should have foreseen. Whether the defendant did, in fact, foresee the risk is not relevant. Although the test is objective, it takes account of the characteristics of the defendant (for example, their age) in determining what is reasonably foreseeable. The precise manner in which an incident occurs need not be foreseeable: it is sufficient that the type of harm which might result (i.e. physical harm) is foreseeable. The risk of death is relevant to the question of whether a breach of duty is "gross", which we return to below. .

376. The requirement of proximity focuses on the relationship between the victim and the defendant. In the Australian case of Sutherland Shire Council v Heyman (1985) (1985) 60 ALR 1, Dean J described the proximity requirement as involving:

> *"The notion of nearness or closeness and embraces physical proximity (in the sense of space and time) between the person or property of the plaintiff and the person or property of the defendant, circumstantial proximity such an overriding relationship of employer and employee or of a professional man and his client and what may (perhaps loosely) be referred to as causal proximity in the sense of the closeness or directness of the causal connexion or relationship between the particular acts or cause of conduct and the loss or injury sustained. It may reflect an assumption by one party of a responsibility to take care to avoid or prevent injury, loss or damage to the personal property of another or reliance by one party upon such care being taken by the other in circumstances where the other party knew or also have known of that reliance."*

377. The concept of foreseeability and proximity overlap: the more an injury to a particular victim is foreseeable, the more likely that the victim will be deemed to be sufficiently proximate. Physical proximity may be relevant, but it is not an essential requirement: a manufacturer is probably many miles from the consumer, but there is a relationship of proximity if the product causes injury. In Muirhead v. Industrial Tanks Specialties

[283] *R v Willoughby* [2005] 1 Cr. App. R 29 at [24].

Limited [1985] 3 All ER 70S, Goff LJ said that proximity is used as a convenient label to describe a relationship between the parties by virtue of which the defendant can reasonably foresee that his or her act or omission is liable to cause damage to the claimant of the relevant type.

378. Whether, having regard to the risk of death involved, the defendant's conduct was so bad in all the circumstances as to amount to a criminal act or omission is a matter for a jury.[284]. However, the breach must be something more than simply falling below the standard of reasonable care:

> *"In explaining to juries the test which they should apply to determine whether the negligence, in the particular case, amounted or did not amount to a crime, judges have used many epithets, such as culpable, criminal, gross, wicked, clear, complete: But, whatever epithet be used or whether an epithet be used or not, in order to establish criminal liability the facts must be such that, in the opinion of the jury, the negligence of the accused went beyond a mere matter of compensation between the subjects and showed such disregard for the life and safety of others as to amount to a crime against the state and conduct deserving punishment.* [285]

379. 'Grossness' remains the most actively appealed area of safety manslaughter cases, notwithstanding that the fundamental legal framework has not changed since *Adamako*.

380. Although criminal liability for gross negligence manslaughter can be founded upon work related deaths, only individuals can be charged with gross negligence manslaughter. Non-natural persons, that is, organisations, cannot be charged with gross negligence manslaughter and instead the statutory offence of corporate manslaughter[286] applies.

381. In R v Singh (Gurphal) [1999] Crim LR 582, (CCA), the Court of Appeal described a model direction as one in which a trial judge had stressed that the circumstances must be such that a reasonably prudent person would have foreseen a serious and obvious risk, not merely of injury or serious injury but of death.

382. In gross negligence manslaughter offences, as with all homicide offences, liability arises upon proof that the defendant's act, the grossly negligent breach of the duty of care, was a substantial cause of the death or otherwise contributed significantly to it

[284] *R v Adomako* [1995] 1 AC 171.
[285] 19 Cr. App. R8 at 11-12.
[286] Corporate Manslaughter and Corporate Homicide Act 2007 (CMCHA 2007).

(in the sense of having more than a minimal contribution) and thus it need not have been the sole or principal cause of the death.[287]

Medical Manslaughter

383. Medical manslaughter is, as a matter of law, no different from gross negligence manslaughter. The term 'medical manslaughter' refers to medically qualified individuals who are performing acts within the terms of their duty of care when the act or omission occurs. Where a medical individual is appointed to take charge of a person, they then take on a duty of care towards them. Simply being a doctor or nurse in a hospital will not necessarily mean there is a duty of care to a specific patient.

Issues For Consideration in this Inquiry

384. Is the issue of criminal liability complicated by the fact that, in this Inquiry, we are dealing with doctors who treated patients, we assume, in good faith and who did not want the outcome of harm, serious harm, or death but went ahead with the treatment anyway knowing of the risk? And then there are those who sought to trial products or experiment, knowing the risks posed to their patients. To what extent, if at all, does the doctor/patient relationship provide any defence to the criminal offences set out above? What amounts to consent and could it amount to a defence? Lastly, are there circumstances which override criminal responsibility, such as a wider public interest in the provision of treatment or testing?

385. It must be noted that consent has, in the evidence before the Inquiry, been a constant theme running through the chronology of the events examined: beginning first with effective consent for treatment, through to consent to viral testing and, ultimately, consent to remove body parts from those who had died of their infections.[288]

Evidence About Treatment and Consent

385. The Inquiry has read and heard a vast amount of evidence from medical professionals who described their historic attitudes to treatment, as well as their state of knowledge as to what those treatments could cause. The Inquiry has also heard disputed evidence about the degree of knowledge held by haemophilia patients. This evidence has not only revealed an area of factual dispute which the Inquiry will need to resolve,

[287] See *R v Pitts* 918420 C and Mar. 248; *R v Curley* (1909) 2 Cr. App. R 96 (CCA) 109; *R v Cato* (1975) 62 Cr. App. R 41 at 46.
[288] Carol Grayson told the inquiry of the removal of Stephen Longstaff's brain at autopsy without the family's knowledge or consent – WITN1055004_0126

but it has also raised the question of whether knowledge can ever, without more, amount to consent and, if so, what level of knowledge is required.

386. In other jurisdictions, statute has defined the concept of consent and how this must be dealt with by the medical profession: for example, the South Australia Consent to Medical Treatment and Palliative Care Act 1995.[289] Although less flexible, the benefits of a statutory approach to consent include ensuring that: the obtaining of consent is treated with the paramountcy that it deserve; little is left to chance; and ambiguity should be minimised.

387. Dr Janet Shirley's evidence provides an example (but is far from the only example) of the doctor-centric approach (as opposed to patient-centric approach) to the treatment of and consent sought from haemophilia patients:

> *"I tended to use cryoprecipitate first for mild and moderate haemophilia patients and if this did not lead to sufficient factor VIII or IX level I would then switch to the factor concentrate provided by NBTS Tooting. For severe haemophilia patients I usually used factor concentrates for bleeding episodes…*
>
> *I do not recall providing any information to patients with a bleeding disorder about the risks of infection in consequence of treatment with blood products prior to such treatment commencing. In my view it was the responsibility of the patients' Haemophilia Reference Centre… Patients should have been informed about this by their Haemophilia Reference Centre once it became known that there were hepatitis viruses in blood. However, there was the need to balance treatment of severe and life-threatening bleeds against the risk of hepatitis B (only hepatitis A and B viruses were known at the beginning). At the time hepatitis B was thought to be a risk worth taking compared to early death and/or severe disability if patients were not treated…*
>
> *In order to treat patients with factor concentrates and other blood products it is necessary to insert an intravenous needle. This cannot be done without the patient consenting. Patients therefore gave implied and oral consent to this procedure and the transfusion of blood products…*
>
> *Patients were tested for HIV without their consent. The reason for this was that insurers would not insure people if they said they had been tested for HIV regardless of a negative result… The approach to obtaining consent for testing was implied or oral."*[290]

388. On the other side of the equation, the Inquiry heard from haematologists attached to Associate Haemophilia Centres, who said that they did not consider it their

[289] Consent to Medical Treatment and Palliative CareAct 1995 (legislation.sa.gov.au)
[290] WITN3901019_0008

responsibility to advise patients about the risks of haemophilia treatment, because this ought to have been done by the haematologist at the reference centre to which the patient was attached.[291]

389. It would appear that Dr Shirley – along with many other treating doctors[292] - took the risk that patients did not understand the risks from treatments, and that her patients had not had those risks explained elsewhere. With those significant gaps in her knowledge, the assumed consent she worked under was valueless.

390. Other physicians told the Inquiry that their usual method of informing patients about the risks of blood products was to place leaflets produced by the Haemophilia Society in their centres.[293] The fact that such an approach could ever be described by a professional as "informing" patients, in circumstances where it cannot be known whether a patient has even laid eyes on the material, is indicative of the profession's slipshod approach to consent. Other examples heard by the Inquiry included patient consent being "implied" by the fact that the patient offered their arm up for injection.[294]

391. If doctors never explained the risks of haemophilia treatments to their patients, then their averments that "*HBV was a risk worth taking*" were baseless: whether a risk is "*worth taking*" or is sufficiently palpable can only ever be determined by the patient. Yet the Inquiry heard time and time again of this assessment being made only by reference to the view of the physician and without the input or consideration of the patient.[295]

392. Some physicians told the Inquiry that they did not seek consent to test haemophiliacs for HIV because they were aware of the difficulties in obtaining insurance if a patient knew of a positive response, and wished to spare their patient such difficulties.[296] Even if taken at face value, a benevolent intention cannot provide a defence at criminal law: such matters of administration clearly fell well short of the exceptions to consent in emergency situations, or the so-called 'therapeutic exception' covering circumstances where material disclosure could be detrimental to the health of the patient.[297]

---

[291] WITN3901019, pages 15-16

[292] Prof Preston states in his report [LDOW0000136_0004] for Peter Longstaff (Carol Grayson's husband) that "in conclusion therefore, during the mid-1970's and early 1980's there was clear evidence that non-A, non-B hepatitis was an important cause of post transfusion hepatitis."

[293] Transcript 11/12/2020

[294] WITN3901019_0018

[296] WITN3901019, page 19

[297] INQY0000241, page 29

393. Even where consent to a broad course of treatment was forthcoming, the experience of Colette Wintle and her parents demonstrates that the profession failed to share key information about the treatment, thus robbing the consent of its 'informed' nature, and therefore validity:

> *"My parents had naturally assumed I was being treated with British produced clotting factors, so it was a complete shock for them to learn many years later that I had actually been infected through imported concentrates… the worst part was that a doctor had struck through the original proposed treatment of choice which was Cryoprecipitate, and instead Factor VIII was written over it."*

394. The Inquiry has heard suggestions that these approaches can be explained by historical differences. For example, Dr Winter said:

> *"Medical practice was very different in the 1980s, particularly in relationship to the issues of patient consent and of patient involvement in decision making. Overall, there was a more paternalistic approach."*

However, an analysis of the materials available at the time demonstrates that those suggestions cannot withstand scrutiny, nor provide an answer to the complaints of those infected by blood products. The British Medical Association's 1980 Handbook of Medical Ethics took a more stringent approach to consent than that outlined in our clients' evidence:

> *"1.8 The patient's trust that his consent to treatment will not be mis-used is an essential part of his relationship with his doctor but for a doctor to touch a patient without consent is an assault. Consent is valid when freely given if the patient understands the nature and consequences of what is proposed. Assumed consent or consent obtained by undue influence is valueless…"*[298]

395. In addition, CTI's presentation set out the contemporaneous guidance available to medical practitioners as regards consent:

> *"The MDU produced a booklet*[299]*… this was also in 1953. The booklet made it clear that consent was a pre-requisite for medical treatment. Of particular interest are the following points: Clinicians were advised to seek written consent from patients, while recognising that this did not in fact often happen in private practice. In order to obtain consent, an explanation as to the need for the examination or treatment had to be given, in language that the patient would understand. Risks must be explained, unless it 'would be undesirable for psychological or other reasons to discuss these matters'. In such cases this*

[298] BMAL0000087
[299] MOJU0000001_008

information must be provided to a near relative who could consent (preferably in conjunction with the patient) to the treatment".

396. The Inquiry's Expert Report on Medical Ethics noted that in the 1970s doctors were given a "*wide discretion*" on a number of matters, including consent. However, notwithstanding that broad discretion, there was nonetheless a recognition that patients must be provided with, at least, a broad overview of the procedure to be undertaken (this included a "*recognition of the need to inform patients about important risks associated with medical interventions*"), and that consent obtained by misleading advice was unacceptable.[300]

397. Indeed, 'everyone was doing it' or that 'things were different then' can never be a complete answer to a charge of criminal misconduct. If it were, how could society and the law develop in the way that it has done? By way of example, the Inquiry's expert report refers to the Alder Hay organ retention scandal,[301] which resulted in an investigation identifying that this wrongful conduct was widespread. The introduction of guidelines, consent forms and new legislation in response to that scandal was not a recognition that the previous conduct had been lawful, but a recognition that criminal and unethical conduct was occurring and needed to be prevented.

398. There was additional BMA guidance (in both the 1970 and 1980 versions of the BMA's 'Medical Ethics' handbook) on 'new' therapeutic treatments and on clinical trials. Both handbooks put it absolutely beyond doubt that: the patient's interest had to come first; standards of ethics had to be high; and that consent had to be obtained "*after the patient has been given a full explanation*".[302] There was no question at the relevant time that the 'newness' of the treatment would give a doctor additional protection or leeway; in fact, as the materials show, this was a factor which justified the need for additional explanation and a careful approach to the treatment, as a matter of logic, ethics and contemporaneous guidance. However, the evidence heard by the Inquiry demonstrated that extremely lax approaches were taken to the concept of patient consent to new, experimental, and courses of treatment motivated by research.

399. Ultimately, as the Inquiry's expert report put it, "*If a patient accepts a treatment unaware of the known risks involved, then that person has in the first place been wronged and may subsequently be harmed*", and "*consent should be dynamic and responsive to the patient's health, needs and views*".[303] In our submission, all of these issues come down to a simple analysis: a patient can consent to treatment which may

[300] INQY0000241, pages 23-37
[301] INQY0000241, pages 10-11
[302] BMAL0000085, page 6; BMAL0000087, page 23
[303] INQY0000241, pages 51 and 13

carry a risk of harm, but a patient cannot consent to harm which may flow form treatment unless they have been provided with information on that harm, which should include sufficient information to enable the patient to reach a meaningful decision on whether to accept that risk. In circumstances where no consent to possible harm has been given, and where harm flows, the medical practitioner has always been liable to face the criminal consequences of their actions where a patient has been harmed or has died.

400. The Inquiry heard an extraordinary amount of evidence to indicate that effective consent was not routinely obtained from patients, who were denied any information about the risks of their treatment which, as these closing submissions have demonstrated, was known from as early as 1946 but emerging exponentially at the time of our clients' treatment in the 1970s and 1980s. These were not mere oversights but, in our submission, criminal non-disclosures and criminally misleading averments that no harm would come to patients (indeed, in some cases, that there would be nothing but a positive outcome).

401. Even by the standards of the day, the clinicians' approach to issues of consent were gross failings, demonstrative of the broader attitude (of which the Inquiry has also seen evidence) that doctors were superior and unimpeachable beings, possessive of deity-like judgement and wisdom, who should not have to explain their decisions to those who were fortunate enough to receive treatment.

402. In our submission, much can be explained by the fact that many haemophilia patients were being treated by (or were having their treatment dictated by) academics and scientists with little and inadequate training on, or knowledge of, the importance of patient care, a bedside manner, and issues of consent, as Dr Winter explained.[304]

Offences of Ill Treatment or Wilful Neglect

403. Pursuant to sections 20 and 21 of the Criminal Justice and Courts Act 2015, it is an offence for any individual to ill-treat or wilfully neglect an individual of whom they have care and, where such treatment has taken place, it is equally an offence if the overarching care provider's "*activities are managed or organised in a way which amounts to a gross breach of a relevant duty of care owed by the care provider to the individual who is ill-treated or neglected*". Those two offences were created as part of the Government's response to the public inquiry conducted by Sir Robert Francis QC into the events at Mid-Staffordshire NHS Foundation Trust, and closed a gap in existing legislation.

[304] WITN3437002_0024

404. The terms "ill-treatment" and "wilful neglect have been considered within case-law. In the case of R v Newington (1991 Cr.App.R. 247, CA.), the Court stated that ill-treatment requires the Crown to prove:

a) Deliberate conduct on the part of the offender which could properly be described as ill-treatment, irrespective of whether it damaged or threatened to damage the health of the victim; and

b) A guilty mind, involving either an appreciation by the offender at the time that he was inexcusably ill-treating a patient, or that he was reckless as to whether he was inexcusably acting in that way.

405. In R v Sheppard [1981] A.C. 394 the Court held that the primary meaning of wilful is "deliberate". Therefore, for example, someone who knows that the person in their care needs medical assistance and deliberately - that is by conscious decision - refrains from calling a doctor would be guilty of wilful neglect. Equally, a person who failed to provide medical care because he did not care whether or not it was needed or not would be reckless and therefore guilty.

406. These offences might have relevance to negligent treatment from the date of their enactment, and perhaps fill a gap that the Inquiry might wish to consider, but unfortunately, they will not assist or be available for those infected with contaminated blood.

Assaults/ABH

407. An assault is any act by which a person intentionally or recklessly causes another to suffer unlawful violence. Lack of consent is an element of the offence of common assault. Lack of consent can be inferred from evidence other than the direct evidence of the victim: CPS v Shabbir [2009] EWHC 2754 (Admin).

408. Actual Bodily Harm ("ABH") is committed when a person intentionally or recklessly assaults another. It must be proved that the assault caused the bodily harm. Bodily harm has its ordinary meaning and includes any hurt calculated to interfere with the health or comfort of the victim: this 'hurt' does not have to be permanent but must be more than transient and trifling. Psychological/psychiatric harm that involves more than mere emotions such as fear, distress or panic can amount to ABH.

409. In Brown (Anthony Joseph) [1994] 1 AC 212 the House of Lords ruled that in the absence of good reason, the victim's consent is no defence to a charge under the Offences Against the Person Act 1861 ("OAPA 1861"). This does not mean that any

harm caused by medical treatment results in a criminal act as in most medical circumstances "good reason" should apply.

Unlawful wounding/inflicting GBH – s.20 and s.18 OAPA 1861

410. The words "grievous bodily harm" have their ordinary meaning of "really serious" harm: DPP v Smith [1960] 3 W.L.R. 546. Life-changing injuries should be regarded GBH.

411. Cases which include the reckless transmission of sexual infection are particularly complex cases but could include circumstances where a patient known to be infected with HCV or HIV was not informed and who then was 'allowed' to carry on normal sexual relations which infected the patient's partner. Such an allegation would be complex as the criminal law has always been reticent to target omissions.

412. There are also other offences that may be relevant, including the following:

    a. Causing to be taken or administering a drug with intent to enable the commission of an indictable offence, contrary to s.22 OAPA 1861;

    b. Administering poison or noxious thing thereby endangering life or inflicting GBH, contrary to s.23 OAPA 1861.

413. Administering poison or noxious thing with intent to injure, aggrieve or annoy, contrary to s.24 OAPA 1861. Where an issue arises as to whether a substance is a noxious thing for the purpose of section 24 of the 1861 Act, it will be for the judge to rule as a matter of law whether the substance concerned, in the quantity and manner in which it is shown by the evidence to have been administered, could properly be found by the jury to be injurious, hurtful, harmful or unwholesome. If it can be properly so regarded, it will be a matter for the jury whether they are satisfied that it was a noxious thing within that definition.[305]

Obstruction of a Coroner

414. One other offence which should be considered is the old common law offence of obstructing a Coroner:

> *"The majority of deaths are not reported to the Coroner and, in most cases the deceased's doctor will issue a medical certificate with the cause of death without*

[305] Offences against the Person, incorporating the Charging Standard | The Crown Prosecution Service (cps.gov.uk)

reference to a coroner, especially if they have been treated for an illness which caused the death.

There is a common duty upon all citizens to give information which will inform a Coroner of circumstances for when an inquest should be held. It is a common law offence to obstruct a Coroner, whether by disposing of a body before a Coroner can openly inquire into the circumstances of a death or acting to prevent an inquest."[306]

415. The offence of obstruction of a Coroner may have been committed by doctors who did not record an accurate and truthful cause of death.

Charging of offences

416. The question of whether any criminal allegation is or should be pursued is complex and is a matter for the Crown Prosecution Service and not for the police. Basic questions will always need to be asked; for instance, does the evidence reveal that there is a better than 50:50 chance of the offence being made out? Complications will also always exist when the evidence is from some years ago and where some parts of the medical evidence is incomplete or unavailable.

417. The fact that allegations may go back to the 70s or 80s does not of itself preclude a criminal case being pursued but it does bring forward other questions such as the age of the potential defendant, which provides no defence on its own, but age may lead to questions of mental capacity or fitness to stand trial.

418. There is also a public interest element to the question of a prosecution which includes the question of cost; for instance, a common assault allegation might not be investigated if the practical financial cost and resource implications would be disproportionate to the outcome of a prosecution in such a case.

419. In conclusion this section has examined the potential criminal offences which might be available; the fact that the passage of time has affected whether allegations can be made or will be made is perhaps a factor which should be reflected in compensation considerations. Ultimately the criminal law is the last line of regulation and perhaps is something that should be given more attention in training within the medical profession if tragedies such as the Infected Blood scandal are to be prevented in the future.

