Submissions on behalf of the Core Participants represented by Collins Solicitors

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Chapter 1 - Introduction

(i) Time

Time stands still

1. *"... like for everybody. It's, like, Christmas, you think of three boys and all the families, all the children. You think what might have been. I can only still see them as 9 and 16 but it's Christmas -- a couple of weeks ago it was Brian's birthday, but Christmas, we put flowers on. And right after Christmas it's Stephen's birthday, in the February, so more flowers. Then in May it's Brian's anniversary. Then in September, it's Brian's birthday. And then October it's Stephen's anniversary. And then we are back to Christmas again. And it doesn't matter how many years go by, you're still asking: Why? Why? Why? And I keep going to the grave and I keep saying -- sometimes I think they are not there, they are going to walk in. I just think no, no, it can't be. I just don't make sense of any of it, and I probably won't. I will probably die thinking like this because I know it will never go out of my head."*[1]

Too much time has passed

2. As you read this, we are 40 years from January 1983 when the meeting took place at a Heathrow Airport hotel between a number of the UK Haemophilia Centre Directors and representatives of Immuno, a pharmaceutical company which manufactured and sold into the UK factor concentrates.[2] At this meeting, the probable connection between factor concentrates and what later came to be known as HIV was discussed. It is utterly wrong that it has taken until now to get to where we now are. It is **trite** that this was the worst treatment disaster in the history of the NHS; it is a **tragedy** that the infected and affected have been treated in the manner that have been over the past 40 years; it is a **travesty** they have had to wait until now and continue to wait for any proper redress.

Time matters

3. One person registered with the current support schemes dies every four days.

Lost time

4. Approximately 380 of those with bleeding disorders who were infected with HIV were children[3]. Most have died.[4]

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[1] Susan Hallwood's oral evidence to the Inquiry on 29th September 2022

[2] Meeting on 24th January 1983 at which the risk of transmitting non A, non B hepatitis by Factor VIII or IX concentrates was also discussed – see PRSE0001511

[3] INQY0000387 at page 5

[4] Expert Report to the Infected Blood Inquiry - Statistics page 22 para 2.10.

(ii) Preliminary

5. These submissions are made on behalf of the following:
   (a) 1037 infected and affected Core Participants ("CPs");
   (b) Three campaigning organisations recognised by the Inquiry as separate entities, who are CPs in their own right:
      (i) Factor 8
      (ii) Families and Friends of Haemophilia Northern Ireland
      (iii) The Fatherless Generation.

6. Within the individuals are a considerable number who have campaigned tirelessly over the last four decades as part of other campaign groups such as TaintedBlood.

7. Within the individuals are also the vast majority of the surviving pupils and the bereaved families of those who attended the Lord Mayor Treloar School in Hampshire.

8. The CPs include those who have so far survived HIV and/or Hepatitis C; parents whose children died; those whose parents have died; family members who lost siblings, husbands, wives, partners and other relatives; those who have for years cared for the survivors; haemophiliacs [and others] infected by contaminated blood and factor products; and men and women infected by contaminated blood transfusions.

9. The opportunity to contribute to these submissions was offered to all those listed in paragraph 5 above. Some CPs responded in considerable detail; some less so, preferring to focus on particular issues. This document reflects their legal representatives' attempt to synthesise and reflect the views of all who expressed them.

10. Collins Solicitors also represent a further 404 clients who are not CPs. Strictly speaking, these submissions are not made on their behalf, but it is hoped that what is set out below nonetheless also represents their views.

11. We, the barristers representing those listed at paragraph 5 above, approach these submissions on behalf of our CPs from our perspective as Counsel specialising in Personal Injury, Clinical Negligence and Inquests. We profess no particular expertise in other areas but are confident that the breadth of experience in other legal teams acting for the infected and affected will ensure balance in the overall submissions made to the Inquiry on behalf of the infected and affected.

12. By his Statement of Approach, the Chair has asked legal representatives to:
   (a) set out our CPs' position (if they have one) as to the factual findings which the Chair should (or should not) make;
   (b) set out the recommendations which our CPs invite the Chair to make, including recommendations as to compensation; and

(c) set out our CPs' position (if they have one) as to why particular recommendations should, or should not, be made.

13. We have noted that the Chair has indicated that:
    (a) It will be of little help to urge that the Inquiry take a particular view (whether positive or negative) of the general quality of the evidence of an individual witness on a purely subjective basis.
    (b) Our CPs are invited to provide submissions on those matters within the Terms of Reference that are of the most importance to them, and that this will, of course, vary.
    (c) Where the Inquiry has produced a detailed presentation or chronology, CPs should not feel it necessary to repeat the factual matters set out within those presentations or chronologies. Rather, the Chair would be assisted by Core Participants setting out the conclusions they invite the Chair to draw, having regard to those factual matters.

14. We bear that guidance in mind in what we say in the following pages and will say later in oral submissions on 17th January 2023.

15. The scope of this Inquiry has been vast and the amount of material immense. CTI and the Chair have shown a detailed command of the issues. It would not be possible, and there is no need, to recite back to the Inquiry in these submissions all the detail which, we are confident, the Chair has well in mind and will address in his Report. We therefore do not do so. We recognise that this is not an adversarial Court process of parties trying to persuade a judge, by submissions, to take one view or another. Rather, it is that the Chair himself has a developed view and understanding of the evidence and the issues, but is seeking to elicit from the CPs what they consider to be the important and significant aspects of the evidence for his Report. What we seek to do on behalf of our CPs is to pick out and emphasise key themes, particularly striking parts of the evidence, and conclusions, which we invite the Chair to draw. We do not pretend to touch on all, or even most, of the evidence, nor will we cover every area which the Inquiry has covered, but are confident that among the submissions on behalf of all the CPs, and the Chair's own approach, none will be overlooked.

16. Where we refer below to examples drawn from evidence of particular individuals, or where we focus on particular Haemophilia Centres or cohorts, we do not for one moment deprecate or minimise the experience of others. We do so only for expediency (to illustrate a point, not to catalogue all evidence on it), confident that the Chair has in mind the totality of all the evidence, oral and written.

17. At the outset we express our CPs' gratitude for the conspicuous care, skill and thoroughness with which the Inquiry has gone about its task, and for the *manner* in which it has done so – treating our CPs with dignity, decency and – above all – listening to them

and allowing them to have a voice. For many, this is the first time that their voices have been heard and their experiences taken as seriously as they deserve.

18. We remind the Chair of what he and Ms Richards KC said on the first day of oral evidence:
    (a) The Chair: *"There may be moments in the testimonies you are about to hear, now and over the coming days, which may bring you close to tears or they might excite indignation in any reasonable person"*
    (b) Ms Richards KC: *"You will hear how lives have been cut short or irrevocably damaged. You will hear how, in a phrase used in one of the many statements received by the Inquiry, people have been forced to live a life that was not the life they were meant to lead."*

    Both of these statements have turned out to be entirely true.

19. We suggest that the Inquiry is bound to find – in due course when it reports – that all the concerns expressed by our CPs and other over the years about their clinical treatment, about how they have subsequently been dealt with, about cover-up, about government obfuscation and delay will be fully borne out. They have battled for years to uncover what has now been laid bare by the last four years of evidence.

(iii) Ultimate responsibility

20. The Inquiry should not hold back from naming individuals, attributing blame and criticising, where appropriate. It is only when the details of failings are properly laid out that lessons can be learned. It is no part of this Inquiry's function deferentially to preserve the reputation of any clinician, politician or civil servant if that is not warranted. Proper attribution of responsibility for unacceptable failings is a huge part of achieving justice, recompense, vindication, closure and restitution.