[306] Coroners | The Crown Prosecution Service (cps.gov.uk)

8. GOVERNMENT DECISION MAKING

Government Knowledge of Risk

420. During the closing parts of Lord Owen's evidence Sir Brian Langstaff asked the following question:

> ***"Sir Brian Langstaff.*** *So just help me, if one were to ask what was the deliberate decision that damaged patients in this case, what would you say?*
>
> ***Lord Owen****: Well, I think that you could ideally have made the decision a lot earlier to go for self-sufficiency. We knew about the contamination of blood supplies. We did know about hepatitis. We didn't recognise AIDS for quite a while but in '82, from '82 onwards, it was recognised, and blood transfusions still went on"*[307]

421. Lord Owen was of the view that better and more coherent decisions had been made under a 'dual hierarchy' system, in which doctors were involved in the decisions:

> *"… in my day a structure in the Ministry of Health which had been introduced by Sir George Godber, one of the great Chief Medical Officers of Health that we have ever had, and this was a dual hierarchy, it was called, and no big decisions were ever taken that weren't taken by two individuals. One would be a representative of the Civil Service within the Department and the other would be a representative of the medical profession. It's one of, I think, the issues which may be, sir, you and your Inquiry will wish to address, that the dual hierarchy system was effectively abandoned in 1980 when the then Prime Minister queried why there were all these doctors in the Ministry of Health. Why weren't they out seeing patients? Why aren't they doing that?"* [308]

422. In the same vein, Lord Owen highlighted what he saw as the drive from the Treasury to dominate the Health Service:

> *"But the Treasury, of course, always wanted it to be run entirely by the Civil Service. They disliked the idea that the Department of Health was different and that there was input from the medical profession."*[309]

423. The knowledge of the risk from blood products was known within Government at an early stage in the infected blood scandal. This much was made clear by Lord Owen's review (for the New Statesman) of Titmuss' book "*The Gift Relationship: From Human*

[307] Transcript 22nd September 2020 p.172/3
[308] Transcript 22nd September 2020; page 16
[309] Transcript 22nd September 2020; page 17

Blood to Social Policy" (1970).[310] In his oral evidence, Lord Owen was referred to the following sections of the book:

a) P.142: *"In the United States, Britain and other modern societies the most dangerous of these hazards [and those are hazards resulting from the use of blood and blood products] is serum hepatitis. It is becoming a major public health problem throughout the world."*; and

b) P.157: *"The first is that a private market in blood entails much greater risks to the recipient of disease, chronic disability and death".*

424. Having qualified as a doctor before entering politics, Lord Owen accepted that he (and, by extension, senior members of the Government) and the medical profession were aware of the risk:

> *"Q. So having read and absorbed and reviewed Titmuss as you did in 1970 you were in no doubt as to the risks from blood and blood products?*
>
> *A. Absolutely. I don't believe that any doctor in the country had not become aware of it."*[311]

425. The ready understanding by Government of the risks from imported blood products was accompanied by an understanding that cryoprecipitate was likely to be less dangerous than concentrates. However, as has already been demonstrated in these submissions, the medical profession preferred the ease and convenience of concentrates:

> *"So the medical profession was saying overall from the start of their research cryoprecipitate is the safest, but that involves blood in bags and being done, could be done at home but very difficult and much more likely to have to go into hospital for it, and cryoprecipitate therefore was safer but all the time there was this pressure for home use"*[312]

426. Lord Owen's evidence was also clear that Government was fully aware of the relative risks of cryoprecipitate and concentrates, the need to tailor treatment to those who had milder forms of haemophilia, and the role of pool sizes and donor exposure in enhancing the risk to haemophiliacs:

> *"**Q**. Were you advised or do you recall any discussions with the Chief Medical Officer or within the department about the relationship between the size of donor pools and the risks of hepatitis?*

[310] HSOC0019917
[311] Transcript 22nd September 2020 p.25
[312] Transcript 22nd September 2020 p.27

***A**. Yes, and there is no doubt. I mean, Rosemary Biggs wrote a book about all of this, and she posed the question: could we use, for the people who have only minor haemophilia, not too frequent bleeds, bleeding, and not many bleeding in the joints, we'd only give cryoprecipitate? Or small donors? Because as your audience will have probably already had explained to them, that the bigger the pool of donors, the greater the risk, because one donation in a thousand will contaminate. So if you come down to a donor pool of, say, 100, the chances are much -- well, they're 10 per cent less. So, I mean, all these were being discussed and tried to be applied but it is difficult to decide. A doctor's trying to do the best for their patient. They explain it to the parents of the child and they may say, "Well, what's the treatment that's least likely to have any bleed?" And he has to say or she says, "This one, but there are chances of ..."*

…

*"**Q**. Was there any advice that was given, as far as you're aware, from the Chief Medical Officer or others within the department to suggest that clinicians should not rely upon imported concentrate so much but should perhaps consider more widely the use of cryoprecipitate?*

***A**. No, I think that they said weighing the decisions and taking account of how serious the haemophilia is. Remember, not every haemophiliac is having a lot of bleeds. The definite advice was if they were not suffering a lot, stick to cryoprecipitate. If they are suffering and it's leading to joint damage and permanent crippling, then they were saying – and that's why they were saying we have to increase in the short-term."* [313]

427. Despite Lord Owen having been informed of that evidence, the evidence seen by the Inquiry has demonstrated that the types of haemophilia treatments were not routinely gauged against the severity of haemophilia: there was a complete failure to form the risk-benefit analysis on which Lord Owen had been advised.

428. By 1973 it was recognised that the production of concentrate in the UK was insufficient for our needs and that *"As predicted by Dr Biggs in 1967 we now have concentrates, commercial concentrates, product licences having been granted to two firms"*[314]. Against this backdrop, the question of what self-sufficiency would mean and look like was also important. A self-sufficiency policy which focused on prophylaxis (as envisaged by Centre Directors) would have been very expensive, as this would have required the source of huge quantities of blood. Instead, Lord Owen's departmental decision making focused on home treatment for bleeds when required:

[313] Transcript 22nd September 2020 p.36
[314] DHSC0100005_033

"It's difficult to be precise in estimating a date for achieving self-sufficiency. Not least because not all are agreed as to what constitutes self-sufficiency. Some Haemophilia Centre Directors envisage prophylactic treatment whereas the Department's programme is based upon home agreement of those patients for whom treatment at home can be recommended."[315]

429. Given that the Government were clearly on notice at an early stage of the risks posed by imported blood and blood products, and of the higher risks posed by blood concentrates relative to cryoprecipitate, how did it all go so badly wrong? In our submission, Lord Owen's evidence had a recurring and telling theme: practicality was the deciding force in most decisions, even against the backdrops of knowledge of significant risk and the need to move toward self-sufficiency, The Government's decision was, in essence, to always continue with these dangerous treatments until self-sufficiency could be achieved, no matter how long that might take. This much was clear from Lord Owen's evidence on negotiations with Armour:

*"**Q:** "Dr Owen agreed that negotiations could start with Armour Pharmaceutical but he asked that it should be spelt out that the overall policy of the British Government was in line with the WHO recommendation to aim for self-sufficiency." What was the purpose of spelling that out to Armour?*

***A.** To indicate to them there's no good coming back and saying, "You've just recently agreed that we can come in and you never mentioned the fact that you were ultimately coming to a point where you would actually say you can no longer supply blood." So it was, I would think, no more than fair practice and honest dealing. You were authorising it but they had to understand that it could be stopped at any moment we were self-sufficient."*[316]

430. This approach to the approval of high-risk blood product treatment pending self-sufficiency was not altered despite the fact that self-sufficiency was, as a target, routinely being missed, as discussed earlier in these submissions:

"From the time I left, I've never been able to find any statement which said we were no longer doing self-sufficiency. It was always claimed that we were, in a variety of complicated ways, but Parliament was never told that it was not doing it. And therefore, to the argument, "Well, you didn't provide the resources", I couldn't provide the resources. I explained it was quite difficult to make anything more than one year as a forward commitment. But if you make a commitment to a policy, you are binding your successors to find the resources, within reason. I think that that's the importance of Parliament..."[317]

---

[315] LDOW0000019

[316] See DHSC0003742_076 and transcript 22nd September 2020 p.100

[317] Transcript 22nd September 2020 p.57

"…we were still carrying on buying this blood and we were putting it into people's veins and we were utilising it and we knew we were going to have to go on doing that for at least two to three years. Until self-sufficiency took place, we weren't going to be able to stop it being used. You know, this went on with the whole problem when AIDS hit us and in '83 again the question was put should you be allowing this to be used and the committee on safety of drugs said weighing all these factors, yes.."[318]

431. The Inquiry also saw evidence of the goal posts of self-sufficiency shifting, including the reclamation of political territory by 'restating' the goal of self-sufficiency in 1982.[319] There was a focus on political one-upmanship, rather than on the chronic delays and failures which had contributed to the infected blood scandal, and required urgent remediation.

432. In this context and in others, much depended on the tenacity of some parliamentarians to press for change, keep matters under review, and never give up. In the context of the infected blood scandal, Alf Morris was a significant figure, and it is concerning to think how matters may have unfolded without his passion and perseverance on behalf of his constituents and the broader infected community:

"The other thing we should remember is that there were Members of Parliament who were becoming very concerned about this issue, and the outstanding one was Alf Morris. He was in the department all this time, looking after disability, and he was seeing -- I think he was the first Minister for Disablement -- and he was -- firstly we discussed it every week, you know, all of --when these things came up collectively, ministerial, but he was seeing the consequences in the disabled children who were coming up with haemophilia, and he never, ever shifted from it. He's an outstanding demonstration of a member of Parliament who gets the bit between his teeth and consistently pushes and pushes and pushes, all through the 80s and 90s. He was behind the Archer inquiry, and his contribution, I'd like to say publicly, was a magnificent one. Quite frankly, he used to come and put pressure on me to do more."[320]

<u>*Governance and its Role in the Infected Blood Scandal*</u>

433. Upon leaving his role of Head of Blood Policy at the Department of Health in May 2003, Charles Lister left a handover note which referred to the "no compensation line" that Ministers in England were "sticking strongly to". However, the handover notes failed to refer to the calls by campaigners for a public inquiry, or on the issues with

[318] Transcript 22nd September 2020 p.61
[319] RLIT0000267; Transcript 22/09/2020 pp.123-124
[320] Transcript 22nd September 2020 p.58

lost or destroyed documents (which we return to later in these submissions).[321] Those were important issues which needed to be known to, and considered by, the next incumbent. Although the note made reference to issues "which will be easiest to explain over the phone", due to a lack of transparency we and the Inquiry will never know whether these issues were noted.

434. In his witness statement, Richard Gutowski (a senior civil servant in the DHSS) stated that he may have been told "*as part of a handover briefing*" that lawyers may have destroyed papers following the HIV litigation.[322] If such conversations did take place, it was a matter of serious malpractice that they were not recorded and were, instead, hidden from the eyes of the public.

435. Baroness Primarolo, Minister of State for Public Health between June 2007 and June 2009, was asked about how handovers between ministers could be improved. It was her view that:

> *"….if there was to be some sort of handover, as you describe it, it should be on the basis, I think, of what are the big issues that were sitting on the minister's desk as she or he left the Department."* [323]

436. There is a distinct lack of clarity as to who sees what, and what information is passed to the incoming minister. For instance, Lord Kenneth Clarke stated in his witness statement that he had no recollection of any involvement in the issue of risks of blood collected from prisoners in the UK, and the DHSS policy on the same, in or around 1983.[324] If this issue was kept from Lord Clarke, that was a significant oversight, as well as a large vacuum in political accountability.

437. Alan Milburn (Department of Health, Minister of State between May 1997 and December 1998); was asked about the system of referring papers to the Minister, which he described as a matter of judgement:

> *"**Q.** As I understand it, there were no set criteria as to what might or might not come to the Secretary of State. Significant policy decisions, things that were particularly high-profile or politically controversial are the examples you have given in your statement of things it would be more likely to come to the Secretary of State?*
>
> ***A.** Yes. I think, as so often with these things, and so many of the issues that we are dealing with -- you are dealing with in this Inquiry -- they really were matters*

[321] DHSC0041246_045
[322] WITN5292001_0019
[323] Transcript 23rd September 2022 at 14..47.31 – 14.48.07
[324] WITN0758001, paragraph 7.104

of judgement. So there was, if you like, as much art as science in determining these things" [325]

438. Similarly, Andy Burnham (as Secretary of State for Health between 2009 and 2010) described how correspondence to a Secretary of State was most unlikely to be seen by the Secretary him or herself, unless written by the Royal Family, Privy Counsellors or other senior parliamentary figures. Instead, correspondence from MPs or the general public would, respectively, be responded to by either a junior minister or the correspondence unit. Again, although the time constraints on senior government officials are understandable, the evidence has demonstrated that civil servants wield considerable power over the pressing issues of the day without any real form of political accountability.

439. There has to be a better way. In the 21st century, does it remain appropriate to treat letters from the Royal Family as having precedence over concerned members of the public, many of whom may have important and lived experience of the issues at hand? After all, a system of parliamentary democracy necessitates the representation of all, not just an elite few. Consider the correspondence sent by Mr Stephen Wintle, on behalf of his wife who had been infected with Hepatitis B and C, marked for the personal attention of Secretary of State for Health, Andy Burnham, and which asked that Mr Burnham "personally answer", and which Mr Burnham apologised for not having seen nor responded to as a result of the aforementioned system.[326]

440. This was far from the only example: internal DHSC memos from 2002 show the degree of concern that campaigners were causing civil servants. On 22 March 2002, advice was given to Yvette Cooper to decline a meeting with Carol Grayson. The note gave background information on Carol and Haemophilia Action UK, noting in a manuscript addition that "*Haemophilia Action UK have sent a very detailed letter alleging a conspiracy in the 1970s. A local journalist has contacted press office with similar questions. Officials are working on a detailed handling strategy…*"

441. It is clear that this practice of stonewalling and protecting politicians from uncomfortable correspondence must stop, and that there must be a move to the handling of correspondence based on relevance rather than title.

442. Had Government listened more and read more, rather than seeking to defend its position at all costs, the course of the infected blood scandal could well have been different. It is here that the extent and breadth of the work of campaigners requires

[325] Transcript of Alan Milburn's evidence 14th July 2022 p.24

[326] WITN1056098 from Mr. Wintle dated the 16 th of June 2009. The letter was described by Andy Burnham as a "painful letter to read", Mr Burnham went on to apologise for the system and said "It is not an acceptable way of dealing with public concern and I had similar with Mid Staffordshire." Transcript 15th July 2022 p.51

recognition: this was not a letter or two written in odd moments, but for all of the campaigners it was a diversion of their lives and health in an attempt to get the Government of the day to listen, wake up, and take action.

443. The work of Carol Grayson and Colette Wintle is summarised below in their A to Z of campaigning. Both women began campaigning in 1994, Carol with her husband Pete setting up Haemophilia North (which later became Haemophilia Action UK) to reflect a national remit and Colette as an independent campaigner. They have fought for all haemophiliacs infected with HIV and hepatitis viruses and exposed to vCJD and their families. Their campaign work and history is as follows:

    a. Writing letters and providing evidence to MPs; briefing both MPs and Lords for parliamentary debates, including the late Lord Morris of Manchester, the world's first Minister for disabled people; initiating contact to work with Lord David Owen on key issues after his concerns had been buried for some years; sending evidence to the APPG on Haemophilia and Contaminated Blood;

    b. Setting up campaign groups, such as Haemophilia Action UK, and developing campaign aims such as a public inquiry and accountability, safe treatment for all, and full "compensation on a parity with Eire" on the grounds on loss and need. The setting up of the Contaminated Blood Campaign Coalition with the national Haemophilia Society;

    c. Meeting health ministers at Westminster; highlighting the impact on male haemophiliacs and the specific issues related to the misogyny of treatment in relation to female haemophiliacs; and highlighting the role of long-term carers (mostly but not exclusively female) and bereaved partners;

    d. Establishing joint media campaigns, such as the awarded Journal *Bad Blood* campaign founded by Carol Grayson, Peter Longstaff and journalist Louella Houldcroft, and the Northern Echo and Hartlepool Mail campaigns. More broadly, contributing to national and international media and setting up a blog;

    e. Attending face to face meetings with ministers at both Westminster and the Scottish parliament;

    f. Organising demonstrations outside parliament, lobbying parliamentarians and attending talks at Westminster Hall;

    g. Media, radio and TV interviews, podcasts, and delivering information to academic journals and travelling to the US, China and Holland to attend conferences and work with other haemophiliacs;

h. Writing a research dissertation on Contaminated Blood for which Grayson was awarded the Economic and Social Research Council ("ESRC") Michael Young Prize 2009;

i. Researching and contributing to UK documentaries such as the awarded Blood Brothers instigated by Colette Wintle with Holly Lewis of Meridian TV, where she was interviewed and Grayson provided background research. In addition, Grayson was the official researcher for an BBC Newsnight documentary April 2007 expose on the blood scandal nominated for a Royal Television Society award;

j. Contributing to international documentaries such as PBS, Red Gold;

k. Domestic and international litigation, public law challenges, these include Carol Grayson's husband Peter Longstaff establishing a legal case to challenge the inclusion of a hepatitis waiver in the 1991 HIV litigation. Peter also initiated a judicial review for recombinant synthetic treatment. Both Carol and Colette provided documentation obtained in 2004 to help win a judicial review in the name of Andrew March to challenge government thinking in relation to the recommendations of Lord Archer following the Archer Inquiry;

l. National petitions and Petitioning the European Parliament;

m. Making official complaints to the police;

n. Submitting complaints to the General Medical Council and the Charities Commission;

o. Writing letters of concern regarding human rights abuses to Amnesty International, Human Rights Watch, Liberty, and Association for Victims of Medical Accidents;

p. Submitting complaints to the Office of Supervision of Solicitors regarding conduct of last solicitors, 1 struck off, 3 other complaints upheld;

q. Writing letters for medical records to GPs and Hospital Trusts;

r. Providing counselling support by phone;

s. Submitting Freedom of Information requests;

t. Campaigning on human rights for haemophiliacs globally, for which Grayson and Longstaff received the Committee of Ten Thousand Action Equals Life award for services to haemophilia, HIV, HCV and for "upholding truth and justice" alongside Dr Don Francis (Former CDC, featured in the film "And the band played on") and Dr Jay Epstein (former FDA);

u. Sending letters to the UKHCDO for patient treatment records and to highlight the Dr Craske Studies and warnings of Dr Spence Galbraith in 1983 which Carol Grayson released into the public domain;

v. Setting up US litigation for UK haemophiliacs with San Francisco firm LCHB;

w. Submitting complaints to Amnesty International, Human Rights Watch, and Liberty on human rights abuses, and campaigning with regard to the abuses of the DWP and disability benefits in relation to Contaminated Blood;

x. Saving all existing blood policy documents existing in 2005 at the National Archives at Kew with Lord Patrick Jenkins and obtaining a government commitment not to destroy any further documents in case of a public Inquiry. Discovering, accessing and returning copies of destroyed government documents to the National Archives, Kew;

y. Sitting on the Joint Partnership Group of Macfarlane Trust, proving key evidence which led to the setting up of Skipton Fund through the Hepatitis Working Party chaired by Peter Longstaff's then Queens Council and sharing evidence at support weekends, delivering lectures.

z. Giving testimony to 3 Inquiries: Archer (and preserving the Archer Inquiry website and record after it had been removed from the internet), Penrose and the Infected Blood Inquiry.

444. The work of Carol and Colette is astonishing, but their persistence must be recognised alongside the work of other individuals and groups.

445. Clair Walton and a fellow campaigner set up Positive Women[327] (HIV via Factor 8) to provide support and to campaign for women who, like themselves, were infected by their bleeding disorder suffering partners and who have had to deal with the repercussions and treatments since the 1980s.

446. Mark Ward established "Haemosexual", which aims to provide what global and national organisations miss: supporting all those with a bleeding disorder infected/affected through the global contaminated blood scandal, along with those who identify as LGBTQI. Haemosexual works to educate people in all countries of the dangers posed by contaminated blood. Mr Ward's correspondence to Ms Milton appears to have suffered the same fate as many other letters from the public and campaigners: his letter[328]was not replied to. Ms Milton states that as her legal advisors

[327] WITN1589023, see paragraphs 5 -7
[328] MWAR0000106

were not able to locate a copy of this letter she "*cannot say for certain whether my office received it*".[329]

447. A great debt is owed to all of the campaigners who have devoted their lives to supporting others who have been harmed by the Infected Blood disaster.

448. All of the letters and information from Ms Grayson certainly had the capacity to demonstrate that the 'Government line' was wrong, however, as a mere member of the public (notwithstanding her level of knowledge on the relevant issues, which surpassed most in Government), her letters were treated with a lower level of attention than they eminently deserved. As Mr Burnham stated, the evidence provided to the Ministry by Ms Grayson should have caused the Government to re-think the government position on there having been 'no foul' by the NHS:

> *"**SIR BRIAN LANGSTAFF:** If you just pause there for a moment.*
> *The line, "there is no evidence that individuals were knowingly infected with contaminated blood and blood products", could be read in one of two ways. One is that those infected didn't know, but I suspect – and you can confirm if you would, that what you meant or what those words that you used were intended to mean was that the person infecting them, by giving them contaminated blood or blood products, or the system that was giving that to them, didn't know that the products could transmit infection.*
>
> ***A.** So, Chair, that's the sentence that stands out in this letter. And I didn't know it at the time but I now believe that to be a highly misleading sentence or, indeed, a false sentence and it is very difficult for me, 13 years on, to see a letter that is in my name but which I now believe I have evidence to say that that is false. What I think it is saying is that there is no evidence that -- you could read it two ways, as you rightly said -- but I think what it is saying, or is certainly heavily implying, that the system, for want of a better word, had no evidence, that there was no knowledge that people were being infected. Now, the reason I say I believe that to be a false statement is because I believe there is -- I believe I could point you now to a document to disprove that or at least cast a serious question on that assertion and if you would like me to I can or if you would like to come to it later that's fine as well. But it is a letter, a circular letter, I believe initially unearthed by Carol Anne Grayson, who I believe has given evidence to the Inquiry, dated 11 January 1982[330], from the Oxford Haemophilia Centre on headed paper of the Oxfordshire Health Authority, which is relevant, I believe, because that takes the link to the Department of Health …."*[331]

[329] WITN6437002_0010
[330] This letter may have been mis-dated and may mean 1983 given the fact that it refers to 'January' i.e. a possible carry over of the year 1982 into 1983
[331] Transcript 15/07/2022 p.60

449. The correspondence Ms Grayson had been trying to bring to the attention of the Ministry referred to the deliberate testing of blood products on previously uninfected persons, as has already been set out in previous sections of these submissions:

> *"It is therefore very important to find out by studies in human beings to what extent the infectivity of the various-concentrates has been reduced. The most clear cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates."*[332]

450. Yet Carol Grayson's correspondence went unanswered, even when she and Hemophilia Action UK chased for a response.[333] This practice of persistently shutting down concerns and warning signs raised by patients and other members of the public was dealt with in the Inquiry's Expert Report "*Public Health and Administration*":

> *"Past public and other inquiries into major service failures in the NHS have repeatedly demonstrated that public involvement in issues of patient safety has generally left much to be desired (Francis, 2013; Sibley, 2022). Concerns raised by individual patients and families, and by groups or associations of patients and carers, have often been dismissed, marginalised, or blocked. In the Independent Medicines and Medical Devices Safety Review, Baroness Cumberlege noted:*
>
> *'The healthcare system — in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers — is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'être. It has failed to listen to their concerns.' (Cumberlege, 2020).*
>
> *Regulatory organisations have frequently been slow to understand the extent and degree of failure and slow to intervene when patients have been at risk. It is not unusual for inquiries to find a trail of concerns raised by patient and public voices over many years until some egregious event, media attention and/or changes in leadership eventually and belatedly trigger the necessary institutional response. Public voices — even of individuals or organised groups with considerable social capital, professional expertise, financial resources and motivation — have consistently struggled to be heard, to be respected and listened to, and to have an impact (Francis, 2013; McQueen et al., 2022)."*[334]

451. Not all ministers ignored Ms Grayson, but the myth of "inadvertent" infection and the idea that HCV was a relatively benign infection was very difficult to irradicate. For example: Anne Milton (who was an ex-nurse and Parliamentary Under-Secretary at the Department of Health between May 2010 and September 2012) did discuss these

[332] HCDO0000252_042
[333] DHSC0004074_028
[334] EXPG0000047_0046

issues in meetings and correspondence with Ms Grayson. However, even after reading Ms Grayson's dissertation, Ms Milton, who does not recall taking any further action, stated to Ms Grayson:

> *".....at that time, experts were divided in their views about the infection risk associated with blood, especially clotting factors which were made from pooled donations. There were a few who advised that the risk was worryingly high. However, the prevailing medical opinion did not support this view. Hepatitis was then thought to be a mild and often asymptomatic infection."* [335]

452. Government and the civil service should be able to accept challenge and be prepared to commission research and reconsider previously held opinions. If this cannot happen because no-one has time or willingness to review advice and decision making, then a similar disaster will undoubtedly happen again.