21. While individuals are mentioned in the following pages, and we will invite the Chair to find that there have been gross shortcomings on the part of some clinicians, we suggest that the failings of clinicians, the health service, the blood transfusion bodies, blood product licensing authorities, the support schemes, the government legal department and the clinical and administrative staff in the Department of Health ('DoH')[5] all – ultimately – devolve back to government itself.

22. The primary responsibility of any state department for health must be to sustain the health and wellbeing of those subject to its authority. For a department of health and social services or health and social care, the obligations are more extensive than even that. The minimum duty, therefore, of the Department of Health, its successors, and its devolved

[5] For ease, we refer throughout these submissions to the 'Department of Health' notwithstanding changes of name the Department has gone through in different periods of restructure.

counterparts, is to safeguard the health of the population. Not only is this a legal duty; it is also a moral duty. It ought to be (and, through the material years, to have been) a continual aspiration.

23. This is not controversial. Indeed, this is how the NHS understands itself. The *NHS Constitution for England* says as follows:

> The NHS belongs to the people.
>
> ***It is there to improve our health and wellbeing, supporting us to keep mentally and physically well, to get better when we are ill and, when we cannot fully recover, to stay as well as we can to the end of our lives.*** It works at the limits of science – bringing the highest levels of human knowledge and skill to save lives and improve health. It touches our lives at times of basic human need, when care and compassion are what matter most. […]
>
> It is available to all irrespective of gender, race, disability, age, sexual orientation, religion, belief, gender reassignment, pregnancy and maternity or marital or civil partnership status. The service is designed to improve, prevent, diagnose and treat both physical and mental health problems with equal regard. ***It has a duty to each and every individual that it serves and must respect their human rights.*** At the same time, it has a wider social duty to promote equality through the services it provides and ***to pay particular attention to groups or sections of society where improvements in health and life expectancy are not keeping pace with the rest of the population.*** […]
>
> Everyone who uses the NHS should understand what legal rights they have. For this reason, important legal rights are summarised in this Constitution […] ***The Constitution also contains pledges that the NHS is committed to achieve. Pledges go above and beyond legal rights. This means that pledges are not legally binding but represent a commitment by the NHS to provide comprehensive high-quality services.*** [6] (emphasis added)

24. The NHS, then, is a service. It exists (and, assuming that the Constitution reflects the basis on which it had always operated, has throughout the material times existed) to meet the needs and demands of its patients: it serves them. Moreover, it is a service that is 'designed' - that is, it is constructed to meet a certain objective. That objective is simply to 'improve our health and wellbeing', as the Constitution says right at the beginning. Not only does the NHS aim to prevent, diagnose and treat illness, it hopes to improve the health of the nation. Patients are endowed with rights, among them is the basic human right to health. The NHS makes pledges: it commits, morally, to do more than the bare fulfilment of its legal duties.

25. As a service that is 'designed', and as a service that commits to doing and being more than is mandated by law, the NHS must have a controlling mind. There must be a

[6] *The NHS Constitution for England* (Department of Health and Social Care, 2021). First published 2012.

design*er*, in other words, who keeps the NHS living up to its ideals. In domestic law, that controlling mind is the Secretary of State. In international law, the controlling mind is the state itself. Both international and domestic law place obligations on those who design the healthcare system. Those obligations are consonant with the characterisation of the (English) NHS in its Constitution above, and are outlined below. The above characterisation is not legally controversial, although evidence in this Inquiry demonstrates that the NHS and/or its controlling minds fell below moral and legal standards.

26. During Lord Owen's evidence to this Inquiry, the following exchange took place between the Chair and the witness[7].

> *Sir Brian Langstaff: As a matter of principle, do you see it as one of the first duties of the state to look after the safety of its population?*
> *Lord Owen: Yes.*
> *Sir Brian Langstaff: So that would extend to the safety of patients receiving blood or blood products?*
> *Lord Owen: Yes.*

27. Lord Owen, being at one time what we have called a 'controlling mind', recognised that the first duty of the state was to safeguard its population. This self-understanding is in accordance with law.

28. In international law, obligations to safeguard the population's health arise under the European Convention on Human Rights and Fundamental Freedoms and under UN instruments (the Charter of the United Nations, the Universal Declaration of Human Rights, and the Constitution of the World Health Organisation), amongst others. At all times material to this Inquiry, the United Kingdom was a signatory to those treaties. Most pertinently, the WHO Constitution states as follows, in its preamble:

> Health is a state of *complete physical, mental and social well-being and not merely the absence of disease or infirmity.*
>
> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.
>
> The health of all peoples is fundamental to the attainment of peace and security and *is dependent upon the fullest co-operation* of individuals and States ... [8] (emphasis added)

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[7] Tuesday 22 September 2020, page 170, lines 6-12

[8] The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (Off. Rec. Wld Hlth Org., 2, 100), and entered into force on 7 April 1948. The United Kingdom of Great Britain and Northern Ireland became a member of the WHO on 22 July 1946. The WHO is one of the specialized agencies referred to in Article 57 of the Charter of the United Nations.

29. The definition of health provided by the WHO Constitution is apt for any state (or state department) whose primary concern is for the wellbeing of its people. In particular, what commends this definition is its holistic view of health as not merely physical and mental, but also social. The evidence of the infected/affected shows how closely physiology and sociality are intertwined, and indeed the Department of Health has from time to time been united with the Department for Social Services/Care.

30. The European Court of Human Rights has explicitly connected healthcare with the duty of Member States to look after the safety of their populations[9]. Article 1 of the European Convention on Human Rights provides that Member States must secure the rights and freedoms enshrined in the Convention to everyone within their jurisdiction. This is the duty to look after the safety of the population, specified by Section 1 of the Convention. The specific rights and freedoms extended to those in the jurisdiction include the freedom from inhuman and degrading treatment and suffering, contrary to Article 3 ECHR.[10] The suffering which flows from illness may be covered by Article 3, when it is, or risks being, exacerbated by treatment for which the authorities can be held responsible. The type of treatment for which authorities can be held responsible includes situations where the authority inflicted ill-treatment on the patient and/or where the patient receives inadequate care from state medical authorities.[11] AIDS has been held to be suffering which meets the threshold of Article 3.[12]

31. In English law, the National Health Service Acts of 1946, 1977, 2006 (as amended latterly by the Health and Social Care Act 2012) place a like duty on the Secretary of State. Common to section 1 of all of these Acts is the Secretary of State's duty to promote a comprehensive health service designed to secure improvement in the physical and mental health of the people of England, and to secure improvement in the prevention, diagnosis and treatment of physical and mental illness. Prior to the 2012 amendment, the Secretary of State had to 'provide or secure the effective provision of' services for that purpose'. Since the 2012 amendment, the Secretary of State must 'exercise the functions conferred by this Act so as to secure that services are provided in accordance with this Act' for the same purpose. These submissions do not discuss the relevance, if any, of the 2012 amendment because it post-dates most events that this Inquiry is concerned with. At all material times, therefore, the duties and functions of the Secretary of State were those provided in the National Health Service Acts of 1946, 1977, and 2006.

32. The duties and functions of the Secretary of State are, by extension, the duties and functions of the Department for Health, or the Department for Health and Social Services/Care as the case may be.[13] In order to have a health service that is

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[9] *Pretty v United Kingdom* (2346/02), (2002) 35 E.H.R.R. 1, [51].
[10] Article 2 (right to life), Article 8 (non -interference in private and family life) and Article 14 (non discrimination) are also relevant tohealthcare.
[11] *Pretty v United Kingdom* (2346/02), (2002) 35 E.H.R.R. 1, [53]
[12] *D v. United Kingdom* 30240/96 [1997] ECHR 25.
[13] Section 1(3) of the 2006 Act confirms explicitly that the Secretary of State retains ministerial responsibility to Parliament for the provision of the health service in England

'comprehensive' (i.e. that addresses all relevant aspects), it is imperative to know what all relevant aspects of 'health' are. This is because maintaining and improving the health of the nation is the objective of the NHS. We contend that that the definition of 'health' in the WHO Constitution assists this Inquiry in interpreting the duties, functions, and aspirations of the Department of Health. The first reason for this is that the NHS was formed, and the WHO Constitution ratified, immediately after the Second World War. That violent conflict, with its profound health and social implications, focused the minds of governments on committing to improve lives and social conditions. It is in such contexts that foundational constitutional commitments are made, and it is the challenge of subsequent administrations to live up to them. In 'peacetime'[14] (to use Professor Sir Jonathan Van Tam's phrase), it is possible to become complacent about such things. Nevertheless, successive Parliaments retained the fundamental commitment enshrined in section 1 of the National Health Service Act 1946, despite replacing the Act in 1977 and then 2006.