453. In our submission, there must also be changes to the way that public correspondence is dealt with: attention must be given to the analysis of relevant information and not to the apparent seniority or standing of the individual drafting the correspondence. Although the Inquiry's aforementioned expert report has set out its proposals "*for effective patient and public involvement*",[336] the report concentrates on communication with patients, rather on the broader question of communication and engagement with the general public. In doing so, the report has failed to appreciate that the systems of evidence gathering, the failure to question assumptions, and the failure to read and appropriately action correspondence have all been shown within the evidence to be a real part of the problem. We do not doubt the need to improve communication with patients (and to learn from the patient experience), but there is also a need for the Government to review how its own processes allow sufficient and appropriate interactions with members of the public, to ensure that, where relevant, they can have a meaningful impact on decision making.

454. The other part of the information jigsaw was the quality of the briefings to Ministers on matters relevant to this Inquiry. An example of this is the Hepatitis C Strategy for England:[337]

> *"Prior to the introduction of viral inactivation of blood products in 1984, and before 1991 when the screening of blood donors was introduced, some recipients of blood and blood products were inadvertently infected."*

[335] WITN6437002_0010

[337] WITN6942004 at page 9

455. In light of the evidence traversed in these submissions thus far, it is patently clear that this briefing fails to (a) recognise, acknowledge or communicate the true scale and cause of infection; and (b) appreciate that blood products remained dangerous beyond 1984. This briefing was referred to by Sir Brian Langstaff as one possible example of "groupthink" and *"perhaps a failure or -- a failure to look back and actually check that that was right, even though there may have been pressures upon them to deal with the current business rather than keep on looking back over their shoulders?."*[338] As with other areas of Government and governance, much seems to have been left as an 'art', or a matter of judgement for the individual author within the civil service.

456. The question of how to resolve issues of "groupthink" or "corporate memory" was explored in Sir Brian Langstaff's questioning of Alan Milburn:

> *"**SIR BRIAN LANGSTAFF**: It follows from that last answer that you wouldn't say that the Minister is at fault here and you wouldn't say that the civil servant is at fault here. So how does it come about then that something which is wrong is said without somebody, somewhere having been or having a responsibility for it? What is the nature of that responsibility? How would you answer that?*
>
> ***A.** I think there is a need, obviously, for corporate memory. That's important, not least given the continual chopping and changing of the politicians, because that's probably just a fact of political life that isn't going to change. So corporate memory is a very important thing. I don't think -- and this is not conjecture on my part, it is a view on my part -- I don't think people like Charles Lister were deliberately serving up a diet of inaccuracy to a minister. They're better people than that, I think. But I think what happens is that some things do just get set in stone, history, which is malleable because it is subject to interpretation, it somehow or other at some point becomes set in stone and that may be for good reasons, maybe because actually the history is not contested. The problem here is that the history was contested. So this is where I come to, to answer the "Who is responsible". I think within the current architecture of decision-making, I mean, one could say that that primarily lies with the Civil Service, as the keeper of the corporate memory flame. But, again, that – things happen to Civil Service corporate memories, so maybe something of a challenge function is required, that is currently missing."* [339]

457. The dangers of the current approach to civil service corporate memory are demonstrated clearly in the infected blood scandal: the 'Government line' that nothing had wrong beyond unintentional and unavoidable tragic mishap, perhaps a product of the malleable interpretation of history to which Mr Burnham referred, held

[338] Alan Milburn's transcript 14 th July 2022 p.43

[339] Transcript 14th July 2022 p.47/48; Sir Brian Langstaff asked that his exchange should be referred to the Expert Group considering Public Health and Administration(p.50)

true for many years. In a letter written to Michael Moore MP on 12 December 2006, which was triggered by a letter sent on behalf of a constituent, Caroline Flint (the incumbent minister with responsibility for blood and blood products) stated:

> *"I am aware of the Early Day Motion ... tabled by Pete Wishart MP calling for a public inquiry into the issue of contaminated blood products. However, as previously stated, the Government does not accept that any wrongful practices were employed and does not consider that a public inquiry is justified. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time."* [340]

458. If the Inquiry approaches the issues of Government decision making on the basis that the Government and its civil servants were at all times approaching matters with 'good faith', then the question of whether mistakes were made and how they were made becomes the central issue. At page 27 of her statement, Dr Diana Walford described the division of civil servants at DHSS as between medical and administrative civil servants. She noted that the administrative civil servants chose when to seek the medics' advice and input, and that the advice received was at times changed before being presented to a minister.[341] In reliance on that approach, it is very clear how much could go wrong: administrative civil servants were not qualified to pre-judge the need for medical input, or to tinker with that advice once received. This was an approach which was also reflected in the structure of the licensing regime, as discussed at length in an earlier section of these submissions. Political power should never have trumped the science in matters of medicine.

459. Dr Walford's statement went on to outline how information would be passed around the DHSS and how, in the case of a grave threat, information would be escalated to the Chief Medical Officer and the Minister. Dr Walford's evidence was that ministers were certainly alerted to the problem of post-transfusion hepatitis, but that she was unsure whether the potential for chronic liver damage was particularly stressed to Ministers. This demonstrates just how dependent any Minister is on both the quality and the comprehensiveness of the briefings and advice provided to them by the civil service which, as explored above, is left to the individual author's discretion.[342]

460. The briefings and papers reviewed by Ministers held the line that there was 'no fault' attached to decisions previously made by the DHSS/Department of Health. In fact, advice on maintaining the historic 'no fault' line, as well as acting in a way which

[340] MACK0001606_002
[341] WITN4461001, page 27
[342] WITN4461001, pages 130 and 154

would not open the floodgates for other groups to claim or demand compensation,[343] occupied great swathes of the time spent on considering matters of compensation; instead, that time should have been spent on (a) researching whether it was, in fact, right to say there was 'no fault'; and (b) the appropriate way to help and compensate the infected community for their infections and experiences.

461. Alan Milburn was questioned about the contemporaneous views he held on the issue of opening a public inquiry into the infected blood scandal. As with the issue of compensation for the infected community, he accepted that the line that he and other ministers had taken was to follow the ministerial briefing which, in turn, meant that he had no cause to believe there to be grounds for a public inquiry:

> *"…I think if I had felt that there was a situation where there was substantial doubt, that issues hadn't been aired in the public domain, that there was evidence of systematic negligence and critically, because public inquiries have a very important role to play in this regard, there hadn't been some evidence of lessons being learned, then I might have concluded that a public inquiry would be necessary. But, I mean, the truth is that -- back to the lines to take, question, and the groupthink that we were discussing earlier -- there was a very well established view in the Department that transcended successive governments and ministers and so on and so forth that "the facts were established"*[344]

462. The evidence heard by the Inquiry raises the following questions: To what degree should statements made in briefings be checked? What attention is given by ministers to the accuracy of such statements? Are briefings to Ministers generally accurate? On these questions, Mr Burnham said:

> *"**Q.** As a matter of general principle, general observation, if a department -- and whether it is this department and this line or another department and another line – is going to say something as forthright as this, "does not accept any wrongful practices were employed", would you expect, as a matter of basic good government and transparency, openness, integrity, that that kind of assertion is only made if there has been some form of proper investigation, interrogation of the facts, so that those who are making it can have a degree of confidence in its accuracy and in the extent to which it is comprehensive and fair?*
>
> ***A.** So I would say that's what normally happens, and in my experience civil servants are very careful about those considerations before giving lines to ministers. And I would say in sort of, you know, over 90 per cent of the times those lines are considered, they are accurate, they are truthful. But I think on this particular issue there is evidence that that wasn't the case."*

[343] SCGV0000243_051; Transcript 14/07/2022; WITN7115001_0144
[344] Transcript 14th July 2022 p. 177

463. However, in our submission, the lack of any proper system or political accountability for the briefings and statements which make their way to ministers, having been crafted in reliance on the judgement of any given individual, is inevitably prone to errors and, given time constraints, oversimplification. Not only must the civil service ensure that information provided to, and promulgated by, Ministers is accurate, but Ministers must probe and query the evidential basis for any 'lines to be taken', particularly when historical in nature and prone to the "malleable" corporate memory of the civil service. In the absence of such a system, any original decision making conducted in error, secrecy or self-interest will be maintained and perpetuated through decades of government decision making, as it was in the context of this Inquiry:

> *".....it gets to the heart of your Inquiry, and it is this: I think embedded deep within the Civil Service psyche, over not just a few years in question but a number of decades, I would say, the response to this particular issue was primarily driven by a fear of financial exposure. That, in my judgement, describes all of the experience that you might -- all of the responses, the lines, everything, kind of came from that feeling originally. And so these letters, I think, are drafted with that primarily in mind. Not with the kind of needs of people who were -- through absolutely no fault of their own, had their lives utterly ruined. In fact, if you look through the paperwork and the letters there is very little reference to that. Instead, it is always this -- I think the kind of sense that any lines that veer into that issue and could open up the Government on this issue are problematic. And I think that explains, to me, anyway, why the UK Government has comprehensively failed the victims of infected blood, I would say, over five decades and that is hopefully what your Inquiry may finally correct"*[345]

The Need for a Duty of Candour and the Decision to Hold a Public Inquiry

464. The evidence that has been considered by this Inquiry (and by other statutory inquiries which are currently ongoing) raises important questions as to whether there should be a general duty on the civil service and Ministers to honestly and openly cooperate with any investigation or inquiry.

465. At present, those in public office (as well as their expert and legal advisors) are governed, to the extent relevant, by the Nolan Principles, the Ministerial Code, and the Civil Service Code. In the search for government transparency, and candour when things have gone wrong, a single and accessible Code of Conduct, governed by a regulator, has many advantages. To suggest that a regulator of such a code would interfere with the democratic process is to misunderstand the role of a regulator, which is not to usurp or overrule professional decision making, but to provide

[345] Andy Burnham, Transcript 15th July 2022 p.27/8

guidance and deal with any misconduct. As recent events have shown, no one – not even the Prime Minister – should be above the law.

466. In a similar vein, there is a need to consider the role and use of public interest immunity ("PII") privilege, which militates against the general duties of disclosure which arise in litigation. As explored during the Inquiry's hearings, the government sought to withhold a number of categories of document from disclosure during the 1990s HIV litigation. Although that application was largely successful at first instance, it was overruled by the Court of Appeal, who ruled that certain categories needed to be disclosed to the claimants on the grounds of relevance. Although PII applications are, it is hoped, scrutinised carefully by the courts, it is a matter of concern – and not in keeping with the spirit of candour – that government routinely seeks to withhold important documentation from those it governs.

467. Unless documents contain information which may jeopardise national security, it is difficult to justify withholding disclosure. That a document may reveal "the inner workings of government" is no adequate ground for withholding disclosure: those governed, and who pay for government and its inner workings, are entitled to see the internal machinations of government. The need for contemporaneous transparency and candour is all the more important in light of failings in documentation retention and destruction: if not released at the time, there is no guarantee that the documents will be adequately preserved for access once they are rendered 'less sensitive'. We will return to the issue of document destruction in the next section of these submissions.

468. By the time of the Archer Inquiry in 2007, the concerns about contaminated blood and blood products had been articulated beyond doubt by campaigners. The clamour for more to be done to establish the truth, compensate all those infected and affected, and protect people in the future became a regular feature of parliamentary discussion.

469. The Archer Inquiry was not a statutory inquiry, nor had it been established by the Government; nevertheless, it was a serious investigation into the issues surrounding the use and supply of contaminated blood products. An internal briefing from Head of the Blood Policy Unit, William Connon recommended, in essence, that the Government should not cooperate with the Archer Inquiry on the grounds of cost, inconvenience, embarrassment, and the risk of legal proceedings:

> *"However there remain a number of significant questions and concerns amongst officials including solicitors branch, regarding any departmental involvement in this inquiry, which I would just like to flag up to you again. They mainly arise from the suggestion that officials should agree to appear as witnesses:*

- *There is no evidence of any negligence or wrongdoing on the part of the department during the period in question (1970-1985). Nevertheless, given the subsequent destruction and loss of a number of files there is considerable scope for embarrassment for the department if officials are asked to appear before the inquiry. With official Government Inquiries there is a clear legal framework under which to operate in the case of an inquiry under the Inquiries Act 2005 and in the case of non-statutory inquiries there are established principles and guidelines. These would not apply to a non-government inquiry such as Lord Archer's one and it is unclear exactly what departmental involvement may entail.*

- *Colleagues are also naturally worried about the vast amount of preparation that would be required to prepare themselves if they were called to give evidence and answer questions about over 6000 documents.*

- *If it is agreed that officials should give evidence, this may in turn raise the possibility of ministers themselves being asked to give evidence. We will inevitably be pressed to release documents without any redaction — and to release submissions. While none of these policy documents gives rise to any real concerns over liability, some are sensitive in respect of potential for criticism or embarrassment of former ministers and senior officials. It may be much harder to maintain the line that we are only prepared to release documents under FOI principles if officials are asked to defend this line publicly in front of the inquiry.*

- *Sol have pointed out that the inquiry will not have any statutory powers therefore civil servants, ministers or others could not be compelled to attend or provide evidence. However, if it is suggested that they should do so, then no doubt the inquiry would draw adverse inferences from any refusal to do so.*

- *There is also a question whether the inquiry would offer legal indemnities to officials against the possibility of legal proceedings being instituted against them as a result of their evidence to the inquiry.*

- *Sol's view is that we should avoid becoming in any way directly involved. For all these reasons, we think it is not advisable to offer in the reply that officials would be willing to give evidence to the inquiry. The offer of a meeting between Lord Archer's team and departmental officials is qualified to explaining about our review and the level of assistance we can provide his team."* [346]

[346] Memo from William Connon, Dep artment of Health (DoH) to Secretary of State, re: Lord Archer letter to Sec of State: public inquiry on Haemophiliacs infected with Hep C DHSC0041193_054_0002

That advice was aimed solely at the protection of the Government, its ministers, civil servants, advisors, and the general Governmental system. No consideration whatsoever was given to the need for the Archer Inquiry to have access to as much information as it required to understand how the infected blood scandal could have unfolded. The submission, in short, suggested that the Government had done nothing wrong, and that that was the end of the matter.

470. Lord Archer was very much aware of the view of the Department of Health:

> *"The Department of Health maintained its view that the Inquiry was unnecessary, and declined to provide witnesses to give evidence in public, but they supplied documents which we requested, responded to questions from us and sent representatives to three private, informal and unminuted meetings."*[347]

471. This appears, at least in the context of the matters explored by this Inquiry, to have been the Government's default position: protect and shield from criticism at all costs, even at the expense of discussion, learning, and improvement. Building on earlier submissions, there is a need for civil servants to regulate the nature of submissions of this kind being sent to Ministers, and a resulting or corresponding need for Ministers to scrutinise, question and push back on such submissions.

472. Looking back, it seems impossible to reconcile the advice to not cooperate with the Archer Inquiry with the Nolan Principles, the Ministerial Code and the Civil Service Code. After all, the issues to be explored by the Archer Inquiry were not matters of state secrecy: there was no question of ongoing police investigations, military operations, or the technological capability of the armed forces.

473. A draft response from the Department of Health to the BBC is, in our submission, telling of the Government's approach to the calls for a public inquiry. The draft response concluded with the text: *"However, the Government does not accept that any wrongful practices were employed and, therefore, there is no justification for a public inquiry."*[348] Not only did this stance rely on the untested and historic 'no fault' line, it put the cart before the horse: given the extensive concerns raised by campaigners, there was a need for an independent inquiry to examine and determine the question of fault, if only to allay public concerns and avoid repetition of similar incidents.

474. Richard Gutowski's witness statement suggests that the civil service's view may have been clouded by the historic 'no fault' line, and workload pressures:

---

[347] ARCH0000001, internal page 9
[348] DHSC0041162_049

> *"we were not expected to "reinvent the wheel" on any particular issue, given the inevitably heavy workload and pressures on time. By this I mean that we were not expected to investigate issues from scratch each time they were raised. If there was an existing response available on any particular issue, that answer or response could be drawn upon and re-sued, provided that nothing had changed since the original response"*[349]

However, this approach relied on an original response having been issued in good faith, without error, and without secrecy, cover up or other malign influences. In the absence of good governance and scrutiny of the relevant issues, reliance on earlier responses could not be maintained safely. Furthermore, there came a 'tipping point' at which sufficient concerns had been aired (mainly due to the immense work of campaigners) which warranted a reconsideration of the government's position. After all, Section 1(1) of the Inquiries Act 2005 states that a Minister may cause a statutory inquiry to be held where it appears to the Minister that *"(a) particular events have caused, or are capable of causing, public concern, or (b) there is public concern that particular events may have occurred*."

Lack of Continuity Between Administrations

475. As has been demonstrated, reliance on the civil service's "malleable" corporate memory can be dangerous, particularly when it is assumed, without evidential foundation, that there has been no human error, failing, or cover up. However, the current operation of Government in the UK inherently lends itself toward a reliance on the headlines of corporate memory, and away from challenge, questioning, and scrutiny. As the Inquiry's Expert Report on Public Health and Administration stated:

> *"The UK Government struggles to think, plan and deliver projects in the long-term. This is arguably unsurprising given that political incentives and the consequent incentive structures which have developed within government often run counter to long-term considerations. Pressures on resources can make it difficult to look beyond the immediate priorities. Public opinion and pressure can shift, and thus make it difficult for government to sustain its commitment to a long-term project. The degree of commitment in government can also wane as initial targets are met and political attention shifts elsewhere. In addition, changes of personnel, whether Ministers or NHS leaders, can lead to new priorities. The time a Minister spends in one post is, on average, about fifteen months and that does not encourage them to take a long-term perspective. Beyond these political pressures, government exhibits a range of more practical weaknesses identified in a recent report from the Institute for Government. These include devoting too little time to assessing early options, failing to understand and communicate fully the project risks, and failing to have*

[349] WITN5292001_0018

contingency plans in place to address problems as they arise. Government, in addition, are too often slow to learn the lessons from past projects or, indeed, to fully evaluate how past projects have fared (Atkins et al., 2017)."[350]

476. Furthermore, there are conflicting positions on the ability of an incumbent Government to access information and documentation from a previous administration. Charles Lister OBE explained a practice whereby ministers' private offices would keep copies of documents that had been provided to Ministers, which may include ministerial annotations. However, due to longstanding convention, those documents would be shredded on a change of government. Although the incoming government would have access to the submissions or documents as stored on the relevant police files, they would not have access to any ministerial annotations or other private documentation which may assist in understanding how particular positions were reached.[351] Again, an incoming Minister would be heavily reliant on the memory and judgement of the civil service.

477. However, the advice of The Cabinet Manual on this issue states:

"Access to papers of a previous administration

11.23 As a general rule, ministers of an incoming administration may not see the papers of a former administration of a different political party that indicate the views of their predecessors, including the advice they received from officials and correspondence with the Devolved Administrations and local government. ***This does, however, need to be balanced against the requirement for continuity.*** *Thus, the Foreign Secretary will often see papers necessary for the continuity of diplomatic relations, and the Law Officers will see advice on matters of law."*

[Emphasis added]

478. A Parliamentary debate on this issue on 24 January 1980 clarified that there were not the only areas were continuity was permitted and required, but also stated that embarrassment to former ministers would be the guiding principle:

"It is an established rule that after a General Election a new Administration does not have access to the papers of a previous Administration of a different political complexion. This rule applies especially to Cabinet papers.

The general principle is clear. An incoming Minister should not have access to any minutes or documents written by a predecessor of a different Party other than those which were published or put in the public domain by that predecessor; nor should he be told—whether directly or by access to

[350] EXPG0000047, paragraph 27
[351] Transcript 8th June 2022 (34) Pages 133 - 136

departmental papers which would tell him—exactly what his predecessor had said. Moreover, it may be equally important to withhold papers which show the advice given by officials to the previous Minister even though there may be no indication on them of his views.

On the other hand, the national interest requires that there should be some continuity of policy. The arguments for continuity are stronger in certain fields than in others. Foreign policy is generally recognised as providing the classic example of a field in which continuity is important; but there are other fields in which some at least of the work of departments ought to continue on broadly the same lines as before. Under modern conditions it is not practicable for departments to make a completely fresh start with all their work.

There is no neat formula which can be used to reconcile the general principle with the practical considerations which sometimes point in the opposite direction. Departments use their discretion in making the best reconciliation possible in each individual case. It is one thing to give an incoming Minister a general account of the basis of departmental policy in a particular field under the preceding Administration and another to allow him to examine the particular personal views of his predecessor on certain points. On personal matters such as these, especially when the political content is high, a department is expected to be very discreet about what outgoing Ministers have said or thought. On the other hand there may be no objection to showing an incoming Minister, e.g. a report which his predecessor saw but on which action remains to be taken, or documents which were made widely available outside Government. It may be possible to draw a distinction between documents recording the way in which decisions were reached and documents announcing these decisions. ***The guiding line must be to avoid embarrassment to previous Ministers****."*[352]

[Emphasis added]

479. It is difficult to see how a modern age of democracy can tolerate imposition on good governance and continuity of business (or, where appropriate, a reversal of a poor position) for the benefit of avoiding embarrassment to a former minister. Government should be in the business of transparency. Decisions which are worthy of embarrassment should receive it. The public should be entitled to know the views of those promoted to the highest levels of government, given that they will directly alter and influence significant aspects of the public's livelihood.

480. This section of our submissions has demonstrated that, at present, too much of governance and public life is determined by the judgement of the Prime Minister[353],

[352] CABINET PAPERS (Hansard, 24 January 1980) (parliament.uk)

[353] "An independent Integrity and Ethics Commission should take on the role of investigating alleged breaches of the code […] It should be able to do so whether the Prime Minister of the day agrees or not, and the Cabinet

Parliament and Civil Servants, at the expense of transparency and candour. Those two principles need not be mutually exclusive. Judgement is required, but it must be applied in accordance with the need for standards in public life to be maintained and applied consistently.