33. The second reason that the WHO definition of health is an appropriate aid to construction is because the UK bound itself, in international law, to the WHO Constitution. This is a treaty that, according to its preamble, is 'dependent upon the fullest co-operation of … States'. It must be presumed that the United Kingdom intended to abide by promises made on the international plain, or at least to aspire to standards imagined in post-war treaties. Thus, the proper interpretation of the commitment to 'health' made in the NHS Acts is a commitment to bringing about 'complete physical, mental and social well-being' for the subjects of the United Kingdom. It matters not, in a Public Inquiry, whether the commitment expressed in the NHS Acts has the force of law (whether that be domestic or international law), nor whether breach of any legal duty gives rise to criminal or civil liability – because the purpose of an Inquiry is not to find civil or criminal liability. The point of these submissions is only this: the proper interpretation of the commitment to maintain and improve the health of the nation, as expressed in the NHS Acts, is a commitment to bringing about 'complete physical, mental and social well-being' for the subjects of the United Kingdom. That commitment may be legal, or it may be moral-political. The fact is that this is its true construction.

34. Far from fulfilling its duties and aspirations, moral and legal, the state made sick people worse. Those who needed blood and blood products, and even some who did not need such treatments, were given contaminated product. Those of our CPs who are haemophiliacs would have preferred to live with their underlying condition (whether untreated entirely, or treated with what would otherwise have been the prevailing and recommended treatment i.e. cryoprecipitate) rather than to take infective factor concentrates.

35. The state did not simply fail to do what it ought to do, it worsened the lives of those it should have looked after – both by the initial medical treatment and subsequently by its

[14] Friday 18 November 2022 - Professor Sir Jonathan Van Tam, 18/11/22, pages 12, 14, 33.

response to their valid outcries. Their intuitive sense of travesty has a sound moral foundation and is well-illustrated by all those cases where the civil law recognises the liability of rescuers who worsen the position of the person they attempt to rescue, even in the absence of any duty to rescue (see e.g. *Capital & Counties v Hampshire County Council* [1997] 3 WLR 331). In the case of these Core Participants, the state certainly had a moral and legal duty – a duty that was not discharged but, in the neglectful execution, instead ruined lives that would have been better with no intervention at all.

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Chapter 2 - People

Introduction

36. We consider it right, at the outset, to focus on **people** – the infected and affected.

37. The Inquiry has (rightly) heard huge amounts of evidence from politicians, doctors, scientists, civil servants and experts. It has received tens of thousands of documents and considered masses of expert evidence, statistics and (through presentations) retrospective analyses of events, chronologies and timelines.

38. But the Chair chose to put people at the front and centre of the Inquiry's processes, and to ensure that their evidence was heard first, and last, because he correctly understands that this Inquiry is, at its heart, about doing justice by people who have been very badly wronged.

39. The statistics expert panel recognised the human aspect at the outset of their oral evidence.[15] In the words of Professor Evans:

> "I think that it is very easy for people to listen to the proceedings today and hear us talking about numbers, but as statisticians, we are very well aware of the human tragedy behind each one of these numbers. And when you hear us talking about numbers and rates and percentages and that sort of thing, it doesn't mean that we are ignoring the individuals who have had major trauma in their lives -- and of course many of them have died, and there will be people who are continuing to be severely affected -- and we acknowledge that. And we're not going to be able to keep on repeating that, but the numbers that we will talk about are a reflection from a statistical point of view of the tragedy, the damaged lives."

40. We explore the human toll below, but – while recognising that each is a life, and not just a number – the numbers themselves are stark and devastating[16].

    (a) Around 1,250 people with bleeding disorders were infected with HIV in the UK between 1970 and 1991.
    (b) Around three quarters of those have died. Around half of those who died, died as a result of their HIV infection.
    (c) Within that, some 380 children with bleeding disorders were infected with HIV – approximately one third of the number of those infected.
    (d) We now know that all those infected with HIV would also have been infected with HCV.

[15] Wednesday 09th November 2022, pg 27, ln 3
[16] We take most of these from the Expert Report on Statistics

(e) In addition, somewhere between a further 2,400 and 5,000 people with bleeding disorders were infected with HCV.

(f) A further number of between 79 and up to 100 people were infected with HIV through transfusion, of whom 85% have died.

(g) The statistics experts estimate that 26,800 people were infected with HCV through transfusion.

41. Towards the end of the statisticians' evidence, the Chair endeavoured to elicit from them a figure for the total number of deaths caused by the infections. While the experts promised to undertake further analysis, the transcript contains discussion between the Chair and the experts of figures of more than 1,000 and possibly up to around 3,000.[17]

42. It has often been said that were this number of people to have been killed or injured in a single momentary disaster, it would have achieved world-wide notoriety and news coverage and provoked outrage. But the fact that infections and deaths have occurred over time has clouded the significance and sheer scale of the consequences of this medical treatment scandal.

43. In this Chapter we seek to include and combine what the Chair asked for at §§9 and 14 of his Revised Statement of Approach and address "Impact" and "Treatment, Care and Support" (which are §§4 and 8 of the Inquiry's Terms of Reference). We note that the Chair specifically states that he does not need the evidence to be repeated or summarised, but rather asks that we set out the overall conclusions we invite him to draw about those matters from the evidence he had heard and read.

44. We therefore pick out what we invite the Chair to find, as established on the evidence of the infected and affected, about how they were dealt with by those in authority (their clinicians, government, civil servants and the support schemes and trusts).

45. We then turn to summarise the impact on the infected, on their spouses and partners, on parents who lost children, on children who lost parents and on carers.

46. In both instances we provide our submissions in a very summary, outline form – confident that the Chair has a clear recollection and understanding of the detail of the evidence each of the issues we raise. In neither section do we draw specific examples from (and therefore we do not cross-refer to) the evidence of any specific individuals but may do so in due course in our oral submissions.[18] In the section on impact, the points we make are drawn from the evidence given by the infected and affected, and from the Expert Group Reports

[17] Wednesday 09th November 2022, pg 27, ln 3 pp.182-192. It is not known whether the experts haveyet been able to conclude their modelling and analysis and write to the Chair. It may be that they will have been able to do so ahead of oral submissions.

[18] Throughout, for convenience, we use the terms NANB, HCV and HIV (even for periods when it was not named and then initially known as HTLV-3)

(including the recent psychosocial group report on childhood bereavement).

Common themes of how men, women and children were dealt with

47. There was a wholesale lack on their part of knowledge of the true risks of their treatment, and of informed consent to that treatment.

    (a) Not one single patient or parent the Inquiry heard from gave evidence of full and informed consent to treatment. Full and proper consent would have involved an explanation of the risks inherent in the treatment and the risks of not having the treatment. We invite the Chair to conclude that in all or almost all cases, the risks of treatment with pooled factor concentrates were not communicated to patients or parents as they should have been.

    (b) Fitting with their recollections, the Inquiry heard repeated evidence from the infected and affected of the dearth of any record in their medical notes (and was able to see in the notes of witnesses whose records were considered during their oral evidence) of them giving of informed consent or of a detailed explanation of treatment risks. We invite the Chair to conclude that this absence of records supports the evidence that risks were not explained.