Secretary and other permanent civil servants who work for the government should be under a legal obligation to cooperate with it" Commission-on-the-UKs-Future.pdf (labour.org.uk) pages 128 et seq

9. HIV LITIGATION AND THE DESTRUCTION OF DOCUMENTS

481. Was there a deliberate and wilful cover up through the destruction of papers which may have implicated the Department of Health, or Government more broadly, in the infected blood scandal? Or is the evidence an example of poor record keeping, a failure of careful document retention, and secretarial tidying up?

482. In short, our submission is that there was too limited an investigation into this issue. Now, with the passage of time, it is tremendously difficult to reach a final and persuasive conclusion as to whether the destruction of documents in the context of the infected blood scandal was human error or a wilful act.

483. The Inquiry has conducted an exhaustive review of the documents available and has concluded that it has all (or at least substantially all) of the documents that have been described as missing. This does not eliminate the fact that documents did go missing, nor the possibility that individuals may have deliberately destroyed documents in an effort to thwart the desire for truth and accountability following the infected blood scandal. This section of our closing submissions examines the main 'batches' of documents that went missing.

Lord Owen's Papers

484. In his written witness statement, Lord Owen referred to his dissatisfaction with the explanations as to why his papers had been destroyed, which did not seem in keeping with other governmental and departmental practices. He drew attention to the fact that his papers were likely destroyed around the time of his making enquiries on behalf of an affected constituent. He also drew parallels with the French contaminated blood scandal:

> *"…In April 1991 an article in France sparked that country's own infected blood scandal which led eventually in 1999 to the prosecution on manslaughter charges of the former Prime Minister, Laurent Fabius, and other individuals. It has been asked whether there was a deliberate decision to destroy all papers in the UK. I do not have the facts to make a considered judgement on this."*[354]

485. Lord Owen also noted that Lord Jenkin told the Archer Inquiry of his own ministerial papers having been destroyed as a "conscious decision".[355]

[354] WITN0663001, paragraph 62
[355] Ibid; LDOW0000351

HIV and HCV Litigation

486. The destruction of documents is firmly intertwined with the HIV and HCV litigation. However, a debate on document preservation must pre-date that litigation, and begin with the relevant policies, guidance and any training given to staff. On this, John Canavan (Head of Blood Policy at the Department of Health between 1989 and 1993) said:

> *"2.219. The Inquiry asks whether I was aware of any polices in place for dealing with the storage or destruction of departmental papers. I think I would have been aware of guidance on the storage or destruction of papers from the years I spent in various DH branches but cannot recall what I knew when or how I knew it. I understand that documents generally should have been retained if they were still required administratively (e.g. for policy or litigation reasons), as required by the Public Records Act.*
>
> *2.220. The Inquiry asks whether I recall any training or government-wide instructions on this issue. I cannot now recall any specific training or government-wide instructions on this issue. This is not to say that there was no training provided. However, I do not now recall any details."*[356]

487. The lines to take document in April 2005 stated: "*many key papers from the 1970s and 1980s have been destroyed. During the HIV litigation in 1990 many papers from that period were recalled. We understand that papers were not adequately archived and were unfortunately destroyed in the early 1990s*".[357] Zubeda Seedat (Higher Executive Officer in the Blood Policy team between 2002 and 2008) could only say that she understood this to be the position, and that this was the information she had been given by Mr Lister. On being questioned by Sir Brian, Ms Seedat could not recall having been told of any reason why these records had been destroyed.[358]

488. Within a memo to Sir Nigel Crisp, which relayed Lord Jenkin's request for another meeting to discuss record management in the Department of Health, Ms Seedat reported the findings of the DoH's internal audit, which concluded that the upheaval of an ongoing review process (which resulted in two experienced members of staff leaving the relevant section) was most likely to have caused a delegation of responsibility without proper instruction, or an assumption of responsibility without proper authorisation. It was said that "*Either occurrence, likely given the*

[356] WITN7115001_0086
[357] WITN4912039 dated 11th April 2005 a memo from William Connon providing the 'lines to take' worked on by Ms. Seedat
[358] Transcript 14/09/2022

organisational context, is the most probable explanation for the decision to mark the files for destruction".[359] Ms Seedat's memo ended by recommending that Sir Nigel decline to meet with Lord Jenkin. Ms Seedat explained in her oral evidence that a draft letter to Lord Jenkin explained the position in full, and that there was nothing more to add.

489. When asked in evidence why the draft letter to Lord Jenkins stated that the documents had been destroyed "*in error*" (which was not apparent from the memo to Sir Nigel), Ms Seedat was unable to provide an answer. In addition, Ms Seedat could not explain why the letter had concluded that the decision to destroy a number of files was "*most probably made by an inexperienced member of staff*": Ms Seedat could not explain or recall why this explanation had been used or where the draft had come from. An alternative but similar explanation was provided in internal government correspondence in April 2005: that the litigation files had been "*inadvertently destroyed in the early nineties as the HEO working in the branch had given them a ridiculously short destruction date*".[360] It is unclear where that explanation came from.

490. In a memo sent to Mr Lister on 19 January 2000, Anita James wrote:

> *"…In Dr Rejman's "personal" papers I have found two minutes which ominously do not appear elsewhere. There are obviously some gaps… What I find surprising is the fact that we had ring binder after ring binder on HIV but there is so little on HCV. I wonder why this is?..."*[361]

491. As Ms James explained in her witness statement,[362] on 26 April 1995, Dr Metters instructed Dr Rejman the formal instruction to provide a chronology and a list of relevant papers that may need to be disclosed in the HCV litigation.[363] On 7 June 1995, Dr Rejman minuted Ms James to say, inter alia:

> *"I have gone through all my files, and have gone through the files made available to me by Mr Burrage, GEB vols 1-14. Unfortunately vol 4 for part of*

[359] WITN3996019
[360] WITN4912037
[361] WITN5426160
[362] WITN5426001
[363] WITN5426017

1989 has apparently been destroyed. Mr Burrage has asked for the individuals responsible to write to him formally confirming this."[364]

Ms James identified this note as the first time that she became aware of the destruction of any documents relevant to the HCV litigation.

492. Upon discovering these omissions, Ms James described this issue as "*a one off case*", having "*no experience of this happening… in any other case*", and "*unusual and unsatisfactory*".[365] In her witness statement to the Inquiry, she accepted that the policy, medical and legal teams of the DoH (headed by, respectively, Dr Rejman, Mr Burrage and herself) should have sent a clear message that no further files should be destroyed. She accepted there was no written record of such a message being relayed.[366]

493. Dr Rejman explained in his evidence that he had understood from his involvement in the HIV litigation that, as soon as it became aware of litigation, the Department was under a duty not to destroy documents.[367] Peter Brand took a note of a conference with counsel on 18 May 1990 in relation to the HIV litigation. The note was certainly in summary form but stated, inter alia, that "*We must stop destruction on the date the litigation comes on. Hepatitis virtually nothing. Most of it has already been destructed*."[368] Although Dr Rejman, who could not recall this conference nor the note's contents, told the Inquiry in his witness statement that he understood that there was a duty not to destroy any documents which may be relevant to the litigation, the phrase "*the litigation comes on*" was an unusual one, and tends to point to the date of upcoming hearing (for example, the July 1990 first instance hearing in relation to the government's public interest immunity application), rather than to the issuing of proceedings, which had already occurred approximately one month prior to this conference. This note shows the Department of Health's careless approach to the management of documentation which, combined with the wording of the note (which was liable to cause confusion), increased the probability of documents being destroyed inappropriately.

494. Tangentially, the date of the Court of Appeal judgment on disclosure (which ordered that categories of documents be disclosed to the plaintiffs, and reversing much of the PII protection granted at first instance) coincides with the date given by Dr Rejman as the approximate date upon which discussions in earnest began

[364] WITN5426018
[365] WITN5426205; WITN5426210
[366] WITN5426001
[367] WITN4486040_0140
[368] DHSC0043223

towards settlement of the litigation between the parties: was this a coincidence, or was the Department of Health encouraged to settle to avoid the prospect of giving disclosure of documents which it did not wish to disclose following its loss in the Court of Appeal?

495. As detailed in his third witness statement, Dr Rejman was involved, through the ACVSB, in discussions relating to the introduction of HCV screening in the UK.[369] He was recognised in the final report of the Penrose Inquiry, at paragraph 31.490, as someone who, at the time "*had emerged as a contributor to the case against introduction* [of HCV screening using the then available tests", notwithstanding Dr Rejman's representation to the Penrose Inquiry as to his role and function on the ACVSB.[370]

496. The Inquiry will also recall that Dr Rejman was responsible for, inter alia, discovery in the earlier HIV litigation (in which the missing files were disclosed to the plaintiffs). He was also staunchly opposed to the HCV litigation, and betrayed the Government's closed mind approach to challenge and the upholding of civil rights. By way of reminder:

a) On 12 April 1995, a minute from Mr Scofield recorded that he and Dr Rejman had agreed the need to set rules for discovery of the papers relevant to the HCV Litigation;[371]

b) In July-August 1995, Dr Rejman sent a memo detailing the reasons why he disagreed with counsel's advice, which concluded that blood was a product within the scope of the Consumer Protection Act (and the EU Directive giving rise to it). Dr Rejman took exception to the fact that opinion relied on a product liability textbook edited by Mark Mildred, who was a lead solicitor in the HIV litigation and with whom Dr Rejman had had dealings in that context.[372] A solicitor in the DHSS later stated that Dr Rejman's "*forays into the law are not always welcome!*";[373]

c) In the final paragraph of a memo relating to the HCV litigation dated 2 December 1996, Dr Rejman expressed his firm opinion that legal aid should not be granted for haemophiliac patients to bring proceedings against the Department of

[369] WITN4486040, pp.73 -113
[370] WITN4486043; WITN4486044; WITN4486045; WITN4486046
[371] WITN5426014
[372] WITN5426036
[373] WITN5426046

Health for damages resulting from their infection with Hepatitis C. In this memo, he concluded by saying:

> *"…I would find it very difficult to understand if the Legal Aid Board were prepared to fund haemophilia patients who acquired hepatitis C and not blood transfusion recipients. In these circumstances I would suggest that Ministers should ask for an independent assessment (? Judicial review) of the process of advice given to the Board and their response. It would be wrong for public funds to be wasted, and I am sure that others also would question whether the views presented to the Board by an individual who stood to gain from continuing litigation were indeed impartial*";[374]

d) While discussing the above memo in his third witness statement, Dr Rejman made the admission that he "*really had no idea who might have some influence with the Legal Aid Board, and so I deferred to my legal colleague*". That Dr Rejman would consider seeking to persuade the Legal Aid Board not to grant funding for litigation is indicative of his broader attitude to the litigation and the need to prevent it; and

e) A government solicitor responded to Dr Rejman's memo of 2 December 1996. She sought to calm Dr Rejman and explained that the Legal Aid Board would make funding decisions based on their own set criteria and will require only that the plaintiffs have an arguable case. She noted that, in light of the Court of Appeal's commentary that the HIV plaintiffs had made out an arguable case (in the discovery proceedings, discussed in more detail in the licensing and justiciability section of these submissions), this test may be met out. She also explained that it would be improper to suggest that a Queen's Counsel barrister had given an opinion on the merits in an impartial way as he stood to gain from the litigation.[375]

497. For those involved in it, the HIV litigation will always be tarnished with the waiver which prevented claims arising out of HCV infection. This was a source of major concern for survivors and campaigners, because the risk and life-threatening consequences of infection with HCV had been concealed from those treated with blood products for decades.

The Investigation into Missing Documents

498. A draft minute prepared for the permanent secretary in relation to the missing documents explained that the Department had been advised by leading

[374] DHSC0006348_022
[375] DHSC0011947

counsel, Justin Fenwick QC (as he then was), to be prepared for the litigation, and it was on that basis that Dr Rejman was instructed to extract the relevant documents from the files. It was noted that when Mr Fenwick QC was told about the destruction of the files, he was "*incredulous*" and "*questioned Mrs James and Mr Lister as to how they knew the documents had been destroyed*".[376]

499. When asked about this in her oral evidence, Mrs James added that Mr Fenwick QC was "*plainly surprised… he had always emphasised how important it was to hang on to documents so I guess he wasn't too pleased about it*". She also added that this issue meant that the HCV litigation had the potential for embarrassment, and that the litigation could be compromised as a result.[377]

500. Mrs James explained that she consulted Mr Fenwick QC on this issue, whose advice was that there should be a small investigation into the destruction of the documents, which should be conducted "*in house and should not by any means take on the characteristics of a public inquiry*".[378] The requirements of that investigation were set out in the aforementioned draft note to the permanent secretary:

> *"The investigator should interview Dr Metters, Ms de Sampayo, the person at DH who signed the destruction authorisation (whom we know to be still at DH) and Dr Rejman. The investigator should then report on that and make recommendations about such matters in the future. Counsel was of the view that as part of the investigation Heywood Stores should be visited. In this way, the Department would have audited what has happened… May I reassure you that this appears to be a one-off case, Sol Litigation has handled three other major writ actions of this kind and will undoubtedly handle others. They have no experience of this happening. Indeed, Mrs James does not recall it happening in any other case."*[379]

501. Ms James was asked in her oral evidence why she thought that the destruction of documents happened in this case and no other. Her answer was:

> *"A. I think because people didn't understand the significance of what they were handling, the documents they were handling, and didn't give any thought in the -- to the possibility of litigation, and were not steered in the direction of thinking about litigation, compounded by the fact that the Department had undergone extraordinary upheaval, where a lot of the what we might call history had gone,*

[376] WITN5426205
[377] Transcript 13/09/2022, pp.91-93
[378] Transcript 13/09/2022, pp. 91-93
[379] WITN5426205

because the people who knew it had gone to other places, and been dispersed, and were no longer interested. I don't mean that they were deliberately not being interested but, you know, they were no longer interested parties in the Department of Health.

Q. So in some senses, are you saying that the corporate memory of the issues wasn't as strong as it might have been?

A. You've put it much better than I just did, that's correct."

502. Clearly, the Inquiry and its Core Participants will approach this issue from a different perspective to that of Mrs James and Mr Fenwick at the time: the Inquiry's examination of the evidence and some of the motivations of those involved in the infected blood scandal inevitably tars one's view of whether events were inadvertent or calculated. However, the following facts were known to Mrs James and Mr Fenwick QC at the time:

a) These files should, in accordance with DoH policies, have been retained;

b) Other files in the series were available;

c) The missing files appeared to target issues at the heart of the HCV litigation;

d) The failure to locate these files was unique in Ms James's experience;

e) The missing files had been considered as part of the earlier HIV litigation;

f) That the files may have been destroyed deliberately was at least a possibility;

g) Leading counsel was at least "surprised" if not "incredulous" at the situation;

h) All of this occurred against amidst the HCV litigation, which could have led to those documents being aired, and to the potential for adverse findings against Government and individuals alike.

503. In our submission, given the above fact pattern, a more targeted, substantive and independent investigation should have taken place. This should have involved a trained investigator reviewing the files (including the HIV litigation files), reviewing access records, conducting interviews, and taking statements. The investigation or "Internal Audit" that occurred was much more limited in scope.[380]

504. The Internal Audit concluded:

[380] WITN5426245_0003

"4.1 There is little documentary evidence to establish exactly why volumes 4 — 17 of GEB 1, which contained the minutes and background papers to the ACVSB between May 1989 — Feb 1992, were destroyed. However, the original file dockets still exist, and the annotations on these provide a reasonable audit trail, so that we can, with some certainty, piece the story together. DRO also have their own record of when the files were destroyed. We interviewed staff members from the relevant section, but their memories of events up to 8 years ago
were hazy at best, and added little to the evidence we had elsewhere…

"Two questions remain unanswered from our review: once the Department was aware it would need to collect relevant documentation together, Dr Rejman, who provided the secretariat role for the ACVSB, and who had previous experience of non-party discovery, began the process of collecting information. This was in 1994. ***However, Dr Rejman did not recall the ACVSB files from DRO, extracting information instead from other policy files. Some of the ACVSB files were still available, unrecalled, as late as 1997 and 1998 therefore****. Dr Rejman retired in 1994 as part of the FMR, and we do not know why the ACVSB files, available at DRO, were not recalled; although volumes 14 --17 were destroyed, volumes 1 —3 survive, having been assigned lengthy review periods, for example volumes 2 and 3 are due for 2"d review, in 2013 and 2014 respectively. These are the sort of review periods all volumes*
should have had, and it has not been possible to determine why volumes 1— 3 were treated differently"[381]

[Emphasis added]

Thus, as per the Internal Audit's findings, Dr Rejman certainly played at least some role in the failure to identify and handle documents properly. The delay to both the Internal Audit and this Inquiry has inevitably obfuscated matters and prevented the truth from being exposed.

Retention and Return of Papers by Carol Grayson

505. Ms Grayson played a pivotal role in ensuring that documents were preserved and that justice was done: despite the DoH's failings in destroying documentation, Ms Grayson and her solicitors had held on to copies of the missing documentation, and Ms Grayson notified the DoH and facilitated their return to the Department. In a letter from Ms Grayson's solicitors, Blackett Hart and Pratt (BHP), to the Treasury Solicitor dated 7 February 2006, BHP explained that it had retained copies of documentation from the HIV litigation, and that it intended to return the documents to the DoH in case the copies held by BHP were of missing or destroyed documents.

[381] WITN5426245

BHP sought an assurance that the documents "*will be preserved pending any request for access to them by Mrs Grayson, or such other persons as may have an interest in them*".[382] As BHP explained, this letter and suggestion was instigated entirely by Ms Grayson.

506. This watershed moment was so significant that it was reported in The Observer on 21 May 2006, as were the perturbing contents of the documents:

> *"…Senior legal figures who have seen the documents told The Observer they contain evidence of 'significant knowledge of risk and fault'. In particular, they claim that officials knew of the risks of contracting deadly diseases such as HIV and hepatitis from contaminated blood products years before they alerted patients.*
>
> *The latest development comes as a complaint was lodged with the parliamentary ombudsman seeking an investigation into the destruction of the original documents, which should have been stored for at least 25 years.*
>
> *Campaigners said they were delighted that copies of the paperwork still existed.*
>
> *'We have waited more than 20 years to find out what happened,' said Carol Grayson, whose husband died after receiving contaminated blood imported to the UK from high-risk prisoners in America. 'We cannot turn the clock back but at last we have some hope in our search to find out the truth.'*
>
> *However, she expressed concerns that they had been returned to the department which had appears to have accidentally destroyed the original files. 'We would have preferred these copies to have been held by some independent or neutral body,' she said.*
>
> *Her solicitor has written to the DoH asking them to provide an undertaking to preserve the documents."*

507. The return of these documents and their importance was also referred to in Parliamentary debate on 24th May 2006, where Lord Jenkins argued that the documents supported the calls for an independent public inquiry.

> ***"Lord Jenkin of Roding** asked Her Majesty's Government:*
>
> *Whether the files of papers about contaminated blood products which have recently come to light, some of which have been returned to the Department of Health, provide evidence to support the claims of haemophiliacs that their infection with hepatitis was caused by such blood products.*

[382] DHSC0015865

The Minister of State, Department of Health (Lord Warner): *My Lords, we have established that a number of documents that have been disclosed by the department in the HIV and hepatitis C litigation were held by Blackett Hart & Pratt Solicitors. It agreed to return the papers to our solicitors, who are now considering them with other departmental officials. Advice has yet to be given to Ministers on the significance of the returned files.*

Lord Jenkin of Roding: *My Lords, the files that have turned up came from the archives of more than one firm of English solicitors. Given the substantial volume of documents passed to the department's solicitors—I am told that there are no fewer than 12 big lever-arch files—and the fact that what they have is a small fraction of the material that has been held in solicitors' archives, and given that the department's paper Self-Sufficiency in Blood Products in England and Wales was expressly dependent on information that had survived the inadvertent destruction of some 600 of its files, are not there overwhelming arguments for a much more open, independent inquiry into what many regard as perhaps the most serious disaster that has ever happened in the National Health Service?"*[383]

[383] https://www.publications.parliament.uk/pa/ld200506/ldhansrd/vo060524/text/6052403.htm

10. TRUSTS AND SCHEMES

Charitable Status

508. The trusts and schemes set up to benefit those who had been infected should never have been developed as charities, which was an inappropriate mechanism for the distribution of Government funds: the continued existence of those organisations was dependent entirely on Government's ex gratia payments. This had the effect of converting charities into hybrid benefits organisations. Inevitably, the funding was at times used to perpetuate the charities' existence, rather than going solely and directly to the recipients who needed the help and support so sorely.

509. These views were held by those who were very much integrated in the day-to-day operation the trusts, including:

a) Mr Alan Burgess, a user trustee of the Macfarlane Trust ("MFT"): *"I think that DoH did indirectly control how the MFT discharged its duty to beneficiaries by simply turning off the taps and underfunding the MFT meaning that the trustees couldn't make grants even when they ought to"*;[384] and

b) Mr Roger Evans, MFT trustee and subsequently Chairman: *"In my view, the establishment of MFT was not the way in which the Government should have been administering funds to support the infected and affected. The Government should have been administering funding directly, and not through arms lengths bodies such as the MFT. As I mention below, it felt as though the MFT operated as a 'punching bag' or 'cushion' between the MFT beneficiaries and the DH/Government."*[385]

510. Following an MFT meeting on 21 January 2013, Kate Rendle wrote to Roger Evans expressing concern about Mr Evan's statement in the meeting that the MFT "*is an arm of government 'whether we like it or not'*".[386] Ms Rendle pointed out that a charity could not be an arm of the government, nor act on its behalf, and that the MFT did "*not exist to carry out* [Government] *policies or to consider their overall financial position*". She queried whether Mr Evans could act in the best interests of the charity in resisting financial restrictions, if he felt unable to "*rock the boat*" in discussions with Government.

[384] WITN1122019, paragraph 36
[385] WITN3859002, paragraph 24
[386] WITN1122027

511. In this and subsequent email chains,[387] Mr Evans was recorded as having described the MFT, in a plethora of ways, as an arm of the state, or otherwise restricted by the state:

a) *"…regarding arm of government DH* [Department of Health] *established MfT to administer its funds"*;

b) *"The money is simply not there";*

c) *You don't bite the hand that feeds you";*

d) *"I am not prepared to rock the boat";*

e) *"Lets not forget the DH set up the Macfarlane Trust and it can close it down";*

f) *"There's only one winner if you pick a fight with the government"*

512. The Inquiry will recall the unhappy and false distinction as between payments for infection with HIV and the initial failure to make payments for infection with Hepatitis. Lord Reid identified that that distinction was not justifiable, and introduced parity.[388] Those mono-infected with HCV were left for decades, with no support whatsoever until this parity was brought about.

513. In his statement to the Archer Inquiry, Peter Stephens (Trustee of the MFT and of other Trusts, Chairman of the Eileen Trust, and Chairman of the Board of the Skipton Fund Limited)[389] made the point that:

> *"the current registrants who had been infected with HIV have now survived much longer than the few years originally expected, and in consequence had present and accumulated needs that MFT could not meet on its present funding."*[390]

This suggests that initial funding decision were made on the basis that the group of individuals who needed the income would dwindle rapidly.

514. The lack of clarity as to whether any payments should be made, as well as the lack of permanence of payments, all undermined the starting point and continuance

---

[387] WITN1122037

[388] WITN0793001, section 8

[389]. Mr Stephens found it difficult to provide all answers to the Archer Inquiry: he stated that there were "*certain things that I might find it difficult to talk about, certain questions I might not be at liberty to answer*", and that there was "*quite a broadly drawn confidentiality agreement*" which covered "*government suppliers and arrangements between the firm and the government*"

[390] ARCH0002992_0003

of the Alliance House organisations,[391] particularly bearing in mind that their recipients were not at fault and were supposed to be being compensated. Such uncertainties are inherent in a discretionary, charitable structure: this would have been known from the outset. As such, charitable structures should not have been used as the vehicle for provision of government benefits, nor should this happen in future.

515. Notwithstanding the above, it must not be thought that the MFT was at all times[392] incapable of working in the interests of the infected community: many infected people would work with dedication to support others through the MFT. However, clarity of aims and eligibility, as well as clear income streams and/or the ability to have guaranteed financial payments from the state, would have provided a surer system to provide financial support, and may have avoided some of the unhappiness and turmoil that the MFT's system created. In the words of WITN1387, who was a user trustee, the MFT "*could have been a vehicle for good but in the end, all it did was generate bitterness and heartache and was at the end, an arm's length organisation*".[393]

Distribution of funds

516. Means testing of funding was a vexed issue which raised equally vexed questions, such as whether disability related benefits income should be excluded from any means testing, and whether entire household income should be taken into account. Beneficiaries understandably resented their partners' income being taken into account, as this placed a tremendous financial onus and burden on the partners of infected beneficiaries, already adding to what was often a significant emotional and caring burden. That these pressures occurred in circumstances where the state's actions were responsible for the harm and financial losses that were being compensated only added insult to injury.

517. There was little understanding or recognition of the fact that the care of infected individuals carried a substantial risk of lifelong physical and psychological

[391] Including the Skipton Fund, which was an ex gratia payment scheme making payments to people who were infected with hepatitis C through treatment with NHS blood or blood products prior to September 1991

[392] Consider the statement of WITN1387 (WITN1387014) at paragraph 164: "In my opinion and in general, the answer to all of these questions is not as simple as yes or no, the MFT went through stages in its history where it could be helpful, contactable, supportive, and informative, the MFT however was never set up as a long term organisation (for obvious reasons) and so really never had a proper formulated plan that it could build upon going forward"

[393] WITN1387014, paragraph 103

damage to the caring partner. In addition, many carers spent so many years caring for their partners that their ability to gain employment or re-enter the employment market after a partner's death was either limited or non-existent, thus furthering the financial and psychological harm done to them.

518. Mr Evans told the Inquiry that decisions as to funding

> *".....raised very difficult issues… many of the decisions for funding had an element of subjectivity. For instance, do we just look at someone's overall health situation, and the impact on their lifestyle or do we try to distinguish between those aspects of their health that are attributable to the effects of receiving infected blood products from those caused by haemophilia? There are no right or wrong answers to such questions"*[394]

519. However, many of our clients believe that there were insufficient attempts to engage and consult with the beneficiary community in order to better understand these issues, the nature of the impacts on the infected and affected community, and to ultimately understand the community's need. Alan Burgess told the Inquiry that user trustee system was not respected or utilised in the way that it ought to have been:

> *"User trustees did not have parity with professional trustees. We attended the board meetings, we sat on committees and on the face of things, we were listened to. But what we had to say was only ever acted upon if it fit in with what had already been decided by the Chair and Chief Executive."*[395]

Decisions, Grants, Loans, and Appeals

520. Summarising the views of the beneficiary community on how the MFT distributed funds, Mr Burgess told the Inquiry: "*The entire beneficiary community was dissatisfied with the unfair and inconsistent manner in which grants were made or denied; this was a persistent problem throughout my experience of the MFT*".[396] The issues experienced by the beneficiary community included (but were not limited to):

a) Satisfying the MFT that beneficiaries had "*tried and failed to obtain funding from other sources before a grant could be made; this meant for example, routinely*

[394] WITN3859002, paragraph 19
[395] WITN1122019, paragraph 22
[396] WITN1122019, paragraph 45

showing a failed application to the local authority for home adjustments to be made to cope with disabilities";[397]

b) The MFT relying on a reporting clinician's opinion as to whether a claimant's infection had been occasioned by drug use, "*regardless of the credibility of a "genuine" route of transmission*";[398]

c) Persuading the MFT (and subsequently the DWP) that issues such as fatigue associated with hepatitis C and haemophilic arthropathy had a significant impact on a beneficiary's life;

d) The lack of any written criteria on how an application would be determined and on the burden or standard of proof to be applied, which raised issues of consistency, transparency, and fairness;[399]

e) Decisions being taken on a partial basis, such as the "*mood of particular trustees at the meeting*", or whether an applicant was "*a 'good egg'*";[400]

f) The lack of any practical support or assistance being given to applicants who wished to appeal decisions,[401] which was a substantial hindrance to those with disabilities and other physical or mental health conditions (which, given what they had been through, was likely to be a relatively sizeable proportion of applicants);

g) The lack of recognition of infected widows, who were only told that they could apply to the Honeycombe legacy after Martin Harvey left the MFT and, more importantly, were denied recognition of their dual status as both infected people and bereaved partners which impacted them not only financially but emotionally as well;

h) Decisions on appeals being made without any right to oral representation. Although Mark Mildred (Chair of the Appeals Panel) told the Inquiry that he was aware that the appeal decision would be amenable to judicial review,[402] there is no evidence that an applicant's public law rights were explained to them, or to suggest that they would have been able to exercise effectively their public law rights.

---

[397] WITN1122019, paragraph 49; MACF0000088_ 022
[398] WITN30700003, paragraph 204
[399] WITN1387014, paragraphs 59 -65; WITN1122019, paragraph 100;
[400] WITN1387014, paragraphs 57 -
[401] WITN5258001, paragraph 35
[402] WITN5258001, paragraph 30

Financial Reserves of the MFT

521. At times the business model for the MFT put its reserves into millions of pounds. This accumulation of funds was clearly not in accordance with what should have been the main aim of the MFT: to provide help to those who needed it, and to whatever degree they needed it. However, set against a backdrop of uncertainty of continued funding, the MFT fell into the trap of continually looking to the preservation of its own existence, and therefore accumulating reserves to fight off financial uncertainty rather than using those funds to further its charitable purpose.

522. Mr Burgess told the Inquiry that he was, at the time, very concerned about the reserves of the MFT, and that he queried whether this was in the interests of the Government's balance sheet, rather than the MFT beneficiaries:

> *"72. My level of involvement in setting the reserves was limited to pressing for them to be run down whenever the reserves were discussed at board meetings. These representations were given no attention and were made to no effect.*
>
> *73. I was told that the reserves were in place in case the DoH pulled funding though I believe that they were maintained at such high levels to ensure that DoH didn't have to provide anything other than minimal funding.*
>
> *74. Four million pounds was an obscene amount of money to have held in bank accounts and investments when there were beneficiaries who needed money to alleviate some of the suffering of their HIV infections. The trust's primary purpose was to alleviate the suffering of beneficiaries and I don't see how that purpose is achieved when most of the money is held away from the beneficiaries and ring fenced.*
>
> *75. In my opinion, the level of reserves definitely impeded MFT's ability to negotiate with government for increased funding but then, I'm sure that was the point of having the reserves set so high."*

523. WITN1387 concurred with those views:

> *"37. I do recollect feeling that the majority of the board seemed more concerned with holding on to the reserves than they did of looking towards the registrant community and how they could be helped.*
>
> *38. I recall there being a constant eye on the maintaining of the trust's reserves at £4m and an absolute refusal to accept the argument put forward by some of the trustees (including myself) that the only way to get DoH to properly fund MFT was to spend what we had.*

39. In my opinion, the reserves should have been utilised to increase regular payments to beneficiaries, to take a more consistent approach to the awarding of grants and to better support the increasing number of bereaved widows."[403]

524. Despite the argument that the maintenance of reserves was intended to protect the MFT's funding, Jude Cohen (former Head of Support Services for MFT) told the Inquiry that she had been informed by the Chief Executive, Martin Harvey "*…that the MFT couldn't have more funding from the government because the previous year they had underspent*".[404] As with many other aspects of the infected blood scandal, those at the heart of the tragedy were ignored, undermined, and side-lined, despite holding relevant, persuasive, and knowledgeable views.

Welfare Support

525. Victims of the infected blood scandal had not only a pressing need for financial assistance, but a corresponding and equally pressing need for other forms of support. The infections that they receive either severely curtailed the lives of the infected, or put them in grave danger. That was a difficult situation to comprehend and deal with, even before one considers the impact of the infected community's continual battle for justice, and against the stigma they so cruelly faced. However, as Samantha Mays told the Inquiry:

"In the early days, after HCV was specifically identified in 1989, there was a complete lack of accurate information, no provision for emotional support and a stigma was often attached to those who were infected. So in 2001 the Trust launched a website, and in 2004 a helpline, to help remedy this."[405]

526. Ms Mays went on to explain that HCV sufferers were given "*poor and confusing information, had little or no support and particularly if they were on treatment, were significantly struggling on a daily basis to manage the physical and mental side effects alone*". In addition, information about NANB/HCV was "*often also delivered in a heavy handed, judgmental and frightening manner and presented as hard fact. This meant that a lot of incorrect information or `urban myths' about HCV and its subsequent confusion with other viruses was passed on.*" Although the Inquiry was told that haemophilia treatment started in the lab before gradually moving towards being orientated on care and patient experience, it seems that this did not reflect the full, lived experience of those who had contracted infections through infected blood products.

[403] WITN1387014
[404] WITN4565001, paragraph 69
[405] WITN0912001, paragraph 6

527. WITN1387 agreed with Ms May's sentiments:

> *"The MFT's formative years coincided with a time of enormous fear for its beneficiaries who either believed that they had a very short lifespan or believed that their partner did and would die soon. This was a time when support services such as a helpline and counselling would have been invaluable but there was nothing of the sort."*[406]

528. In the late 90s, Anne Hithersay (Chief Executive of the MFT) established the Partnership Group, of which WITN1387 became a member. The Partnership Group was intended to be a voice for the beneficiary community which would be heard by the MFT.[407] However, the beneficiaries did not feel that the Group was successful in that aim:

a) WITN1387 told the Inquiry:

> *"118. My recollection was that the Partnership Group's purpose was to act as a voice for the beneficiaries which would be heard by the MFT. The Partnership Group had some successes such as the appointment of user trustees to MFT but its success and influence waned until the point at which it was ultimately done away with by Roger Evans, very few times did trustees attend.*
>
> *119. I think the chief barrier to the Group's success was the lack of interest shown by the trustees – the lack of engagement was even noted in some of the minutes of Partnership Group meetings (notably HSOC0005423) where the absence of any non-user MFT trustee is recorded and commented upon.*
>
> *120. It is my opinion that the trustees had an idea of how the MFT should be run and that Partnership Group proposals would be incorporated, providing they were in keeping with that idea but would be discarded if they were not"*;[408] and

b) Alan Burgess was of the view that:

> *"The Partnership Group had very little if any impact on the MFT's operation; I understand that the addition of user trustees to the MFT board was as a result of PG pressure, but this is the only achievement I can think of in terms of changing the way the MFT functioned".*[409]

---

[406] WITN1387014, paragraph 33
[407] See the minute of the inaugural PG meeting on 14 May 1999: MACF0000007_204
[408] WITN1387014
[409] WITN1122019, paragraph 159

529. Before what has become known as the 'dispute' meeting on 29 January 2015, concerns and issues were raised in Parliament about the operation of the trusts and schemes, following on from the publication of an All-Party Group Report on 14 January 2015 which ultimately led to reform of financial support, decades after those concerns had been raised repeatedly by beneficiaries. These concerns included the following points:[410]

a) That the organisations "*do not treat people equitably*";

b) That the MFT is neither "*able or capable of reform*";

c) That the organisations should not be "*an arm of government, nor seen to be*";

d) That the "*current system of support is not fit for purpose*";

e) That the funds had become "*part of this degrading process, where sufferers, who are largely reliant on benefits, are effectively begging for resources*".

That such a system was able to remain in place and unaltered for so long, despite the chorus of objection raised by the infected community, speaks volumes of the low value that was placed on the lived experience of the infected community.

530. That same low value was echoed in the experiences and views of WITN1387, particularly in the discrepancies between user trustees and professional trustees:

> *"97. Many of the professional trustees and chief executives simply had a very different life experience to the beneficiaries of the trusts. The circumstances of a haemophiliac infected with HIV were so remote that there was no way that they could understand the perspective of the beneficiaries and therefore, it was very difficult to empathise.*
>
> *98. Some of the trustees were simply, in my view, unfit to be anywhere near a charity of any kind; they were entirely devoid of empathy.*
>
> *99. I recall certain trustees were consumed with running the MFT like a business rather than a mechanism to alleviate the suffering of the beneficiaries – running the MFT almost like a pay-day loans company was a perfect example of this.*
>
> *100. I think also that those few trustees who ventured to a Partnership Group meeting saw the most able-bodied and vocal registrants and resented the money paid to them through the MFT. I think that the immediate perception was of people who looked relatively healthy; certain trustees had not the medical or*

[410] As quoted in the emails as WITN3078020

historical insight to understand the true problems being experienced by even the healthy-looking beneficiaries."[411]

The Closure of the MFT

531. The closure of the MFT following the Government's reform of financial support resulted in the need to close out the MFT's accounts. Alasdair Murray (MFT trustee and Chair as of May 2016 onwards) described MFT's decision to distribute its funds in accordance with a time-limited grants programme: the staff team selected criteria for the grants, which were described by Mr Murray as "*predominantly big-ticket expenditure items… [which] were likely to have the biggest impact and would meet needs that were not expected to be covered by the NHS BSA scheme*."[412] While this was a laudable aim, this approach disproportionately excluded other categories of beneficiary (such as infected partners) who might not have had expensive medical equipment requirements. This was but one example of the many ways in which non-haemophiliac members of the infected community were left out of the picture, or forgotten about.

532. The residual balances of the MFT (approximately £1million were transferred to the Terrence Higgins Trust[413] ("THT") upon MFT's closure.[414] Many haemophiliacs and their infected partners do not consider that the THT should manage the residual MFT funds and have suggested that the THT cease to represent MFT beneficiaries and to release the remaining funds.[415] There are also deep-rooted tensions which have never been satisfactorily resolved.[416]

Strained Relationships within the MFT, including the MFT's Treatment of Women

533. This section of our submissions has demonstrated the strained relationships both within the MFT, and as between the MFT and its beneficiaries. Each and every breakdown in relationship or communication cannot be detailed here, but it is worth recalling some of the more egregious issues or events which contributed to an enormous amount of disharmony in and around the MFT's operation:

---

[411] WITN1387014
[412] WITN3076002, paragraphs 124 -125
[413] This also had the effect of the Charge on Ms Walton's property established under the aegis of the MFT which have been long disputed and fought over by Ms Walton, being changed under "Lendor" to the Terrence Higgins Trust WITN1589023_0008
[414] WITN3076002, paragraphs 51, 129
[415] An example from Positive Women is WITN1589025
[416] WITN1589026 and WITN1589028

a) Ms Cohen told the Inquiry that the CEO and Chair of the MFT felt that "*many beneficiaries were frankly a nuisance, rather than the charity's raison d'etre…. they also spoke disparagingly of some registrants and appear to try and undermine their attempts to raise complaints or concerns*";[417]

b) Email correspondence in which Peter Stevens and Gordon Clarke referred to the MFT beneficiaries as "*whinging haemos"* and "*the great unwashed*" respectively;[418]

c) The note within MFT meeting minutes and correspondence that there had been a breakdown in communications between the MFT and the beneficiary community, as well as between the beneficiary community and the Haemophiliac Society;[419]

d) The dispute between Jan Barlow and Roger Evans on the one hand, and Liz Carroll on the other, which is neatly set out at paragraph 17 of Ms Carroll's 4th statement and responded to at paragraph 186 of Ms Barlow's statement.[420] Ms Carroll alleged that, in response to a discussion about government's response to the Penrose Inquiry, Ms Barlow had said that *"the Department of Health should wait as long as possible before making any decisions as more people would have died and there would be less people to pay."* Ms Barlow and Mr Evans deny the allegation but, in our submission, Ms Carroll gave credible oral evidence and the Inquiry has no reason to presume that she would have invented the incident. Where the truth lies will remain a mystery; and

e) Ms Cohen's breakdown in relationship with Martin Harvey, which resulted in her leaving the MFT and entering into a non-disclosure agreement.[421]

534. Speaking about the system of user trustees, Mr Evans told the Inquiry that his "*only regret is that no widows/partners were ever appointed*".[422] This was a substantial gap in representation on the Board, bearing in mind not only the lives of many women spent looking after their infected partners, but also the lived experience of female haemophiliacs, whose existence was denied for decades.

535. WITN1387 describes the support given to widows (or, perhaps more accurately, lack thereof) as "*not adequate and remains inadequate to this day*".

[417] WITN4565001, paragraph 167
[418] WITN1122019, paragraph 173
[419] MACF0000024_002; WITN3078029
[420] WITN3078009 and WITN3108003 respecti vely
[421] WITN4565001, paragraph 42
[422] WITN3859002, paragraph 109

WITN1387 also highlighted that although £2 million had been allocated to MFT by the Department of Health for the purposes of supporting widows, half of this was spent on those termed "*primary beneficiaries*". There was, in the view of WITN1387 and many more of our clients, a complete failure to understand and identify the harsh realities that women experienced as a result of the infected blood scandal:

> *"42. It is important to consider that haemophilia widows/widowers have not suffered a spontaneous bereavement; they nursed and cared for their infected partner up until their death and had to deal with horrific experiences which scarred them. They had to endure the stigma of AIDS with their infected partner and they experienced the same social isolation and abuse. They did this knowing that they would outlive their partner and that for many of them, they would be left in destitution; there was nothing that could be done about this, they couldn't work more or get a better job (or in some cases, even work at all) because their time was dedicated to the care of their infected partner.*
>
> *43. These experiences left many of the bereaved, disabled – either physically through the labour of lifting and caring for their partners and/or psychologically through the sheer trauma of what they had been through.*
>
> *44. This is a point that has never been fully appreciated by the DoH, DWP or many of the MFT trustees. In the case of the trustees (and probably as a result of their interactions with government) there was a pervading belief that any additional support for widows would come at the cost of additional support to infected or primary beneficiaries. The use of the term 'primary beneficiary' is of itself interesting because the logical inference is that the widows were secondary beneficiaries…"*[423]

536. The experiences and treatment that female haemophiliacs and female partners endured (whether infected or affected) was a result of, and indeed demonstrative of, outdated and wholly unacceptable attitudes towards women: that their concerns were overstated (perhaps even 'hysterical'), or not to be believed; that their symptoms were simply part of 'women's problems', rather than warranting medical attention and support; and that they were not deserving of financial assistance and other forms support in light of their 'natural' role as carers. This was no way for the state or supposedly enlightened professionals to act; it is nothing short of misogyny, and we invite the Chair to deprecate this treatment in the strongest of terms.

England Infected Blood Support Scheme ("EIBSS")

[423] WITN1387014, paragraphs 42 -46

537. Although EIBSS has improved the experiences of beneficiaries (for example, known eligibility criteria, an uplift in payments, payments being linked to the Consumer Price Index, enlargement in the scope of payments and potential assistance),[424] issues with the scheme still remain, including other governmental departments failing to disregard EIBSS income for the purposes of means testing.[425] The Inquiry also heard that the DWP continued in its refusal to recognise female haemophiliacs until as late as 2018.

538. Although steps have been made in the right direction, it is unacceptable that the infected and affected have suffered so immensely, and for so long, and are still having to fight these tiresome and stressful battles on a daily basis, particularly in dealings with the state.

[424] WITN4688055, page 11
[425] WITN4496001, paragraphs 244 -245

11. THE CAMPAIGN AND THE CAMPAIGNERS

539. As the scale and toll of HIV infections amongst the bleeding disorder community became apparent, the campaign for justice for those infected and affected was born. From the genesis of the campaign, in the early 1990s, a core group of campaigners devoted themselves to challenging the government and fighting for recognition and recompense; tragically, few of that core group remain alive to see the work of this Inquiry, its final report, and its recommendations.

540. The Inquiry heard powerful and moving evidence from those who have been campaigning for three decades. Those campaigners' lives have been consumed by their fight for truth and justice. To try to summarise their efforts in these closing submissions would do them a disservice. Instead, we ask the Inquiry to revisit our clients' witness statements and oral testimony. The third statement of Carol Grayson[426] and the third statement of Colette Wintle[427] are essential reading and set out the extensive history of the campaign;[428] indeed their efforts were recognised by Lord Morris in the House of Lords when he spoke of them both as belonging in a "Gallery of Heroines" who had campaigned tirelessly.[429]

541. The campaign for justice over the years has been multi-faceted, characterised by the campaigners having to fight simultaneously on a number of fronts, including: domestic and international litigation; public law challenges; demonstrations; and lobbying parliamentarians. It is incontrovertible that campaigners looked down every alley in their search for justice. This included making complaints to the police, which were never properly investigated, and making complaints to the General Medical Council ("GMC"), which had such an opaque complaints procedure that the complaints were never properly investigated, and patients were never given sight of the response evidence provided by doctors. This was a woeful response by the bodies charged with criminal conduct and medical negligence: patients were failed by the very people who were supposed to protect them. Both the police and GMC have subsequently – and in our view rightly – expressed regret over the manner in which they dealt with these complaints.