    (c) The Inquiry heard clinicians explain that they believe they *would have* sought consent or that it was their *usual practice* to explain risks and obtain informed consent to treatment. But, one after another, all of the factual witnesses who were patients or were the parents of child patients gave evidence that risks were not explained, that no-one pointed out to them the dangers of pooled concentrates, or identified the balance of risk of one type of treatment as against another. We invite the Chair to prefer the evidence of the parents and patients, particularly as many of them recalled raising concerns which they had read in the press or seen on television media. Their consistent evidence is that clinicians dismissed those concerns as unwarranted scaremongering or as ill-informed mischief-making by journalists.

    (d) Some clinicians (and – curiously – politicians and civil servants, notably Lord Kenneth Clarke in his oral evidence) sought to pass responsibility by saying that their haemophiliac patients were 'experts' in their own condition and so should be assumed to have had all the knowledge that they needed. While it is true that many patients knew as much as they could find out about their own condition of haemophilia (not least because it is an inherited condition and there would almost always have been others in previous generations in the family who had experienced it), they did not know the science or the medicine behind factor concentrates, pool sizes, donor selection, the risks, the difference between UK and US-produced concentrates, the comparative risks of concentrate as against

cryoprecipitate or other treatments, or the risks of not being treated at all as against the risks of being treated with one or more those products.

(e) It was also suggested that none of them asked. But if they were not told the risks / differences, and were told by doctors they trusted that treatment with concentrates was quicker and easier than previous treatment (some gave evidence of having been told, in effect, that factor it was a 'wonder product' which would transform their care), why would they ever have questioned it?

(f) As we now know, clinicians were or ought to have been aware from at least the 1970s that factor concentrates transmitted hepatitis, and that NANB was a disease which was not merely mild and chronic but which could have long-term and serious consequences. We contend that the Chair should conclude that it ridiculous to suggest that patients (or their parents) knew and consented – or would ever with full knowledge have consented – to be given material which would 100% likely give them HCV and highly likely HIV.

(g) The patients and parents themselves cannot possibly have known about the risks of NANB. That was for medical professionals to know, and to communicate to patients who were at all times in their trust and care.

(h) There are common themes through the evidence of not being told of developing medical knowledge of risks of NANB and of HIV / AIDS when it appeared.

48. Those with bleeding disorders were a trusting community of patients whose trust was abused.

(a) Initially at least there were close bonds with, and those with bleeding disorders had considerable respect for and trust in, their treating clinicians.

(b) In part that was because of the hereditary nature of the disorders, and the fact that previous generations of their families had grown up familiar with medical treatment with regular contact with (and reliance on) medical professionals.

(c) In part it was because almost all of those with bleeding disorders would have been diagnosed as children and so would themselves have grown up familiar and comfortable with regular interactions with haemophilia clinicians.

(d) The fact that was not a 'single-event' illness and it was known that this would be a life-long relationship between patient and clinician probably also served to engender trust and familiarity.

(e) As a result, we invite the Chair to find that the community of patients with bleeding disorders was – until awareness of the matters this Inquiry is considering – one which relied on and was close to their clinicians. Some witnesses described them as being like part of the family.

49. Paternalism

(a) The Inquiry heard repeated evidence from the infected and affected of patients and their families being treated in an unacceptably paternalistic manner, even by the standards of the 1970s and 1980s, by their clinicians.

(b) Chiming with the issues of consent above, the impression was that 'doctor knows best' and that decisions about the patients' treatment were really being made by the medical professionals.

(c) That is most starkly illustrated by the approach at Lord Mayor Treloar School, which we consider in a separate chapter below.

50. Condescension

(a) The infected and affected were very badly let down by the design and operation of the MFT and the other Alliance House Schemes.

(b) Set up as charities, with limited resources, an understanding that they had to preserve their initial capital funding and uncertainty over what annual budgets would be into the future, they failed properly to support those who depended on them.

(c) In general terms they were condescending towards, and were disparaging and sceptical of, applicants, rather than generous.

(d) Applicants were left to discover for themselves what might be applied for, rather than any proactive and positive process being undertaken of reaching out to the infected community the trusts and schemes were intended to serve, to make their assistance known and available.

(e) The decision-making processes and rights of appeal therefrom were opaque.

(f) They were not sufficiently generous in their support of those upon whom it had been intended should confer benefit.

(g) Particularly bearing in mind that part of their funding came from the injection of funds following the settlement of the HIV litigation – which the claimants

not unreasonably thought should have been money which was able to spent on the immediate relief of their needs.

(h) Their approach led to those who needed the fund having to provide detailed justification for their need and spending.

(i) They adopted an approach of providing the bare minimum – requiring the applicants to produce more than one quote for an item before funds would be released.

(j) The whole process reduced applicants to being perceived as recipients of charity, having to go cap-in-hand for even basic needs.

(k) The trustees were dismissive of those they were there to provide for, describing them as the 'great unwashed', 'Welsh windbag', etc and removing them from their office premises. And, subject to the Chair's factual finding on this issue in due course, there was even a threat of defamation proceedings between trustees over whether views were expressed about a number of beneficiaries dying sooner freeing up funds.

(l) There has been evidence of those diagnosed with HCV not being told about availability of schemes and/or not being told by their clinicians when they passed the medical threshold to qualify for schemes or for different stages in schemes.

(m) There was considerable and powerful evidence of trusts and schemes adopting an attitude of critical disbelief of applicants, rather than assessing applications of a tests of balance of probabilities. Applicants were rejected by schemes when, through no fault of their own, they could not produce their medical records – see the evidence of the Skipton panel of witnesses – self-clearers weren't given the benefit of the doubt, those who lost records were excluded.

(n) We invite the Chair to conclude that the trusts and schemes were run in a way which did not suit the needs of the beneficiaries, that the trustees unduly restricted and limited the number and categories of those they could assist and the nature of support they could give.

(o) We invite the Chair to find that providing relief through the basis of arms' length bodies operating under charitable principles of minimal assistance of doing no more than lifting beneficiaries out of poverty was misconceived.

(p) We invite the Chair to draw sharp distinctions between how the trusts and schemes operated and how the future support scheme should operate.

51. Stigma

(a) The Chair has heard graphic accounts of truly awful patterns of stigma, abuse, misunderstanding and isolation forced upon those who were infected and their families in part perhaps by ignorance or fear on the part of others and in part perhaps by the societal attitudes of the time, stoked by the media.

(b) There have been striking descriptions in evidence of violence and abuse directed at the infected and their families, of families having to move to escape being known, of children being insulted at school, of infected individuals being driven into a life of isolation and solitude, of them not even telling close relatives, friends or colleagues and of living lives of enforced secrecy.

(c) The Chair heard repeated evidence that the stigma was such that it was easier for parents of infected children to say that they had cancer than to be open and truthful about infection with contaminated blood products causing HIV.

(d) We will return to stigma in oral submissions in due course, but for now note that there remains such a lack of appreciation and understanding of how severe it was that even the Cabinet Office Minister, Jeremy Quin MP told the House of Commons on 15.12.22 that it was only when he took on his cabinet role that he appreciated the true nature and extent of the stigma suffered.

52. Suspicion and repeatedly having to explain

(a) There was evidence of the DSS conducting what we invite the Chair to conclude invasive, demeaning and time-consuming investigations into potential fraud on the part of those who received payments from the trusts and schemes.

(b) This ought to have been avoidable, not least because the funds which aroused suspicion had been provided by another (albeit arms-length) government body, one of the trusts or schemes.

(c) Even short of fraud investigations, the Chair heard cogent and compelling evidence of the distress experienced by the infected and affected (even to date) in having regularly to explain their situation and what happened to them.