542. In addition, those involved in the campaign have also worked to support the infected and affected community more generally; for example, Haemophilia Action

[426] WITN1055004
[427] WITN1056009
[428] Also summarised in the campaigning A -Z earlier in these submissions
[429] HSOC0002256_0004

UK and the Birchgrove Group. In her oral evidence, when asked if there was a lack of availability of support, Ms Grayson said:

> *"Absolutely. People just didn't know who to turn to, and I guess because I'd had a counselling role, I sort of took that on, and for years we would have people ring us day and night at 3.00 in the morning they would ring us and, you know, we said, "You can ring us at any time", you know, we – but obviously that's very difficult as well, you know its stressful. But we wanted to give that support and we wanted to help them [the infected/affected community] to find a route. Because they wanted to know more but they didn't know how to go about it in a practical way, how to get medical records, who to contact."*[430]

543. WITN1387 also spoke of the role that haemophiliacs played in supporting and assisting one another through the work of the Birchgrove Group:

> *"In 1998, I joined the Birchgrove Group which was started by a small group of infected haemophiliacs. Birchgrove (probably like other campaign groups) wasn't simply a campaigning organisation, it offered support and advice to infected haemophiliacs. By this, I mean that Birchgrove wasn't just trying to fulfil the advocacy gap left by the Society's inaction – it was doing everything that the Society ought to have been doing for its members…*
>
> *I think that Birchgrove tried to do all of the things for infected and affected haemophiliacs that the Society ought to have been doing and the main vehicle for this was the Newsletter. The Newsletter included stories from infected and affected people with the intention that those reading would see that they weren't alone in the struggles they were facing. Later, the Newsletter included information and articles which we sourced from the US on the latest HIV treatments so that people could understand the options open and have some understanding of the drugs they were being prescribed..."*[431]

544. These two pieces of evidence capture the essence of the campaign. It was always so much more than just activism: the heart of the campaign was fraternal support. Campaigners were forced into a position of fighting for justice whilst supporting their own community because the body that was supposed to represent their interests, the Haemophilia Society, was at that time unfit for purpose. Their efforts in assisting one another must be applauded, but the unavoidable conclusion is that they should never have been forced to bear this additional emotional and psychological burden. They needed, and so rightly deserved, outside help and support to mitigate the harm that had been inflicted on them without their knowledge or consent of the risks.

[430] Transcript 08/07/2022, Pg 68, Line 19 – Pg 69, Line 6.
[431] WITN1387015_0004/5

545. Keeping the issue within media attention has been another feature of the campaign: Carol Grayson appended a 134 page list of links to her media involvement to her third statement[432]; a list which has subsequently grown to 151 pages and continues to grow. She was the driving force behind campaigns in the Northern Echo, Newcastle Journal, and Hartlepool Mail, as well as being a key researcher for the BBC's 2007 Newsnight focused on contaminated blood.

546. Equally, Colette Wintle has been deeply involved in local and national media throughout the campaign; she was instrumental in the making of Meridian Television's Blood Brothers documentary[433] which won regional documentary of the year in 2001.

547. The collective efforts of the longstanding campaigners have borne remarkable results.

The Statutory Public Inquiry

548. The campaigners' need to fight so ardently might have been dispensed with entirely had various governments admitted mistakes, been open and transparent about what had happened, and paid meaningful compensation. Instead, the infected blood scandal has been marred by the closing of doors and ranks, and it took a government with no majority to be forced into commissioning the present Inquiry. Had the 2017 government been in a stronger place, it is entirely possible - probable even - that the fight for a public inquiry would still be ongoing.

549. Through the evidence of the campaigners, the Inquiry has seen the thousands of letters written to various members of Parliament; many went unanswered and, as the Inquiry heard from many of those MPs, many of the letters never even reached them, having been filtered out by a civil servant. One of the revelations of this year's evidence has been the fact that ministers were shielded so thoroughly from the correspondence sent to them: many ministers had not even seen the letters addressed to them as part of their preparations for appearing to give the Inquiry evidence.[434]

[432] WITN1055005
[433] ITVN0000005 and ITVN0000040
[434] Transcript 27/07/2022 Pg 18 – Jeremy Hunt believed the practice of Civil Servants filtering all critical correspondence was wrong and insisted on receiving one letter a day from a member of the public.

550. The call for a public inquiry has been a cornerstone of the campaign from its earliest days right back to the 1990s: Carol Grayson even had a letter published in the British Medical Journal calling for doctors to support campaigners' demands for a public inquiry.[435] Various reasons have been given for failing to hold an inquiry at an earlier date, perhaps the most honest came from Jeremy Hunt when he said:

> *"When I did become Health Secretary it was made clear to me that the Treasury would not support an inquiry because of the potential cost to the taxpayer which (taking into account any decisions on financial support which might follow, such as a recommendation for a compensation scheme similar to that in place in Ireland) could amount to billions of pounds. I did not therefore pursue the issue and followed the official government 'line' in correspondence with all campaigners."*[436]

551. The excuse most commonly cited for not holding an inquiry sooner has been that the Government did not consider that there had been any wrongdoing:[437] an excuse which, as has been shown in earlier sections of these closing submissions, was both naïve and disingenuous. On any view, the infection of thousands of haemophilia patients with HCV (and the coinfection of over a thousand of those individuals with HIV) was clearly a matter which was more than capable of arousing public concern, and had already done so (so much so that the Government had made ex gratia payments, largely in recognition of that concern). There can, therefore, be no question that the provisions of Section 1(1) of the Inquiries Act 2005 (set out earlier in these closing submissions) were satisfied. The only outstanding matter was ministerial inclination.

552. Successive governments between 2005 and 2017 erred in their understanding of the Act, and missed the entire purpose of instituting an Inquiry (whether deliberately or otherwise). Against the backdrop of government's account of circumstances having been loudly and continuously disputed over the course of decades, it was wrong for successful governments to refuse a proper investigation. As already set out in these submissions, it was clear that government's corporate memory on these matters was weak and, irrespective of government's belief, the concern held by the general public (as well as their need for information and independent assessment) should have outweighed government apathy toward an Inquiry.

---

[435] WITN1055064
[436] WITN3499001_0005
[437] Caroline Flint's written evidence WITN5427001_0129 being a prime example

553. The argument that Government sincerely believed that there had been no wrongdoing appears all the more disingenuous when one recalls the opening submissions made on the DHSC's behalf by Ms Grey KC at the Inquiry's preliminary hearings. Before the Inquiry had heard any evidence, DHSC was content to say:

> *"Things happened that should not have happened and so, on behalf of my clients, I say, unreservedly, that we are sorry. We are sorry that this should be so, that this happened when it should not have done. This is the beginning of a journey to uncover exactly what happened and why, but from those I represent it begins with an expression of sorrow and regret."*[438]

554. While Ms Grey's words were welcome and clearly sincere, our clients wonder why DHSC could not come to the same realisation, or give a similar expression of sorrow and regret, at any time prior to 2018? Instead, the infected blood community faced decades of stonewalling. The answer to this question is simple, and given frankly by Mr Hunt: government was afraid of the financial cost of putting things right. Successive governments failed to have the faintest regard for the very real human cost of prolonging the fight, prolonging the denial of a path to understanding, and ultimately prolonging the denial of access to justice. This human cost has only added to the injury already inflicted upon this community, as the stress and anxiety of battling with those wielding the utmost power has had further adverse impacts on the health of the infected and affected. Furthermore, while the Inquiry itself has been universally welcomed by our clients, the emotional cost of engaging with these issues, in some cases so long after events and after the deaths of loved ones, has been a fresh source of traumatisation.

The Recovery and Preservation of Documents

555. One of the great successes of the campaign has been to recover and uncover a vast amount of documentation. Much of that success is attributable to Carol Grayson who, as explained earlier in these submissions, identified that Blackett Hart and Pratt may have held copies of documents destroyed by the Department of Health, and directed their return on the proviso that they would be held securely and made available for public access.[439] In her oral evidence, Carol was asked what led her to continue with her tireless campaigning activities and specifically, what caused her to make enquiries with Blackett Hart and Pratt; she replied:

> *"Because I wanted answers for everybody, because if I can describe, haemophilia is a bit like a big family and it can be dysfunctional at times but there was a core*

[438] Transcript 26/09/2018 PM, Pg15, Line 18 onwards
[439] WITN1055004_0131

group of us that were in touch and, in many ways, haemophiliacs are in contact with each other all their lives because quite often they'll go to like Treloar's together, they'll be at the same treatment centres together, they'll be – they'll go to each others' weddings together. They used to go on the Haemophilia Society caravan holidays together. So this was a group of people that was like a big extended family, and – you know, they became my family. And I wanted to find answers not only for Pete but for other people as well, and that was [my] motivation.[440]

556. As the Inquiry knows, not least from the evidence heard during the course of 2022, those documents were ultimately returned and, after briefly being made available on the Department of Health's website, were made available for public access through the National Archives at Kew. As Carol said in her oral evidence:

"…in 2005 Lord Patrick Jenkin and myself worked hard to find out more about what documents were available and we then managed to get an agreement by Government not to destroy any further documents. So basically, anything that's there blood policy-wise in NA, Kew, has been saved because we fought to save it…"[441]

557. The outcome of campaigners' efforts to discover, collect and preserve documents has been the enormous pool of evidence which the Inquiry has had available to it. Without those documents, one wonders whether an Inquiry would have taken place and, even if so, whether its findings would have been the same.

558. It remains unsatisfactory that there is nothing at Kew to denote the struggle to preserve the documents which now reside there. The uninitiated could easily believe that the papers relevant to the infected blood scandal were transferred as a matter of routine, rather than as the result of a decade long fight. The National Archives have thus far refused requests to add a history page to the collection, highlighting the role of Ms Grayson and certain parliamentarians in preserving the documents. Our clients consider this to be wrong: this is an important piece of history, and one which should be learnt from so that it can never be repeated.

559. Nevertheless, it would be a mistake to consider the documents preserved at Kew as the totality of those sought, found and utilised by campaigners. Vast amounts of research was undertaken by campaigners. On this, Ms Grayson said in her written statement:

[440] Transcript 08/07/2022, Pg 54 Line 15 onwards
[441] Transcript 08/07/2022, Pg 185 Line 17 onwards

"It is important to point out there was no "quick fix" online research facility in the early days and I would wait patiently for documents to arrive from the US and Canada from other haemophilia campaigners by snail mail…

I keenly researched all I could get my hands on regarding plasma and plasmapheresis before writing about it. As I started to get to grips with my research findings, the severity and scale of the Contaminated Blood scandal in the UK haemophilia population became much clearer. I knew that research would be a large part of my role in campaigning as the material was at times so alarming it was almost hard to believe myself and I did not want to be dismissed as an unreliable "conspiracy theorist". Indeed this was part of the problem in my early days of campaigning getting not only the media but haemophiliacs themselves to accept the background to what had happened to them and for a time, many were in denial as they had put their absolute trust in those securing and providing factor concentrates…

Now when I watch the doctors and scientists giving evidence to the Infected Blood Inquiry, I am already very familiar with much of the evidence from both academic journals and government documents which I accessed years earlier and know some of these articles like the back of my hand. As far as the research articles go, although the content can be quite grim, it is in a way also like being among old friends…"[442]

560. Further still, an enormous amount of information emerged from the relentless correspondence that campaigners engaged in over decades: Colette Wintle's third statement is drafted in large part as a chronology of the day-to-day correspondence she engaged in. Colette was not alone, as is evident from Carol Grayson's third statement: alongside both was a core group of longstanding campaigners, who pursued answers from government tirelessly. Colette was honoured to be the first UK speaker to address the International Hepatitis C Conference: in 2000, she addressed the Fifth Conference on the topic of living with haemophilia alongside HBV and HCV infections.

Academic Work

561. In 2006, DHSC published "*Self-Sufficiency in Blood Products in England and Wales: A Chronology from 1973 to 1991*".[443] The report found that, despite government's best efforts, the demand for clotting factor products increased so far and so rapidly that the continued importation of products remained a necessity. The report further found that NANB hepatitis was long considered mild and often

[442] WITN1055004 paragraphs 105, 111 and 113
[443] DHSC0200111

asymptomatic, and that patients had balanced the improvements they offered to quality of life against the dangers of acquiring infection.

562. The report apportioned blame to the Haemophilia Society for its appeal to Government that American blood supplies should not be banned, and for encouraging haemophiliacs to continue with their treatment. The report seemed to disregard the state's own responsibility to ensure that all licensed medicines were safe and efficacious. The report was silent on the state's own role in the scandal. Carol Grayson was incredulous at the report's content and, despite being in the depths of grief over the death of her husband, she was determined to make use of her and Pete's experiences. In Chapter 4 of her seminal dissertation,[444] Carol carefully, comprehensively, and with devastating efficacy, deconstructed the Self-Sufficiency report. Her dissertation was so effective that it ultimately lead to the report's withdrawal.

563. Without Carol's detailed research, hard work, and dogged determination, it is entirely plausible that Government might still now be placing reliance on that report, which was necessarily an incomplete account, having been prepared without the benefit of the documents returned by Carol, through Blackett Hart and Pratt. As the Inquiry heard, the report was also prepared with deference to the long-held "lines to take" about patients having been given the best possible treatments available at the time, and without which they would have died.

Lesser Celebrated Aspects of the Campaign

564. The milestones of the campaign, being so profound as they are, can draw attention from lesser celebrated aspects and achievements. We highlight three areas which are important to our clients.

565. First, the way in which the campaigners gained recognition of the extent to which gender has played a role in the harm done to members of the infected and affected community. This recognition has only come relatively recently, and women were treated (and continue to be affected) in a number of appalling ways:

a) First and foremost, and as already touched upon in these submissions, there was until very recently a near complete failure to recognise that women were not merely carriers of the haemophilia gene, but could also be haemophilia sufferers. The correction of this misconception has long been campaigned for by

[444] CGRA0000208

Colette Wintle, herself a female haemophiliac, and Carol Grayson. It was because of Colette's efforts that the Haemophilia Society initiated its campaigns "Women Bleed Too" and "Talking Red";

b) The historic relegation of female haemophiliacs as "*symptomatic carriers*" in medical terminology often had a negative impact on their medical care and treatment by haemophilia clinicians;

c) Clair Walton and WITN1388 have long campaigned for proper support and recognition for those women who were infected with HIV by partners who had, in turn, been infected through blood products. Some of these women were amongst the first cohort in the haemophilia community, and whose lives were devastated with absolutely no support or recognition. The stigma of HIV silenced their voice. They should have been, and going forward must be, supported;

d) The language used to describe the female members of the infected community was, put bluntly, shocking and degrading. As the Inquiry heard, female haemophiliacs were referred to as "*symptomatic carriers*", which presumed that their experience was less than that of a male haemophiliac.

e) The 1991 Settlement Agreement's use of the phrase "*infected intimate*"[445] was, on any view, offensive and belittling. Even if a less offensive term had been adopted, there was again a false presumption that women were not primary beneficiaries and fell into a second class[446]. It is well understood that language and labels can substantially alter the life experiences of those to whom they are applied and, as the Inquiry heard, the aforementioned labels had a negative impact on the outcome of treatment, healthcare, and applications for financial support;

f) Similarly, the MFT's processes, and its failure to have regard to the voices of infected females, meant that women were subject to the decision making of the MFT without being heard;

g) The partners of haemophiliacs were often, by necessity, the main wage earners in a household, despite also fulfilling a physically and emotionally demanding caring role. The immense difficulty posed by that position was exacerbated where partners were infected and themselves unwell, but were forced to continue working to provide for their families due to a lack of adequate support;

[445] This term was frustratingly re-used when EIBSS came into operation

[446] Ms Walton believes that "the use of the term "infected intimates" directly led to less favourable financial treatment from the MFT: "if categories had to be used, then there is no reasonwhy …. should not have simply been set alongside our partners, as primary beneficiaries" WITN1589023_0003

h) As a result of their treatment as relegated, second-class citizens, the support to women often dried up following the death of their partners, notwithstanding the immense and life-changing grief that this brought about;

i) So many women were deprived of their chances to have children as a result of their treatment, including but not limited to the callous and ignorant advice of the doctors advising them on fertility issues which, in some cases, amounted to no less than coercion to seek an abortion;

j) To this day, there is stigma surrounding HIV. Partners who have been infected as a result of blood products have to attend GU clinics for treatment. At these clinics, assumptions are made about how these women came to be infected, which can be immensely degrading. These women have unique health and social care needs which need to be understood and accommodated in a more appropriate and compassionate way going forward. This issue demonstrates the importance of the Inquiry having regard to non-financial recommendations, and we ask that the Chair take a broad view of the recommendations he can make on the evidence he has heard.

566. It has been a remarkable achievement by Colette, Clair, GRO-A Carol, and other campaigners like them that they have highlighted these issues and brought about change, against a backdrop of protracted hostility to their cause. All of them did so through failing health, and notwithstanding the impact and further consequences that their efforts would have upon their health. They were selfless in their quest for justice for all, and must be recognised as such.

567. The second lesser celebrated aspect of the campaign is the way in which it brought those in desperately tragic circumstances together, as part of what Ms Grayson called "*a family*". More recently, the Inquiry's hearings have provided a forum for those infected and affected to meet people in similar positions and with similar experiences to them. This has, in turn, led to new buds emerging from what might traditionally have been considered the core campaign.

568. Among our client group, Stuart Mclean, Fiona Rennie, and several of our anonymous clients have been instrumental in uniting those who were misdiagnosed with haemophilia and treated, entirely inappropriately, with clotting factor products, resulting in their infections. This work has not only provided support to those in similar situations, but has helped collate knowledge of (and evidence of) issues with diagnosis methods, and of treatment with factor concentrates in circumstances where synthetic alternatives were available and were, on any view (even the

mistaken view that the individuals had the mildest forms of haemophilia) more suitable.

569. Thirdly, more recognition must be had for those who worked both within and against the trusts and schemes, particularly people like Carol Grayson, Alan Burgess, WITN1387, and Clair Walton, all of whom participated in the MFT's Partnership Group, seeking to bring fairness and empathy to the way in which it conducted itself. As explained in these submissions, Alan and WITN1387 would later become user trustees of the MFT, seeking to bring some humanity to proceedings whilst trying to curb the excesses of some of the less empathetic trustees. Furthermore, the information and documents retained by those involved with the trusts and schemes has enabled the Inquiry to scrutinise the schemes' actions in its characteristically careful and detailed way.

570. Finally, it should not be forgotten that moves to recombinant blood products and the implementation of the vCJD lookback were largely accomplishments of the longstanding campaigners who refused to accept the continued risk to which they were being exposed by human derived clotting factor concentrates.[447]

571. To conclude this section of our submissions, we reiterate the straightforward (but incapable of being overstated) premise: the fact that the Inquiry exists, that it will shortly report, and that Government is considering meaningful compensation, are all achievements of the campaigners who have fought so tirelessly, selflessly, and tenaciously for justice across three decades. We are privileged to represent some of those individuals.

[447] WITN1055004_0058

12. NON-FINANCIAL RECOMMENDATIONS

Introduction

572. In August 2022 we made interim submissions on the recommendations which the Chair ought to make in his final report. Some of those recommendations required additional evidence to be heard. With the conclusion of hearings in November 2022, we are now able to provide more detailed submissions on some of the recommendations sought.

573. We rely upon and hereby incorporate our submissions made on 9 August 2022 in their entirety. The submissions that follow are supplementary.

Recommendation 2

574. In our interim submission, we said:

> *"That those in the infected and affected community who are in receipt of disability benefits be excused from any/all future eligibility assessments and it be recognised that their conditions will not improve.*
>
> ***Because***
>
> *The Inquiry has heard a wealth of evidence from its HIV, Hepatitis and Bleeding Disorder Expert Groups that those infected will not see any improvement in their conditions.*
>
> *As to those affected, those who have suffered disability as a result of contaminated blood/products (whether that be through psychological injury such as PTSD or through the physical exertion of caring for an infected person) are unlikely to see improvements in their conditions and should be similarly excused. It is important to remember that PTSD brings with it physical manifestations impacting on the body. The Inquiry heard evidence from many affected people about the impact which their experiences have had on them throughout the hearings which took place in 2019 (WITN1056009_0002-0006 & 0034 being important written evidence on the point in addition)."*

575. These closing submissions have demonstrated the sheer weight and volume of the suffering that the infected community have had to endure for decades. For those reliant on disability benefits, their plight was augmented by repeated eligibility reassessments, despite the Inquiry having heard expert evidence that their conditions are not going to improve, even if they can be arrested. We reiterate our submission that the Chair seek to end this unnecessary suffering, and recommend that the DWP examine ways in which those infected or affected by infected blood

products can be excused from any eligibility reassessment. We suggest that this could be achieved by applying reassessment exclusions to those accepted onto the compensation framework.

Recommendation 3

"Haemophilia centres should be transformed into centres of excellence for all people who have been infected or affected through contaminated blood products as well as younger generations of patients who suffer from bleeding disorders without the complication of infection(s).

These centres of excellence should be inclusive clinics for all those infected and affected by contaminated blood products – whether infected with or affected by HIV or Hep C, whether diagnosed (or misdiagnosed) with haemophilia or not whilst still providing the highest quality of bleeding disorder care for sufferers outwith the tragedy of contaminated blood products.

The centres should give a patient-centred approach and NOT disease focussed treatment which is what is needed to deliver the most appropriate yet dynamic care and treatment when indicated. They should follow the NICE guidelines and quality assurance already in place to support this type of model. Any financial support should be directed to this model not given to the current haemophilia centres which are disease focused.

Each person should have a named individual that coordinates their care and treatment using specialists who are fully informed of the infected blood product disaster and can be called upon to bring their own expertise to the table; Psychology teams, Haematologists, Endocrinologists, Pharmacists, HIV specialists, HCV specialists, Hepatology, Transplant Specialists, Radiographers, and many more would be required to deal with the complex care needs of all patients.

The term "haemophilia centre" should be reconsidered in order to recognise those with other blood disorders who are treated there and also all people (such as infected partners) who do not have a blood disorder but who have been infected by contaminated blood products.

In summary, there should be:

Recognition within the treatment centres of all those who have been infected and affected by contaminated blood products;

Increased funding;

'One stop shops'; to allow for all treatments (including dentistry) to be dealt with under the new centre of excellence umbrella;

Specialist haematologists to coordinate treatments for the infected and affected and to be present during consultations with other medical professionals;

HIV/HCV specialists to be brought in when required to consult on treatments and medical options;

Specialists in HIV infected women need to be identified and made available through the specialist centres;

Collate information and learning regarding the aging population of HIV/HCV infected individuals within the UK;

That as recommended by the Psychosocial Report[448] *a "dedicated psychology service […] within the haemophilia centre" as recommended by the haemophilia quality standard" are established*[449] *in each haemophilia centre to offer support for affected and infected individuals. This should also apply to the thalassaemia and sickle cell centres.*

That the card system set out below be used to determine eligibility and access to these treatment centres.

Because

Lack of funding and a movement away from specialist treatment has caused issues for the infected and affected community whose experience has been that medical care has become increasingly variable and lacking in knowledge of the issues confronted by all of those who have been infected and affected.

Infected wives and the misdiagnosed don't have centres where their conditions are understood or, sometimes, recognised. They need to be brought within the specialist centres so that support from those with, at least, the best knowledge of their infected status can be brought into their treatment.

There are no ongoing studies within the UK into long term survivors of HIV and/or HCV infection in men or women and the symptoms and co-morbid conditions and medical consequences of HIV and/or HCV infection albeit there are studies being commissioned in the USA.

The understanding of how HIV causes long-term infection continues to deepen, and in doing so provides new opportunities for potential cure. However, none of the above approaches has shown sufficient promise to be available for widespread clinical use in the next 10 years. A combination of approaches is likely to be needed to effect a cure. With over 80% of those infected with HIV living in sub-Saharan Africa, most healthcare systems will have insufficient

[448] EXPG0000003_0034

[449] The Expert Psychosocial (Supplementary Report) recommends that adequate funds are made available to access relevant and appropriate psychological support (EXPG0000042_0037)

resources to deliver a complex medical intervention at scale. Consideration needs to be given to prioritising therapies that can be delivered in resource-limited settings" HIV Expert Report to IBI [EXPG0000004_0069].

The likelihood of long-term comorbidities alongside HIV[450] *is increasing particularly as people with HIV grow older, some of which are the inevitable consequence of old age and others are directly related to HIV and its treatment. As life expectancy has increased the broader HIV care agenda that is emerging needs whole system approaches focusing on integration of care across teams, disciplines and organisations. HIV services are becoming less self-contained. Close working relationships between HIV specialist services and primary care is particularly important. However current commissioning arrangements for the HIV pathway are complex and split across multiple commissioning bodies which can risk fragmentation of care.16 NHS England has a national service specification that is used as the basis for the commissioning of HIV treatment and care. A working group exploring long-term condition management for HIV has been established by NHS England." HIV Expert report [EXPG0000004_0089]*

Reporting of HIV-related data is undertaken by clinicians on a voluntary and consensual basis and is processed through the HIV and AIDS Reporting System (HARS). Information sent to PHE is `de-identified' and the NHS number is not part of the dataset so potential linkages to other conditions are not made in the way they could be if the number were available 19 National surveillance of HIV infection and vertical HIV exposure is carried out by the National Surveillance of HIV in Pregnancy & Childhood (NSHPC) and covers all infants born to HIV positive women in the UK and Ireland, as well as all children diagnosed with HIV (regardless of country of birth) before the age of 16.20 There are several comprehensive research data sets that investigate secondary health conditions and complications. Public Health England has recently completed a nationally representative survey of patients attending HIV specialist care in England and Wales, Positive Voices. This has given rich data on secondary health conditions and complications as well as quality of life, social needs, and treatments. Currently this is running as a research project." HIV Expert Report [EXPG0000004_0092]

The long-term effect of treatment for HCV, the question of an increased incidence of cancers and variations in care across different geographical parts of the NHS all require careful study and report. There should be monitoring of those with HCV currently and those who have achieved an SVR and have then been, in effect, discharged from care.

---

[450] This also applies to HCV: see J Med Virol. 2017 Dec; 89(12): 2158–2164.Published online 2017 Aug 30. doi: 10.1002/jmv.24848 PMCID: PMC5656818 PMID: 28480974 Comorbidities and medications of patients with chronic hepatitis C under specialist care in the UK Benjamin Hudson, Alex J. Walker, and William L. Irving

The warning flags on medical records for infected haemophiliacs which refer to HIV/HCV/vCJD cause huge issues with medical professionals and dentists not understanding what they should do, how they should treat or whether they will treat people with this in their files. The misdiagnosed we represent report that warning flags consistently fail to appear on their files which means they have delays in treatment, they are concerned about how they might inadvertently infect others and they have to constantly repeat their case histories.

Warning flags need to include everyone that has received infected blood.

The services provided by the proposed centres of excellence should be assessable by those infected and affected by blood products irrespective of whether they themselves have a bleeding disorder this is because there must be recognition that whether as a result of being infected by a haemophilia suffering partner, widowed to a haemophiliac or misdiagnosed with haemophilia these are people have spent significant parts of their lives in haemophilia centres and feel more comfortable in that setting. This we suggest must be a matter of choice for the patient whether they wish to avail themselves of these services or not. If an individual does not wish to use the specialist centres that has to eb their right after so many years of stigma and discrimination, if so alternative treatment routes must be made available.

For some people such as Infected wives, widows and partners attending a haemophilia centre is or can be uncomfortable and re-traumatising as for some people it has been decades since they attend a haemophilia centre. Provision for sperate support for those who have been ignored and repeatedly traumatised by a male orientated (because of the higher percentage of male haemophiliacs over women haemophiliacs) must be made.

576. The Inquiry has heard no evidence as to why such centres of excellence would not be capable of being created and indeed, the evidence of the Irish HAA card system discussed below would support the establishment of such centres.

Recommendation 4

"An NHS card system be adopted for those infected and affected to explain that they have been infected or affected by this scandal and to explain to any treating clinician the possible range of consequential symptoms and their possible treatments with fast-track access to a specialist treatment team for those infected and affected. As above the card system would also serve as an access path to treatment at the specialist centres for those who have been infected and affected by contaminated blood products.

Sir Robert Francis QCs report published on the 7th of June 2022 states (at 2.87) "The scheme should have a support unit to provide or arrange for the provision of medical, psychological and social support to infected and affected persons.

The Archer Inquiry recommendation of a card entitling beneficiaries to benefits not freely available on the NHS should be revisited to consider whether such a facility should be made available via the compensation scheme or otherwise".

Within the Republic of Ireland those infected through contaminated blood products are entitled to a Health Amendment Act Card (HAA).

Persons who contracted Hepatitis C through the administration within the State of contaminated blood and blood products and who therefore hold a Health Amendment Act (HAA) card are eligible for a range of primary care services and hospital-based services including:

GP Services

- *Prescribed drugs, medications, aids and appliances*
- *Dental services*
- *Aural services*
- *Ophthalmic services*
- *Home support*
- *Home nursing*
- *Counselling*
- *Complementary therapies*
- *Chiropody services*
- *Physiotherapy*

Because

Infected and affected people confronted by a new symptom constantly have to repeat and explain their complex background medical history (when both ill and sleep deprived) to a new generation of the medical profession for whom the blood contamination scandal is believed to have been part of a previous medical profession's history. Fasttrack access to those who understand and have knowledge of the treatment and diagnosis of these complex and interacting infections and the consequential effects on those who have been infected and affected would improve treatment effectiveness and outcomes.

Many people with blood disorders have had the same experience of being asked questions which demonstrate a profound lack of expertise or even basic knowledge of haemophilia/VWB; questions such as 'how did you get haemophilia' or 'are you on warfarin' are just two examples. For others the assumption is made that they have contracted HIV through drug use, or if a woman, because they are thought to be a sex worker."

577. The recommendation sought goes beyond the card system in place in Ireland in one minor respect: it ought to identify the bearer to their clinician as someone who is a victim of the infected blood scandal in order to save them the need of

explaining the source of their infection each time that they meet with a new doctor or nurse, which adds to their trauma. This would also signal to treating clinicians the level of care and potential emotional or psychological damage which may have been inflicted on their patient by the healthcare system in the past.

578. In his oral evidence, Brian O'Mahoney spoke of the importance of the Health Amendment Act card system to Irish haemophiliacs:

> *"**Q.** Now, you were asked in your statement whether you thought the HAA card was a success and you've said unequivocally yes. Why is that? Why is that your view?*
>
> ***A.** I would have said if we were speaking back in '95, '96, '97, our members were much more concerned about compensation on these issues and the forthcoming inquiry than they were about the HAA card. But when I look back on it now with the benefit of hindsight, the HAA card has been absolutely crucial because it gives people prioritised access to a lot of the healthcare and services and support they need on an ongoing basis. It has been invaluable for people when they run into trouble health-wise. And when people are at the point where -- if they are getting near to the end of their life, it has been absolutely amazing in terms of the help and support we can put in place very quickly."*[451]

579. While it might be said that Ireland has a different healthcare system to the UK, it was clear from Mr O'Mahoney's oral evidence that there were direct parallels to be drawn which justify the introduction of a card system in the UK:

> *"…But for people in Ireland without a medical card, then you pay for -- unlike the UK National Health Service, you pay for your GPs visits, you pay for your prescription drugs. And we have a two-tier healthcare system: we have the public hospitals, which are free for the vast majority of the population, or you can also have private health insurance. There are private hospitals or private beds in public hospitals. So it's a mixed two-tier system."*[452]

580. In his written and oral evidence, Mr O'Mahoney explained that the HAA card procures priority access to treatments in the public health tier of the Irish system. In circumstances where the public health system cannot react within a prescribed timescale of two weeks, a referral may be made to the private tier.

581. In our submission, this is directly analogous with the NHS and private system in place in the UK. The mere fact that Ireland does not have a national health service

[451] Transcript 08/11/2022, Page 62, Line 7 - 24
[452] Transcript 08/11/2022, Page 50, Line 13 - 22

does not create such a significant difference that something akin to the HAA card system could not or should not be adopted in the UK.

582. Another potential challenge to the adoption of such a system is public reaction: some have expressed fears that members of the public may not support certain patients being able to 'queue-jump' and obtain priority treatment, which could cause conflict. Mr O'Mahoney was very clear that this had not been the Irish experience:

> *"**Q.** Was there a concern when this scheme was enacted that it would be unfair or amount to some form of queue jumping because it was prioritising or conferring an entitlement upon a particular group of individuals that others would not have?*
>
> ***A.** No, because the 3,500 individuals had developed serious medical conditions as a result of medical treatment already provided by the state, so you're effectively giving additional and faster healthcare to people who have already had their health impaired by the actions of the state.*
>
> ***Q.** So it wasn't something that was -- has led to any resentment or any sense of unfairness from the rest of the population to your knowledge?*
>
> ***A.** No, none whatsoever."*[453]

583. There is no evidential basis to suppose that the UK experience would be any different. In fact, the evidence heard by the Inquiry has shown that, on the whole, the general public have been supportive of the infected community, including coming behind the campaigners' cause and lobbying for a public inquiry. The findings and work of this Inquiry have only strengthened that considerable sympathy and empathy.

584. Given the strength of Mr O'Mahoney's evidence on the Irish experience of their HAA card system, we submit that a corresponding card system would be of significant benefit to the infected and affected victims, and is probably the most meaningful non-financial recommendation which the Chair could make for the benefit of the health and well-being of the infected and affected community.

Recommendation 6

[453] Transcript 08/11/2022, Page 54, Line 25- Page 55, Line 14

"An assessment of the past and present insurance, life assurance, mortgage availability and employment management arrangements that have applied to those people infected and affected by contaminated blood.

In the Republic of Ireland if an individual has received compensation or is the holder of a HAA card then they are entitled to access an insurance scheme.

"The Hepatitis C Insurance Scheme was set up under the Hepatitis C Compensation Tribunal (Amendment) Act (No.22) of 2006. This Scheme enables all persons with State Acquired Hepatitis C and/or HIV to take out Life insurance as if they were not infected. The Scheme provides for three different types of Insurance Cover to be taken out; Life Assurance, Mortgage Protection Cover and Travel Insurance.

Because

The availability of insurance, life assurance and the effect of infection on mortgages and employment have prevented infected and affected people from eligibility for life assurance, engagement in some career paths, taking holidays and breaks and buying properties. The criterion used for assessing, as an example, a previously HCV infected (but self-cleared) individual is currently a barrier to obtaining life assurance."

585. In his written and oral evidence, Mr O'Mahoney set out the three limbs to the Irish scheme which enabled HAA card holders to obtain: (a) life insurance; (b) mortgage protection insurance; and (c) travel insurance. The insurance is provided at the same rate as it would be healthy people of a similar age. Mr O'Mahoney spoke of the difficulties that had been endured in devising the scheme, he said:

"There was a little bit of resistance initially, but, again, as the personal stories come out from Lindsay, as the public awareness increased -- and Government were genuinely sympathetic and their response was sympathetic, so there was a willingness to explore this, but from a practical point of view it was still quite difficult to put it in place, so we had – you know, we had four legal teams, we had a team of actuaries, we had a couple of insurance specialists and brokers, we had the Department of Health, we had the four organisations. I think we had 35 excruciatingly long steering committee meetings over those four years. I know my colleague -- or former chairman, who was at those meetings with me, when he left the Society board later and I asked him back about 2012, to come back on the board, he made me promise he'd never have to go to an insurance meeting again."[454]

586. The Inquiry has first-hand of the difficulties of the victims of the infected blood scandal obtaining insurance, and there is a clear need for the infected

[454] Transcript 08/11/2022, Page 74, Line 11 – Page 75, Line 3

community to receive support in obtaining insurance products. Given the time that has passed, life insurance and mortgage protection insurance may be of a more limited value in the UK, however, subsidised travel insurance is still likely to be of enormous benefit.

587. Mr O'Mahoney described how HAA card holders pay the ordinary premium for each insurance product they take out under the scheme, and that the Irish government either pays the added premium attributable to their ill health, or reinsures for those who are coinfected and deemed uninsurable.

588. Given the difficulties described by Mr O'Mahoney in devising the scheme, we submit that there is no need to reinvent the wheel, and that the Chair should recommend that the Irish policy be adopted in the UK, thereby saving further delays to the support which the infected community ought to have received much earlier.

Recommendation 8

> *"The Inquiry has heard evidence about the failure to properly record (or record at all) the batch numbers of blood products used to treat or mistreat patients. The Inquiry should consider any necessary recommendations to improve record keeping, particularly in relation to transfusion therapies.*
>
> ***Because***
>
> *This Inquiry is best placed to recognise the importance of good record keeping and the consequences for those whose records were inadequate. The Inquiry has already heard evidence that historically, inadequate record keeping has hampered lookback exercises and impeded the ability of those infected to (i) understand the pathogens to which they have been exposed; and (ii) seek justice and/or recompense."*

589. In his evidence, Professor Bellamy set out the haphazard fashion in which blood transfusions are still recorded, he said:

> *"…For example, in the Trust where I work, blood transfusion does not feature in the electronic patient record. It is still prescribed, administered and recorded on paper, which then sort of disappears into some giant library somewhere and, in theory, gets scanned and put on the system. Now, if a patient receives a blood transfusion relatively early on in their journey – for example, somebody comes to an intensive care unit, receives multiple transfusions, then goes back to perhaps a respiratory medicine ward or then goes on to a rehabilitation ward, then goes home and is looked after by their general practitioner – it is highly unlikely that the junior doctor writing the final discharge summary on the rehabilitation ward*

will even know about the transfusions early on, let alone have any access to the detail, such as the unit numbers, and so on, and the GP has no means of knowing about it."[455]

590. After all the evidence the Inquiry has heard about the infected blood scandal, it is astonishing that such an obviously unsatisfactory practice is continuing. The system is particularly astonishing when one bears in mind the difficulties which infected core participants had in finding the evidence to prove that they had received a transfusion (in the case of those infected via whole blood), or what specific blood products they had received (in the case of those with bleeding disorders or who were misdiagnosed).

591. In response to CTI's question on whether a national transfusion database recording all instances of blood or blood product transfusion would be meritorious, Professor Bellamy replied:

"I think if it could be deliverable within the NHS as we know it, it would be a very major step forward. Hugely useful, both for helping protect individual patients, for helping spot problems, complications early, and pick up patterns early, and for making sure that the information that we've got is actually reasonably accurate as regards dates and timelines and – and by directional traceability and so on…"

592. There has been no evidence to suggest that such a record system would be undesirable or unachievable. In the digital era in which we now live, and considering some of the technology and capabilities used during the Covid-19 pandemic, it should be sufficiently straightforward to adopt an electronic logging, scanning and/or QR code system. A straightforward scanning system would not add to a clinician's workload, but would provide a considerable benefit to both the individual patient, and to the broader community (in that issues with any batches or products could be identified much sooner). We therefore submit that the Chair ought to make a recommendation that the DHSC commission investigations as to how a national transfusion database might be created and implemented.

Recommendation 9

"That the remainder of the residual MacFarlane Trust monies held by the Terence Higgins Trust be surrendered by the THT and be divided into four equal parts and transferred to the national Haemophilia Societies of the four Home Nations for the purposes of constructing a monument in each nation to those

[455] Transcript 16/11/2022, Pages 93-94

infected (whether directly or indirectly) with HIV through the use of contaminated blood products and their affected families.

Because

There are complex reasons why it is inappropriate for the Terence Higgins Trust to administer the residual monies which it received from the MFT but at its simplest, there is a profound and fundamental conflict of interest which stems from two basic facts: -

The victims of the contaminated blood disaster have historically (whether rightly or wrongly) been labelled as the 'innocent victims' of the AIDS pandemic. This implies that those infected through other routes of transmission (such as through sexual transmission) were not innocent. THT is a sexual health charity and historically, its core body of beneficiaries were infected with HIV through sexual contact. There is a natural tension between THT's core body of beneficiaries and those it has adopted following the closure of MFT.

Whilst not diminishing the stigma suffered by those infected through contaminated blood/products they are, if they so wish, able to give an explanation for their infection which elicits social sympathy in a way that those infected through sexual contact are perhaps less able to do. This means that the focus of THT's activities is heavily centred on continuing to break down the stigma associated with HIV infection through sexual modes of transmission; a point that is evident in their 'U=U' campaign which fundamentally tries to convey the message that by taking a daily pill, your infection is controlled, and you cannot pass the virus to any other person.

Whilst no criticism is made of THT for such campaigns (and to the contrary, they are worthy of recognition) these campaigns advance a message which is completely different from that which many of those infected through contaminated blood/products wish to convey. Our clients want to see a push for research and treatments for the long-term effects of living with HIV and the co-morbidities associated with it; to argue that taking a pill everyday gives someone with HIV a completely normal life is simply at odds with our clients' lived experiences.

We suggest that it be recommended that the money be divided amongst the four national haemophilia societies and used for the purposes of creating monuments (suitable for all faiths and none) because there is unlikely to be any other way of spending the money which would generate a broad consensus of opinion from the former registrants of the MFT and because monuments can have a very real purpose not only in commemorating those who have suffered but in acting as a reminder of mistakes which were made.

It must also be recognised that the MFT was a malevolent presence in many people's lives, an uncaring organisation from which they were forced to beg for

financial relief. MFT naturally came to be regarded as exerting a degree of control over the lives of those infected and affected and that control persists whilst ever its funds remain; many from the former MFT community have expressed outrage at THT's attempts to advocate on their behalf. The only way to end the re-abuse of the infected and affected perpetrated by the MFT, is for the last of its funds to be spent. In this regard, it is not so much the THT's administration of the fund which is objected to but the fact that any organisation should seek to continue the MFT's sad legacy."

593. The residual MFT funds continue to be depleted upon things which appear to have no discernible benefit for the former MFT beneficiaries, and/or which are directly contrary to their wishes. Moreover, THT have now used the residual funds to pay an independent contractor (Factor8 and Jason Evans) to conduct "*research and communications*" work on behalf of the former MFT beneficiaries: in short, campaigning and advocacy work. This work was commissioned without any consultation with the beneficiary community and without any apparent tender process.

594. The commissioning of this work is precisely what was feared by those of our clients amongst the former beneficiary community: it is the exercise of power by imposing a voice and advocacy upon people who are capable of speaking for themselves. The Inquiry should not allow the mistakes of the MFT to be repeated. THT's power only exists because of the residual MFT funds, and in our submission it is imperative that a recommendation is made for the surrender of those funds by THT.

Recommendation 11

"After hearing all of the evidence setting out the causes and reasons for the Infection of all of those who have been treated with contaminated blood products, the Inquiry should, we suggest, review the current protection of the blood supply. The lack of haemo-vigilance is a matter of real significance to this Inquiry and a review of current haemo-vigilance should ensure that, as at the close of the Inquiry that current measures ensure that blood products are safe.

Because

This is still very important to those with Thalassemia, Sickle Cell and of course bleeding disorders who do not have access to synthetic treatments or developing countries reliant on treatment donated."

595. The November 2022 evidence of Professors Neuberger and Bellamy on the current haemo-vigilance systems in place was reassuring, however, it was clear that

much depended on the generosity of those who volunteered their time to SHOT and SABTO.

596. Both professors agreed that it would be better if there was some form of remuneration for those participating in SHOT and SABTO. Professor Neuberger explained that SABTO was having difficulty in recruiting, because those volunteering were being challenged by their employing trusts who, by losing their time, were effectively paying for their participation. Professor Neuberger suggested that it would be helpful if the employing trusts of those volunteering for SHOT and SABTO were remunerated for the time spent away from ordinary employment.

597. In our submission, every effort should be made to ensure that the very best and most able individuals are involved in haemo and pharmaco-vigilance work which, in many ways, is at the forefront of the UK's novel pathogen detection systems. The Chair should therefore recommend that the employers of those members of SHOT and SABTO be remunerated for the time spent away from ordinary duties.

Recommendation 12

> *"The role of patient advocates be expanded across the NHS and be offered to anybody diagnosed with a life altering or chronic condition.*
>
> ***Because***
>
> *As we understand matters, the current patient advocate system relies upon an application being made for an advocate to be appointed; such a system inevitably deprives those most at need of advocacy from the services of an advocate because the most vulnerable are also the least likely to make such an application.*
>
> *Upon diagnosis of any chronic condition with life altering consequences and prior to the recommendation of any course of treatment aimed at treating such condition, the role of a patient advocate should be explained to the patient and an appointment with an advocate offered."*

598. In their panel evidence, the following exchange took place between Counsel to the Inquiry and the Expert Group on Public Health and Administration:

MS RICHARDS: *Next question I think is probably for anyone on the panel who has a view, although it arises out of, I think, the discussions that I was having with Professor Vincent in particular. Should there be a new and independent patient advocacy service, a properly resourced patient advocacy service, as part of the NHS across the United Kingdom? Professor Vincent, and then I'm going to ask Professor Farrell.*

PROF VINCENT: *Presumably you mean in the sense of a single national organisation, or more challenged locally?*

MS RICHARDS*: I think the premise of the question is a new and independent patient advocacy service.*

PROF VINCENT: *Yes.*

MS RICHARDS: *I think there may be different ways of delivering it, but a universal, essentially, independent advocacy service for patients.*

PROF VINCENT: *Okay. It's certainly worth looking at. I'd have to be quite careful not just to create another organisation on top of other things, but as Allyson was saying earlier, I think it would be valuable to have a proper resourced service which was capable of more challenge than currently. And, you know, there are a number of organisations and people who work with best intentions, but if they're not resourced and they can't -- so they aren't vocal enough, if you like, say, not through their fault, but a bit more challenge to the Health Service and a bit more ... I think I'd like to see it not so much in the terms of advocacy of individual cases but of a sort of collective intelligence about, you know, really trying to get hold of what major patient concerns are in this area and communicate them quite forcefully. So the idea not just of advocating for single patients but aggregating patient concerns in a serious manner, now that would have something to recommend it. But it would need resourcing and it would need, you know, thought about, you know, how to integrate what's already there.*

599. The evidence before the inquiry has demonstrated unequivocally, the consequences of patients not been given information, not been in a position to give informed consent and not having their complaints listened to when something has gone wrong. In our submission, a modern, properly resourced and funded patient advocacy body is essential to reduce the risk of further medical disasters and the Inquiry should recommend the creation of just such a body.