(d) In the clinical context, the Chair heard repeated evidence of those with HCV having their condition attributed to alcohol / lifestyle – ignoring the stark and obvious explanation.

53. Testing

(a) The Inquiry heard a consistent picture through repeated evidence of patients being tested without their knowledge or consent, and blood being stored without consent for later testing.

(b) We invite the Chair to find that this was an almost universal practice in light of:
  (i) the apparent approach of the clinicians at the material time towards issues of consent;
  (ii) what we set out above about the patient's trust in and familiarity with their clinicians (and the patients' consequent lack of questioning of blood being taken and what it was to be used for);
  (iii) what we set out above about the paternalism of clinicians at the material time and what we set out in a later chapter about the over-arching attitude of the clinicians being that they could act in what they believed were the best interests of the patients as a cohort or group, rather than as individuals (the Chair will be aware of the approach apparent through UKHCDO minutes of treating bleeding disorder sufferers as a homogenous group to be dealt with as they, the clinicians, felt best).

(c) There was repeated and compelling evidence of non-communication of diagnoses and test results.
  (i) Positive HIV and HCV results being recorded in the patients' records but not communicated to them at the time, or only belatedly, or sometimes not at all.
  (ii) Lack of prompt communication of positive results put family members at risk.
  (iii) Lack of prompt communication of results prevented the infected from seeking out treatment or making life choices to try to mitigate their situation.

54. Inappropriate communication of diagnoses

(a) There was repeated and uncontroverted evidence of patients or their parents finding out their diagnoses by accident, e.g. from sight of notes or stickers on medical records.

(b) Patients were told in corridors and public places.

(c) Some were told by letter of a life-changing and terminal diagnosis.

(d) Some patients or their parents were told in group meetings or in groups at school.

(e) Diagnoses of potentially terminal conditions were delivered in many cases without compassion or brusquely at short appointments and patients were simply sent away to deal with it themselves.

(f) There was strong and repeated evidence of common themes of not being offered support, education, guidance, counselling or follow-up when a diagnosis was given, while at the same time the patients were unwittingly behind the scenes being followed up and reported by medical professionals.

(g) We invite the Chair to find that none of this should have occurred.

55. Isolation and obstruction

(a) Hard though it may be to recall, this happened before the age of the internet, the web and easy, instant communication.

(b) Patients and their families in many cases believed that these were one-off events happening to them on their own.

(c) Until effective campaigning groups were formed (and even after that) individuals have had to take the role of David against Goliath.

(d) The infected and affected have been marginalised and divided by Government policies of distinguishing between different groups of the infected and affected, and by including some within support schemes while excluding others.

(e) On an individual basis, there was overwhelming evidence of whole sets of medical records being lost or of certain (vital) parts of medical records being missing. We invite the Chair to conclude that in many of those cases records were not inadvertently lost but, on the contrary, wholly or partly disposed of to cover-up what had occurred in respect of treatment.

56. Misled and fobbed off

(a) The infected and affected were constantly rejected and knocked back in their search for answers and their fight for a full and proper Inquiry.

(b) Lord Archer had no powers of compulsion and received limited co-operation in his Inquiry.

(c) The infected and affected were repeatedly told (wrongly as they always believed and the Inquiry has now shown) that there was nothing more that could have been done and that their treatment was the best available at the time.

The impact on the infected, on their spouses and partners, on parents who lost children, on children who lost parents and on carers

57. We are acutely aware that the Chair has asked that written submissions do not repeat or summarise evidence he has received and will undoubtedly have clearly in mind. From our perspective as Counsel specialising in negligence, personal injuries and clinical negligence work, we know (and we recognise that the Chair himself, with his background as a Barrister then as a Judge will know) that every single case is unique and tragic.

58. It seems brutal to simply list a range of effects, consequences and symptoms. In doing so we do not for one moment seek to diminish the awful severity of the consequences for those damages, both infected and affected, by this scandal. On the contrary, however, we hope that by doing so, and by seeing the extent of even a simple cataloguing of some but by no means all of the symptoms and consequences, their true magnitude can begin to be appreciated.

59. For the infected:

(a) The terrible physical and psychological effects and symptoms of infection with HIV or HCV
(b) The compounding effect of co-infection
(c) The physical and mental side-effects, both in the short and long term, of treatment (experimental treatment at an early stage) with (among other things) interferon and ribavirin
    (i) For some, the failure of treatment totally after undergoing it.
    (ii) For others, failure after a long course and then having to undergo it and its side-effects again.
(d) Long-term compromised immune systems
(e) Long-term dependency on medication
(f) Long-term symptoms interfering with all aspects of work, social and domestic life
(g) Fear of infecting or actually infecting partners, spouses, family or friends
(h) Fear of further illnesses, vCJD
(i) Psychological trauma and poor long-term physical prognosis by not having diagnoses of HCV communicated until many years too late
(j) Relationship breakdown
(k) Not forming relationships or marrying
(l) Not having children and/or being advised to terminate pregnancies

(i) Not having family, the enjoyment of family life or children and grandchildren around in old age

(m) Living with a predicted shortened lifespan
(n) Social isolation
(o) Stigma
(p) Loss of friends (multiple bereavements) and survivor guilt
(q) Knowledge that their trust in clinicians was abused
(r) Knowledge that they were used without consent in clinical trials and denied their autonomy
(s) Having their genuine concerns disbelieved and dismissed and being marginalised and belittled by government and by trusts and schemes
(t) Being made to feel of no value or made to feel a burden by the actions of government, trusts and schemes
(u) Loss of careers and promotions
(v) Loss of independence, being defined by an illness and living a life other than expected
(w) Financial insecurity, reduced earnings, reduced pension
(x) Inability to obtain insurance, life assurance, mortgage protection policies
(y) Having to fight constantly for recognition, vindication and justice
(z) For some, becoming all-consumed by the campaign for justice

60. In addition, for those infected as children or adolescents:

(a) Social isolation in formative years
(b) Destructive and self-destructive behaviour on being told of a foreshortened future
(c) Dropping out of education or not pursuing it as they would otherwise have done
(d) Being handicapped educationally as a result in respect of the type and extent of work they can do, with long-term effects on earnings and pensions
(e) Awareness of friends dying very young

61. For bereaved spouses and partners:

(a) Loss of their life partner
(b) Emotional and psychological reaction
(c) Ongoing and incessant grief reaction
(d) In many cases having given up work and career to care for their spouse
(e) Having their genuine concerns disbelieved and dismissed and being marginalised and belittled by government and by trusts and schemes
(f) Being made to feel of no value or made to feel a burden by the actions of government, trusts and schemes

62. For parents who lost children:

(a) The psychological and emotional trauma of loss of a child
(b) Ongoing and incessant complicated grief reaction[19], triggered by birthdays, anniversaries of deaths, Christmas and other occasions
(c) Guilt over failure to protect and having perhaps been involved in the administration of factor concentrate
(d) Concern about the effect on other surviving children of the loss of a sibling and about the effect of their own reaction
(e) Suicidal thought or actions
(f) Exclusion from support schemes has itself been damaging

63. For those who were children and lost one or both parents:[20]

(a) Grief, emotional and psychological reaction[21]
(b) Stigma of loss of a parent
(c) Many children were already living with high levels of stigma and trauma prior to the death of a parent.
(d) Psychological disorders arising from childhood bereavement
(e) The effect of lack of communication / keeping secrets
(f) Loss of a parental influence and role models in formative years
(g) Absence of a parent and grandparent later in life
(h) Loss of security and stability of family life
(i) For some, a decision not to have children themselves for fear of replicating loss
(j) Compounding effect of psychological loss on attitudes towards their own children
(k) Loss of a parent during childhood or teenage years has a significant impact on school attendance, exam performance and grades, and thereby on work, earnings and pension
(l) Children and adolescents who lose one or both parents do not just lose their carer(s). Younger children lose the support and stability of their attachment figure without being developmentally able to fully understand the reason for the loss and subsequent changes to their life
(m) A significant theme of negative social effects and stigma runs through all witness statements of children whose parent/s died
(n) There is also some evidence that early childhood trauma has a long term impact on the immune system and represents 'a significant health risk that continues to exert a deleterious effect in adulthood' (Simons et al., 2019).

[19] As defined in DSM – see oral evidence of psychosocial experts
[20] See the Expert Report on Psychosocial Issues– Childhood Bereavement (Supplementary)
[21] Expert Report: none of the best practice principles of communication and support, which were known at the time, were considered or in place when the witnesses lost their parent(s)

(o) Most studies point to a negative relationship between the chronic illness of a close family member and young people's educational outcomes ... causing reduced engagement at school and disruption to the child's education
(p) Exclusion from support schemes has itself been damaging

64. For those currently excluded from any support schemes, the sense of exclusion, and decision from others of the affected groups, have been damaging. We invite the Chair t consider that the line taken by Alex Burghart MP (in the Nov '22 Westminster Hall debate) saying that the government "stands side by side" with those impacted by the contaminated blood scandal – when for the majority of bereaved families, doing literally nothing to help them cannot be said to be standing side by side with them – is both is ridiculous and insulting.

65. The impact on those who lost parents even when they themselves were adults must be considered to be barely less than those who were children. Similarly those who lost children when those children were already in adulthood.

66. For family members other than spouses / partners – typically adult children – who were or are carers for the infected, irrespective of the age of the infected person

(a) Constant emotional toll and burden
(b) Practical financial and self-esteem loss of giving up work and careers and (if returning to them) being slower to return and handicapped in career progression
(c) Feeling (ab)used by the state to discharge the burden of caring for those harmed by the state
(d) The stress of care-giving, not only psychological but physical and on the immune system

67. In all, we invite the Chair to consider that for those most seriously infected and affected the injuries rank amongst the most serious kinds of injury which might ever come before the Courts.

68. It is important that the nature and extent of the harm, the clinical setting in which the harm was inflicted, and the numbers to whom that harm has been done, should be fully understood and never forgotten.

69. Those matters are all relevant when the Chair comes to consider compensation, with which we deal later in these submissions.

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Chapter 3 - Myths and lies

Introduction

70. Forty years or so have passed since some of the key events which this Inquiry is considering.

71. Over that time, as we set out in Chapter 4 and elsewhere, either intentionally or unintentionally certain inaccurate and untrue points of view and assertions have taken root and become entrenched as established thinking, seemingly unchallenged as 'gospel' truth. These are what we refer to in the title of this chapter as 'myths and lies.'

72. As the Chair will have in mind, the Inquiry has already scrutinised many of these, not only their truth with the benefit of hindsight but by assessing what was actually known at the time when these assertions were first made, so as to give the Chair an understanding of how they came to be made at all and whether they should – even at the time – have been known to be inaccurate, untrue and misleading.

73. Our Core Participants have invited us to identify a number of these myths and lies, so that the Chair may in his report focus on them, deal with them specifically, and call them out for what they are. It is important to our Core Participants as part of the function and purpose of the Inquiry that the record is set straight on these issues, unequivocally and finally.

74. Again, in this chapter we are mindful of the Chair's encouragement not simply to regurgitate evidence with the he will be familiar, but instead to focus on the conclusions we invite him to draw from that evidence.

Lie 1 – that this was all unavoidable

75. It is simply untrue to assert that "all this was unavoidable" or that it was "best possible treatment in line with the standards of the time" – the position which was adopted by Lord Clarke and others in government, as we set out at Chapter 4, and was adopted with a retrospective, self-exculpatory purpose by some (but not all) of the clinicians from whom the Inquiry heard evidence. For the reasons we give there, and elsewhere throughout these submissions, we anticipate that this will be one of the Inquiry's key findings.

76. The contaminated Blood Scandal that unfolded in relation to factor concentrates was *not* unavoidable or inevitable. Simplifying massively, it arose from a combination of pharmaceutical companies' greed and unsafe practices; the skipping of known safety steps (as referred to in Ch11), insufficient regulation, foresight and planning by government; over-enthusiasm on the part of clinicians blinding them to the obvious risk and dangers of pooled blood products; failure on the part of the government and clinicians to respond appropriately and quickly to the threat of HIV; and failure to apprise patients and their

parents of the true state of affairs, which would have allowed them to exercise their own choices over treatment rather than be allowed only to be the passive recipients of what others (wrongly) thought best for them.

Lie 2 – that factor concentrates were essential

77. We said in our opening submissions at the Preliminary Hearing in September 2018 that start of the Inquiry that this is untrue. We described it then as the 'narrative of necessity' and we identified the comparative safety of the existing treatment with cryoprecipitate over the obvious dangers of pooled blood products from paid donors.

78. There are four aspects to this lie: (i) that haemophiliacs would die if not given concentrates; (ii) that it was not desirable to use a different treatment and that patients did not want to; (iii) that cryoprecipitate was too old-fashioned, cumbersome and fraught with problems; (iv) that it could not be done.

(i) Haemophiliacs would die if not given concentrates

79. This was not, in fact, necessary "life saving" treatment in almost every instance.

80. The huge surge in demand for concentrates was generated by clinicians and others, not patients, and came with the introduction of prophylactic treatment. While the possibility of allowing those with blood clotting disorders to gain an increased level of protection in advance of activity, and so live a more robust and active physical life, that is an argument, at best, about *quality* of life, rather than the *preservation of life itself.* The Inquiry has already heard plenty of evidence from haemophiliacs that they were well aware of the limitations of their condition, and of what they could and could not safely do without provoking bleeds. Many who were mild or moderate have described in the written and oral evidence leading lives of considerable activity in any event.

81. Haemophiliacs do not bleed to death from paper cuts – in other words it was not necessary to protect them from every single incident of bleeding. The Chair has heard considerable evidence that the vast majority of factor concentrate treatments were given for non-life threatening situations.

82. Regardless of severity, not all haemophiliacs require the same type and extent of treatment.

83. There is no substantial evidence for the proposition that cerebral haemorrhage was a real risk and shortened life expectancy *in the absence of concentrates* across the board for all haemophiliacs. On the contrary, the Chair has received evidence that the main step-change in life expectancy came from the introduction of cryoprecipitate treatment, and that only marginal gains may have been made through factor concentrates. The Chair will recall

CTI's discussion of papers on life expectancy in the oral hearings[22]. The data as to significant reduction in life expectancy are old, and apply only to severe haemophiliacs.

84. We suggest that the evidence establishes that no sufficient distinctions were made between severe / moderate / mild haemophiliacs, and whether the bleeding episode itself was serious or mild. A carefully calibrated approach to treatment, bearing the precautionary principle firmly in mind, ought to have been adopted. Life expectancy risk were *not* such that a blanket approach of concentrates for everyone, for every kind of bleeding incident, and on a prophylactic basis, was ever appropriate.

85. We note that the 14.12.84 UKHCDO paper recommends cryoprecipitate for "virgin" patients or children, without specifying severity of their haemophilia (in adults) or whether there had been previous exposure (in children). We suggest that this supports our contention that life expectancy risks were not on true analysis considered such as to mandate concentrates for severe haemophiliacs

(ii) It was not desirable to use a different treatment and patients did not want to

86. Dr Tedder's evidence that it was always policy at the Middlesex in the late 70s and early 1980s not to give concentrate unless one absolutely had to, and of maintaining patients on cryoprecipitate.

87. Professor Preston approached matters in the same way in Sheffield. The Chair has already commented in the course of evidence on the difference this approach made to the nature and level of infection in his patients, and we revert to that in the next chapter.