Recommendation 17

"The Psychological Expert Group (Supplementary Report) made a number of recommendations[456]*; these need to be considered with the relevant training organisations who should be requested by the IBI to report back on what training is currently offered in these areas and what further improvements can be made.*

Because

Duty of candour, effective and sensitive communication and the policies and practice to ensure no harm should be included in the training of all healthcare workers and other associated groups such as NHS managers and national level policy makers. Staff need to feel part of a non-punitive working environment with a culture of openness. Case studies from the Inquiry could be utilised as examples within such training.

As a core part of healthcare training and continuing professional development, there should be full recognition and acknowledgement of the ways in which implicit and explicit biases affect interactions with patients and families. Training could include case studies drawn from the Inquiry, professionally developed and evaluated to establish efficacy.

The Infected blood Inquiry should provide an example of a case study that is included in all training of (a) healthcare professions — to draw out principles of duty of candour, effective and sensitive communication and (b) other groups including NHS managers and national level policy-makers — to draw out the principles of policies and practice to ensure no harm, and that staff feel part of a non-punitive working environment with a culture of openness. The case study should be professionally made and comprise multiple materials including footage of the infected and the affected giving evidence to the Inquiry.

In challenging new healthcare situations, where expertise, experience and knowledge is not yet developed, healthcare professionals should look to the evolving dedicated, specialist multidisciplinary teams for patient management care and treatment as well as acknowledge, respect and involve the expertise of both infected and affected individuals, and work in partnership with them.

As a core part of their training and continuing professional development, the education of all healthcare professionals needs to ensure that there is full recognition and acknowledgement of the ways in which their implicit and explicit biases affect all their interactions with patients and their families. This training, which could include case studies drawn from the Inquiry, will need to be professionally developed and properly evaluated to establish its efficacy.

[456] EXPG0000042_0037

Key requirements of this training are to increase awareness of the nature of stigma and its impacts on both patients and families/carers; reduce fear of contact with patients due to incomplete knowledge; assurance regarding necessary precautions and provision to facilitate this; challenging assumed links with negatively valued behaviours. This requires a multi-strategy approach to increasing knowledge, changing attitudes and translating this into behaviour change.

More generally, there needs to be a focus on the general population's beliefs and enacted stigma, much of which was linked with how public campaigns were interpreted and the effects of media scare stories at the time. It is therefore important that national policies take account of the Inquiry experience and include use of the mass media to mitigate prejudicial beliefs and fears in order to reduce stigmatising attitudes and behaviours among the general population. This also has implications for health professionals who are themselves influenced by the beliefs and fears prevalent in the community."

600. In his oral evidence, Professor Collin Melville told the Inquiry that the GMC was not in a position to mandate the use of case studies in medical education, but did say that they were frequently used as useful teaching examples.[457] We found Professor Meliville's evidence on the current steps being taken by the GMC to enshrine the importance of ethical principles (particularly the duty of candour) in medical training to be reassuring.

601. Therefore, by way of modification to our August submission, we submit that the Chair should make a broader recommendation: all medical education providers should ensure that the infected blood disaster, as an important case study, forms part of the curriculum for all new doctors.

Recommendation 18

"*The duty to inform of risks has been discussed within the Inquiry's proceedings. It should be recommended that the GMC commission the creation of a module to be compulsorily taught on all undergraduate medical degrees which incorporates :-*

i. The history of the contaminated blood disaster including how the dangers of pooling plasma were recognised in the 1940s only to be forgotten with the advent of pooled plasma coagulation products in the 1960s;

[457] Transcript 15/11/2022

ii. *The dangers of medical paternalism and the importance of patient freedom of choice, which can only be achieved through the frank exchange of information with patients;*

iii. *The inherent danger of blood transfusion and the importance of its conservative use;*

iv. *The findings and recommendations of the IBI final report.*

v. *Captures the evidence of a number of those infected with Hepatitis (A, B, C etc), Hepatitis and HIV, HIV alone and those who are threatened with possible infection with VCJD.*

vi. *Captures the evidence of wives/partners/carers - to understand the impact on their health both physical and mental - the consequences and impact of creating additional patients that had not previously existed*

vii. *Captures the evidence of those who were mis-diagnosed and therefore mistreated and infected.*

Because

The benefits of such a recommendation would be threefold:-

1. *It would help to ensure that the mistakes of the past were not forgotten and that the lessons learnt through the work of the Infected Blood Inquiry will not be forgotten but will instead be instilled into the minds of all future doctors; and*

2. *It may reduce the instances of those surviving, infected haemophiliacs having to recount their life stories and mode of infection to every new clinician charged with their care.*

3. *It may reduce the instances of infected wives and partners having to preface any encounter with a medical professional with an explanation. It may reduce the assumptions that some is a drug user and misinterpret debilitating illness from intoxication or side effects of drug use."*

602. Notwithstanding Professor Melville's evidence, there is no reason to suggest that it would be impossible to mandate the teaching of a new module. Indeed,

Professors Bellamy and Neuberger, when asked their opinion on developing a mandatory learning resource focussed on the infected blood scandal said:[458]

a) Professor Bellamy: *"…It's highly topical and I think, because of that, it would not be difficult to create training materials that would be rapidly adopted, and I'm pretty sure there would be and appetite for that."*; and

b) Professor Neuberger: *"It's a question that doesn't even need much thought to answer. I think it would be very helpful, because I think , on the whole, people learn from example, you know, this is an immense Inquiry, as you will know far better than I, thank goodness, and I think there will – you know, its already clear, just from today's discussion, there's an awful lot of lessons to be learned, areas of improvement…"*

Recommendation 21

"That the Liver and Cardiac Advisory Groups of NHS Blood and Transplant give weighted consideration to those who have been infected and repeatedly infected with HCV (and Hep A, B, D etc) and/or HIV as to the increased likelihood of liver disease (and heart failure in the case of HIV) and the probability of need for such patients to have early inclusion on Transplant lists.

Because

The liver plays a central role in the clotting process, and acute and chronic liver diseases are invariably associated with coagulation disorders due to multiple causes: decreased synthesis of clotting and inhibitor factors, decreased clearance of activated factors, quantitative and qualitative platelet defects."

603. In his evidence, Professor Derek Manas said that a bleeding disorder would be treated as another co-morbidity, and that those suffering from bleeding disorders would face no impediment (as a direct result of their bleeding disorder) to obtaining a transplant.[459]

604. Professor Manas did not, however, consider the potentially curative nature of liver transplant in haemophilia.[460] This should be an additional feature which ought to be factored into the TBS calculations which are used to determine a patient's position on the transplant list. In short, rather than determining a patient's position solely by reference to the fact that they require a transplant as a result of NHS treatment, it should also be taken into account that a transplant has the ability to be

[458] Transcript 16/11/2022, Page 173-174
[459] Transcript 10/11/2022
[460] EXPG0000001_0055 AND

entirely transformative for those with haemophilia, as it holds the possibility of curing their bleeding disorder.

Additional Recommendation 1

605. The Inquiry has heard a lot of evidence on the Civil Service and Ministerial Codes, including whether those codes should be on a statutory footing, and whether they should contain a duty of candour to the extent that they do not already do so. Most recently, Alex Chisholm told the Inquiry:

> *"I think, first of all, it's important to understand that the Code, the Civil Service Code, already has a statutory underpinning, the Constitutional Reform and Governance Act 2010 does reinforce the Code. The Code doesn't exactly say a duty of candour but it says, in many ways in a way, you know, even more helpfully, it does say not only acting with integrity, honesty, objectivity and impartiality but:*
>
> *"Always act in a way that is professional and preserves or retains the confidence of those with whom you have a dealing. Deal with the public and their affairs fairly, efficiently, promptly, effectively and sensitively to the best of your ability. Set out the facts and relevant issues truthfully and correct any errors as soon as possible."*
>
> *It also says what you mustn't do:*
>
> *"You mustn't ignore inconvenient facts or relevant considerations when providing advice or making decisions. You must always – you mustn't act in a way that unjustifiably favours or discriminates against particular individuals and interests.*
>
> *I think that does all of we want from the duty of candour. It does have the statutory underpinning it. I think the more, the bigger area of opportunity is one Andrew described as saying, you know – making sure that leadership and training and practice, across the Civil Service, lives up to these standards and that everybody fully understands their responsibilities under the Code."*[461]

606. In relation to the Ministerial Code, the Public Health and Administration Expert Group told the Inquiry that each Prime Minister sets a ministerial code built on the bedrocks of the Nolan principles and Cabinet Collective Responsibility; they then had the following to say:

> *"Q: …Is it right then to understand from this [the Civil Service Code] that, ultimately, adherence to the Ministerial Code or enforcement of the Ministerial Code lies in the hands, essentially, of the Prime Minister?*

[461] Transcript 14/11/2022, Page 66, Line 7 to Page 67, Line 10

Lord Bichard: Absolutely, and I need to underline that. At the beginning of 1.4:

"It is not the role of the Cabinet Secretary or officials to enforce the Code."

Nor should it be, because in a democracy officials should not be controlling democratically elected representatives. So it is not the Cabinet Secretary's responsibility; it is, at the end of the day, the Prime Minister's responsibility, and the Prime Minister will make a judgment on reports that he receives…"[462]

607. We understand the concerns set out by Lord Bichard that there is potential for unforeseen outcomes in tinkering with a fundamental aspect of our democracy, notwithstanding the fact that enforcement of the Ministerial Code relies on the moral judgment of the Prime Minister alone, which may well be considered unsatisfactory. However, those concerns should not preclude the establishment of a permanent Regulatory structure composed of a cross-party group empowered to set and enforce the standards within the Ministerial code.

608. The Civil Service Code is a different matter: this a code, with a statutory footing, which applies to non-elected officials and which the Inquiry heard was policed irregularly. Lord Bichard told the inquiry that where a breach of the Code is raised, there will first be an internal, departmental investigation. If that investigation does not resolve matters:

"The [Civil Service] Commission carries out an inquiry. It is not in a position where it can impose sanctions and it is not in a position where it can recommend dismissal or anything like that. But they will publish a report. If a civil servant still feels that they have a grievance, then the judgment they must make is to whether or not they resign, and I think we should never forget that. There may be times when, as a civil servant, you're asked to do things which offend your own value set, which you think are inappropriate or which breach the Code. You are then in a situation, after the Commission has dealt with your complaint, to either stay or go."[463]

609. In short, the Civil Service has a code with no proper means of enforcement. Unlike ministers, there can be no possible democratic objection to the regulation of civil servants, Despite their lack of elected status, the Inquiry heard a wealth of evidence (as summarised earlier in these closing submissions) which indicated the sheer level of power which civil servants hold in a system of revolving ministers and administrations. There is therefore a great need for the Inquiry to recommend the creation of a Civil Service Regulation Authority akin to the Solicitors' Regulation Authority or the General Medical Council, which would be empowered to investigate

[462] Transcript 03/10/2022, Page 21, Line 11 onwards.
[463] Transcript 03/10/2022, Page 56, Line 20 onwards.

breaches of the Civil Service Code and to apply sanctions where such breaches are established (including, ultimately, dismissal). Complaints to this regulator should be capable of being made by Members of Parliament, Civil Servants and the public at large. The Civil Service has little practical difference from other professions and, given the considerable impact and control that the service has on public life and public safety, it should be regulated to the same degree.[464]

610. In summary, we seek the following recommendations:

a) The establishment of a permanent Regulatory structure composed of a cross-party group empowered to set and enforce the standards within the Ministerial code (for example, an Independent Integrity and Ethics Commission, as has been suggested by the Labour Party);

b) The establishment of a Civil Service Regulatory Authority;

c) A single set of standards[465] to be applied across all parts of Government, including the Ministers involved, their advisors (SPADs), expert advisors, and legal advisors, with all those involved subject to the same overarching standards and that such standards should apply;

d) That such set of standards be proposed and approved by both Houses of Parliament, and not by the Prime Minister of the day: standards in public office should not depend on the government of the day;

e) That guidance be drafted with clear examples of potential breaches and the consequences ranging from warnings to removal from office;

f) That questions of ministerial conduct be separated out from the day-to-day procedures for the operation of government. Instead of the impossible position of the Prime Minister or his/her adviser investigating breaches, any

[464] The need for comprehensive regulation is demonstrated by the callous way in which officials were shown to have calculated how to spend the money saved on dead haemophiliacs– there was no proper route of complaint when this incident came to light– see WITN1196018_0015

[465] "We therefore propose that the existing cabinet manual, which sets out in some detail the constitutional expectations on those in government, should itself become part of the ministerial code of conduct.It too should be approved by Parliament, both the House of Commons and the new second chamber, and failure to follow the principles of that Manual should be regarded as a breach of the ministerial code of conduct

breaches of the code must be policed within the appropriate[466] regulatory structure;

g) The decisions of such a body must be implemented as final (albeit there will need to be an appeal mechanism);

h) The duty of candour must be embedded in a single code;

i) Handover documents must be mandatory, even from administration to administration, and set out within an agreed structure;[467]

j) Papers from previous administrations and previous Ministerial incumbents must be available to following administrations. The Ministerial Code and access to previous ministerial papers and previous administration papers must be clarified and reviewed; and

k) Finally, there needs to be a new office established within Government - a Campaign Minister dedicated to the consideration of campaigner correspondence, willing to meet with and discuss issues with campaigners and adequately resourced to commission expert reports.

Additional Recommendation 2

611. Finally, to ensure the preservation of the evidence which will result in the Chair's final report, it should be recommended that the Inquiry's evidence (with appropriate redactions) be permanently preserved in an online resource which is freely accessible by anyone including those who have participated in the Inquiry as well as any other medic, academic or other interested person.

[466] For instance MPs and Ministers will need to be regulated from within their own numbers to avoid constitutional issues which might serve to undermine the separation of powers." Commission-on-the-UKs-Future.pdf (labour.org.uk)

[467] Probably caveated that they cannot be used for political purposes or subsequent memoirs

13. FINANCIAL RECOMMENDATIONS

612. With the interests of brevity in mind, we make no further submissions as to the reasons why compensation ought to be paid in principle beyond that which is set out in Section 3 of these submissions. This is particularly so given Sir Robert Francis' recommendation that compensation be paid on moral grounds if on no other basis. Save where we state otherwise below, it should be assumed that our submissions support the recommendations of the compensation framework.

613. Sir Robert Francis KC and those assisting him should be commended for the content of his compensation framework, and for the work which went into it. Sir Robert's achievement in preparing comprehensive principles for the architecture of a compensation scheme in such a short period of time is remarkable.

614. However, because Sir Robert was necessarily unable to consider the breadth of evidence available to the Inquiry, there are areas of his recommendations which, in our submission, require amendment:

a) Paragraph 2.8 on qualifying criteria: Sir Robert says that a case for compensating those with a transient mono-infection with HBV is not made out, though there may be a case for those chronically infected with HBV. In our submission, the Inquiry has heard of the severity of illness caused by chronic HBV infection and therefore ought to recommend that chronic HBV infection be a qualifying criteria for entry to the compensation scheme;

b) Moreover, and again in relation to paragraph 2.8, our clients were relieved to see recognised by Sir Robert that co-infection with HCV and HBV is more likely to result in serious consequences. This is an important point for our clients who have suffered both infections (some with HIV in addition) and it encouraged them to see the inference from paragraph 2.8 that the cumulative effect of the totality of their infections will be recognised;

c) Paragraph 2.14: Sir Robert stated that indirectly infected people should be eligible for the scheme if they were infected by a person who was, in turn, infected via infected blood or blood products. We agree with this, but in our submission the final compensation recommendations should make clear that indirectly infected people should be treated *pari passu* with those directly infected by infected blood/products. An equivocal statement to this effect is

necessary to avoid a repetition of the abuses perpetrated on this class of claimant by the old trusts and schemes;

d) Paragraph 2.19: Sir Robert suggested a discretionary eligibility for those who are neither married to an infected person, nor otherwise in a close familial relationship. He suggested that such discretion be limited to people who:

i. Were family of, or long-term friends with, the infected person;

ii. Have maintained a close relationship with that person since the onset of their infection; and

iii. Have in fact, suffered a mental or physical injury as a result of their relationship with the infected person.

We support the inclusion of a safeguard to ensure that someone who ought to be compensated is not denied eligibility to the scheme due to rigid criteria. However, we submit that the safeguard mechanism proposed by Sir Robert falls short of achieving its aim, as it could exclude many who are worthy of recognition and support.

In this regard, we think of our client GRO-A who has suffered mental ill-health as a result of his experiences at Lord Mayor Treloar College. His ill health stems from what he witnessed happening to haemophiliacs at Treloar, and through the knowledge that all of his school friends are now dead. GRO-A has been moved sufficiently by the infected blood scandal to actively participate in the Inquiry's proceedings from their inception, and was awarded core participant status because of the impact that the scandal had on him. GRO-A does not seek financial compensation, but he does seek and require mental health support. GRO-A would not satisfy the above criteria, as he has not maintained a close relationship with the infected person: yet he could not do so, for they have died.

We therefore submit that there should be provision for GRO-A and other people in his position to access mental health assistance through the scheme: it may be that a more flexible criteria be adopted for the provision of mental health support, as compared to financial assistance.

d) Paragraph 2.36: Sir Robert recommended that a financial loss award should be made to the infected but not the affected. On this, we submit:

i) Sir Robert's logic in recommending that a financial award be paid only to infected claimants appears to be that a line had to be drawn somewhere. When asked whether it was right that the parents of dead children were unable to claim financial losses, such as lost income, Sir Robert said:

> *"… I'm trying to produce something which is completely new, which does its best to cross the whole range of people here. I may have failed. I may have failed. But I'm trying to create something or suggest something which is completely new, which is going beyond in some ways what people aspire to get in legal proceedings, and at some point – fortunately it is not me that has to make the decision – a line has to be drawn, if you – those who listen to this and say what you say, a line has to be drawn there, well then a whole range of financial losses suffered by people who have not been infected themselves could conceivably come in. Where that stops makes it quite difficult to know where this fund stops."*[468]

ii) The Inquiry has heard and read a vast amount of evidence from the affected core participants and, particularly, the bereaved. The Chair is best placed to assess the scale of damage done to the affected who, by way of examples: gave up careers to care for their infected partners or children; lost their careers through the stigma associated with their partners' infections; and/or were ultimately rendered unable to work through the physical and mental injuries sustained in nursing their infected partners or children to their deaths.

iii) Sir Robert has conceded, in stating that he is not the one who has to make a decision, that the Inquiry and the Chair are best placed to decide where a line ought to be drawn, and that this could legitimately differ from his recommendations.

iv) It would be entirely inequitable to exclude affected claimants who have suffered a diagnosable psychological and/or physical injury as a result of their relationship with an infected person. Those individuals would most likely be eligible for compensation in civil suits as secondary victims and/or dependants. As stated earlier in our submissions on justiciability, we invite the Chair to adopt the recoverability of damages in civil and HRA proceedings as a baseline. However, the Inquiry is not bound by that baseline given its flexibility and the harm that has been inflicted on these individuals for decades. The Inquiry should therefore redraw the line proposed by Sir Robert: for example, by only allowing financial losses

[468] Transcript 12/07/2022, Pg 147 Lines 9 - 21

which can be evidenced and be shown to have been caused, on the balance of probabilities, by the infected blood scandal.

v) When asked about the impact on bereaved parents who would, under his proposal, not be eligible for an award, Sir Robert's hesitation in his own evidence (copied below) betrayed an unexpected result of his recommendations. The answer to CTI's question is, in our submission, that it would be unfair and unjust to exclude bereaved parents or partners from recovering financial losses, particularly where those bereaved have suffered diagnosable physical or mental injuries.

> *"**CTI** - Will there be any recognition or recompense for the financial losses of parents caused by the impact of their child being infected and dying, the need to have to move to escape stigma, loss of job, change of working patterns to enable them to cope with caring, marriage break-up caused by stress and strain of caring for an infected child and loss of child? I think you answer in terms of your recommendation, is that there is no recompense for such financial losses, is that fair? Is that just?*
>
> ***SRF** - Sorry, I ask, is that the result of my recommendations? We are talking about parents who are – of children?"*[469]

e) Paragraph 9.60: Sir Robert recommended that there should be no award for the cost of fertility treatment, as it is assumed that such treatment will be and would have been available via the NHS. While this may now be the case, it has not always been so, and the Inquiry has heard traumatic evidence from infected and affected people who attempted to have families in spite of the infections that befell them. On that evidential basis, it follows that money spent on sperm washing, IVF, or other fertility treatments should be recoverable.

f) Paragraphs 10.09 and 10.10: Sir Robert recommended that existing disregards for benefits assessments should continue, and that all monies received under the scheme should be exempt from income tax. We agree entirely with Sir Robert and only highlight these comments because of their significant importance to our clients. Moreover, no geographical boundaries should be placed upon an infected or affected person's continued ability to claim whatever welfare payments they are currently in receipt of;

[469] Transcript 12/07/2022, Page 146

g) Paragraphs 12.1 to 12.3: Sir Robert discussed the various ways in which legal support could be provided, where necessary, to support the infected and affected in making their claims to the compensation scheme. We submit that Sir Robert's suggestion that the RLR's be utilised on a fixed fee basis is the simplest and most suitable solution. It must be borne in mind that over the past four decades many of the claimants have developed a deep mistrust of the government and, albeit to a lesser extent, the legal system. Trusted relationships that have been built with the RLRs will be essential for many to navigate the compensation scheme. We submit that representation should be available to all claimants who want or require it, though we hope that, for many, the scheme will be sufficiently simple to render representation unnecessary.

615. We consider that a compensation scheme which abides by the principles set down by Sir Robert, save with the amendments outlined above, is likely to satisfy (at least in financial terms) the infected and affected people who are likely to claim under it.

Sam Stein KC
Scarlett Milligan
39 Essex Chambers

Ben Harrison
Milners Solicitors **16th December 2022**