88. We offer these as merely two illustrations of the proposition we invite the Chair to agree with, that a body of reputable clinicians correctly concluded that it was desirable not to move to wholesale use of concentrates but instead to retain cryoprecipitate as the main treatment choice.

89. We refer also to the position taken in Finland, where the decision was taken not to use Factor concentrates until they were virally inactivated, specifically due to the risk of Hepatitis. They stated: "*the large-pool preparation was not introduced to clinical use because of the increased risk of viral infection, i.e. hepatitis.*" [23] Unlike the UK, most haemophiliacs in Finland were maintained on cryoprecipitate throughout the 1970s and 80s until heated products were available. And the majority of those patients had severe haemophilia. The result was that only 2 haemophiliacs became HIV positive in Finland [RLIT0000469], and only about half were infected with Hepatitis C [PRSE0004403]. Accordingly we invite the Chair to consider that:

[22] See WITN3289047_0001, WITN3289052 and PRSE0001620_0001
[23] RLIT0000469

(a) Cryoprecipitate was suitable for use in people with all severities of haemophilia, in particular, severe haemophilia. There is no evidence from Finland that it was only suitable for use in mild or moderate haemophilia, quite the opposite.
(b) It would have been reasonable and safe not to introduce FVIII in the 1970s, specifically due to the risk of Hepatitis.
(c) There is no evidence from Finland to suggest that people with haemophilia were infected and died as a result of being given cryoprecipitate.
(d) There is no evidence from Finland to suggest widespread development of inhibitors or severe reactions as a result of cryoprecipitate being the treatment of choice.
(e) While relying on cryoprecipitate as the primary treatment, Finland was self-sufficient in blood and blood products.
(f) The UK would have been equally self-sufficient in such circumstances.

It is submitted that the Finnish approach was the only sensible approach until a method of stabilising FVIII against heat or other viral inactivation method had been found.

90. Both clinicians[24] and politicians[25] used patient demand as part of their retrospective justification for continuing with concentrates and not reverting to cryoprecipitate. As we invite the Chair to conclude in Chapter 2, patients themselves knew about their haemophilia and its limitations and the risks arising from it, but were utterly unaware of the risks arising from concentrates. Any 'clamour' from patients for concentrate treatment over cryoprecipitate was rooted in a total lack of understanding of their respective risks. Had risks been properly explained, and patients been given proper choice, we invite the Chair to consider that there would not have been the same (or perhaps any) level of demand for concentrates save in the most extreme and truly life-threatening circumstances. That is borne out by the answers given by many of the infected and affected to questions from CTI.

91. The consistent evidence heard by the Inquiry is that patients had been told by clinicians that this was a wonder drug and had not been told of potential side-effects or viral risks. Had they been so told, there would not have been the demand. They *might* have consented for the gravest, life-and-death scenarios, but not otherwise. In other words, demand would have been, at a minimum, substantially reduced. Or, it is possible that if patients had been properly told of risk, there would have been demand for small-pool UK-produced concentrates (and expressly not for US large-pool concentrates) which would then have led to increased UK manufacture of safe concentrates.

92. In this context, we note the 11th meeting of UKHCDs (30.11.80)[26] at which there was discussion of offering prizes to those entering trials of prophylactic concentrate therapy (suggesting that there was certainly no such pent-up demand or enthusiasm then) and noting

[24] See the evidence of Drs Lee and Mayne, for example
[25] See the evidence of Lord Clarke at transcript 27.7.21 pp186-7 at 13-15 and p.184 at 20-24

[26] PRSE0003946

that the amount of concentrate used for home therapy was same in 1979 as in 1978 (but with an increase in cryoprecipitate for home therapy between the same years). That suggests that what has been described as patient-led demand for concentrates was in fact at least partly nurtured by the pharmaceutical companies and the clinicians. We refer also to the submissions in our chapter on Treloars relating to incentives from pharmaceutical companies.

(iii) Cryoprecipitate was too old-fashioned, cumbersome and fraught with problems

93. The Inquiry heard evidence to this effect from a number of clinicians.

94. But we suggest that is a self-exculpatory narrative which has grown up in the last c.40 years as part of the defence of using concentrates, and that it is simply wrong. They invent and over-exaggerate disadvantages of cryoprecipitate.

95. That is at least in part countered by evidence from others (such as Tedder and Preston, referred to above).

96. And on the contrary, cryoprecipitate was effective, easily made and produced few, if any, serious side-effects.

97. It could and should have been used throughout not only for mild and moderate haemophiliacs and children (to whom the guidance in 1983 was directed) but also for severe haemophiliacs as it had been done for the years before concentrates.

98. We refer to a number of published papers from 1967 to 1970 which establish that cryoprecipitate was widely considered to be effective.

    (a) It was a new treatment devised by Pool et al in the 1960s. Advantages were initially described as small volume, immunological inactivity, ease of production and low cost.[27] It was also described as stable, with no side effects, inexpensive and offering "First rate quality, outstanding simplicity of preparation and blood bank economy."[28]

    (b) It was easily produced (required only a lab technician in a hospital with a centrifuge) *"requiring neither costly apparatus nor special technical skills"*[29]

[27] RLIT0000679
[28] RLIT0000680_0010
[29] RLIT0000681_0006

(c) BMJ April 1967: *"... extremely valuable therapeutic material for the treatment of haemophilia, particularly ... in young patients ... from many points of view it is the therapeutic material of choice"*[30]

(d) It could be used very effectively at home and prophylactically[31] even for a 19-year old with severe haemophilia

(e) BMJ December 1967: *"... it has further been possible to teach him to administer his own cryoprecipitate intravenously, and from the intermittent administration of a relatively small dose on alternate days it would appear that the course of his disease has been reduced from one causing major to one causing minimal incapacity"* [32] [NB this was a 21 year old with <1% clotting factor]

(f) It did <u>not</u> give rise to problems of circulatory overdose for children and babies (which plasma had done) as small volumes were needed[33]

(g) In most cases a single dose was sufficient to alleviate symptoms and allow early movement and mobilisation of the affected joint[34]

(h) There were no or almost no allergic side-effects (and such as there were, were easily controlled)[35] Bloom (1967) said that side effects were uncommon and there were no instances on serum hepatitis or inhibitor development in his study.[36] A Californian paper of 1970 also referred to lower costs, decidedly lower risk of hepatitis and to in most cases one infusion being enough to end the episode.[37]

(i) It enabled complex operations (including surgery for cerebral haematoma) to be carried out successfully and gave rise to much-improved survival rates, such that *"A timid approach to surgery in the haemophiliac patient is no longer justified"*[38] Was also reported as enabling an operation for a ruptured spleen[39] (*adequate plasma levels ... were easily obtained*) with a comment about changed mortality rates for surgery.

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[30] RLIT0000682_0004
[31] RLIT0001854
[32] RLIT0000684
[33] RLIT0000682_0003 and RLIT0001514_0010
[34] RLIT0000682_0003
[35] RLIT0000682_0003
[36] RLIT0001514_0011
[37] RLIT0001850_0001
[38] RLIT0001513
[39] RLIT0001852

(j) It was considered even then (in the late 1960s) to be safer than pooled products. A US paper by Cooke et al[40] identified it as being as effective as commercially available concentrates, able to be prepared easily and economically and contrasted its risk with commercial concentrates made from pools of 500 to 1,000 units which *"appear to be heavily contaminated with the virus of serum hepatitis"*[41]

(k) It was regarded by clinicians as "highly satisfactory" and "effective." It was described by Professor Bloom in 1967 as *"an established and effective therapeutic material"*[42] and *"a major advance in the treatment of haemophilia"* and he considered that variation in potency could be overcome by selection of high-level donors[43] Later (p_0011) he said it successfully controlled bleeding in all but one of the 28 episodes considered in his paper – which included severe haemophiliacs.

(l) By 1969 Bloom regarded it as an established therapeutic material, the effectiveness and ease of administration of which had led to such increasing demand that he was examining various production techniques to determine which were simplest and most convenient.[44]

99. We refer again in this context to the fact that it was used in Finland to the exclusion of concentrates.

(iv) We could not revert to cryoprecipitate

100. Some practical arguments have been advanced as (we say) retrospective attempts to justify the continued use of concentrates. One was whether it would have been possible to have made sufficient cryoprecipitate to meet anticipated need. However on this point, Dr Walford accepted in her oral evidence (20.7.21, transcript, p.59) that *"I think making more cryoprecipitate for the treatment of mild haemophilia is a perfectly valid concept."*

101. She went on to suggest that this would reduce the volume of plasma going to BPL – i.e. there would have been decisions of balance to be made – but she accepted that an approach of maintaining concentrate production and not switching back to cryoprecipitate had to be balanced against the risks of viral dangers.

102. There is no evidence to suggest that there would have been a national cryoprecipitate supply issue (in the way that there was with FVIII). This is because:

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[40] RLIT0001851_0001
[41] RLIT0001851_0008
[42] RLIT0001514
[43] RLIT0001514_0009
[44] RLIT0001853_0001

(a) Cryoprecipitate could have continued to be efficiently produced at RTC's around the UK.
(b) Cryoprecipitate was cheaper and simpler to make than FVIII.
(c) There is no evidence of national cryoprecipitate supply issues in the UK prior to the advent of FVIII.
(d) ARCH0002566 records, even in 1983 with FVIII as the predominant treatment (and therefore draining the available plasma supply) that Dr Chisholm could get *"unlimited supplies"* of cryoprecipitate.

103. On a lighter note (and dealing with the practical argument made by those who suggest it would have been unworkable to have home treatment), domestic freezers were so popular by the mid to late 1970s that Delia Smith wrote in the Evening Standard in 1977 of there being a "deep-freeze culture". This should not have been regarded as an obstacle to home treatment, as they could have been provided by hospitals or social services if necessary.

Lie 3 – that patients themselves were aware of, and chose to run, the risks of concentrates

104. We have referred above to the suggestion by Lord Clark and others that patients were aware of the risks of concentrates.[45] As we set out elsewhere, patients and their parents had insufficient knowledge of the science and medicine behind commercial pool blood products properly to understand the risks for themselves. The clinicians failed to point them out (see our section on consent, under the previous Chapter). There is in any event a significant gap between on the one hand even partial knowledge of product risk and, on the other, full and informed consent to the administration of one treatment as against another, or to the use of one treatment as against none.

Lie 4 – that there was no conclusive proof of the link between blood / products and HIV infection

105. We deal with this also in chapter 4 below. Aware that the Chair does not invite detailed repetition of evidence, we simply remind him of the evidence of Dr Walford on the issue of how and why the "line to take" of "no conclusive" proof was maintained for so long, in such a misleading way.

[45] See the evidence of Lord Clarke at transcript 27.7.21 pp186-7 at 13-15 and p.184 at 20-24

Lie 5 – that the risks of viruses in concentrate weren't known

106. The Chair will have the evidence on this very clearly in mind, and we deal with the issue in detail elsewhere in these submissions, but identify it here as a myth to be specifically dispelled.

107. In the now-discredited 2006 DoH report on self-sufficiency, the myth that *'the prevailing medical opinion in the 1970s and the early 1980s was that NANB was mild and often asymptomatic'* was repeated.

108. One obvious example to dispel this is in the evidence of Dr Walford[46]:

> *"I must emphasise that 90 per cent of all post transfusion (and blood product infusion) hepatitis in the USA and elsewhere is caused by non-A, non-B hepatitis viruses which (unlike hepatitis B) cannot, at present, be detected by testing donor blood.* ***This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage****..."* (our emphasis)

109. Put simply, it was known since at least the 1940s that there were hepatic viruses in blood and therefore inevitably in pooled blood products. It was known then that serum hepatitis could be fatal. When HAV and HBV had been identified, it was still known that another form of hepatitis remained. There was no reason at all to consider that it would be any less severe in the long-term than HAV or HBV would be, if unchecked. As such, it ought to have been considered at all material times that it could have serious and long-term consequences. It did not become any more potent when named HCV rather than NANB – it ought always have been understood to be a disease with serious and long-term consequences.

Lie 6 - that heat treatment or other methods of viral inactivation were achieved as quickly as possible

110. The Chair will have the evidence on this in mind, but we deal with the issue in detail elsewhere in these submissions. Again, we identify it here as a myth to be specifically dispelled.

[46] Transcript 19.7.21 p.111 referring to Minute to Mr Harley of 15.9.80

Lie 7 – that there would be insufficient blood donors

111. We see this myth turned into an assertion at several different stages. Perhaps most prominently when considering restricting the groups of those who could donate when surrogate screening was being considered for HCV. When asked about it in the context of more donors being needed if the UK was to pursue self-sufficiency, Lord Owen considered that sufficient voluntary donors would step up. The Inquiry has not so far as we are aware received any convincing evidence than anyone ever formed a considered view (whether based on surveys or otherwise) that donor numbers would drop to an unsustainable level or that fresh donors would not altruistically volunteer.

Lie 8 – it has not been possible to offer compensation because legal liability has not been admitted

112. It has been repeatedly suggested that the UK could not implement a compensation scheme such as that in the Republic of Ireland, because there they admitted liability first, then set up the scheme.

113. That is simply incorrect, as the evidence of Brian O'Mahoney establishes. There was no admission of liability before the Haemophiliac HIV Trust was set up, and it was done before the Lyndsay Inquiry. Even without admission of legal liability, then, the Irish scheme was able to provide full and comprehensive compensation on the basis that *inter alia*:

(a) "Dependents" includes parents.
(b) Loss of medical records is no impediment to receiving an award.
(c) There was an option for provisional damages (replicating common law).
(d) The Tribunal approached it as if an assessment of damages and paid for legal representation for applicants.
(e) There was a right of appeal to High Court.

114. In other words a full and complete compensation scheme was set up without admission of liability.

Lie 9 – that haemophiliacs were fully compensated by the settlement of the HIV litigation and the funding of the MFT

115. Not by the settlement - see the evidence of Justin Fenwick KC and Mark Mildred. What was paid was no more than a proportion of that which was claimed, and in any event no-one approached the figures assuming that the claimants would live very long.

116. Nor by the funding of the MFT – see the evidence of David Mellor who said that he never thought the initial £10m given to the Macfarlane Trust (MFT) in 1988 would be

enough, he said. While DoH officials may have told the MFT informally not to hold back on distributing grants as more money would come, this was not officially recorded and appears never to have been acted on – see our submissions above about how the MFT went about its work.

117. Further, David Mellor criticised what he described as 'shoddy' legal advice he received as health minister in 1989 that the DoH did not have a duty of care towards those infected with HIV through contaminated blood products. He said this was a 'Pontius Pilate defence' and felt 'proper compensation' should be paid.

Lie 10 – that no-fault compensation could not have been paid for fear of setting a precedent

118. Again, we deal with this elsewhere under the Chapters on government and on the litigation, but this is patently untrue. Lord Waldegrave makes the point that dealing sympathetically and properly with the haemophiliacs' truly exceptional and unique case would in fact have strengthened the government position, rather than destroyed the integrity of its stance, towards other group claims.

Lie 11 – support for the "affected" and "bereaved"

119. In recent years, the government has consistently stated to parliament and to the press that they are supporting those "affected" and "bereaved". Whenever there have been uplifts or so-called parity to the support schemes, this untrue language has been used, disguising the sad reality. We know that most both bereaved families (as a collective) and most of those affected (individually) have not been receiving support. Therefore, we submit that these statements (below) were and are misleading, designed to give a public perception that the government was supporting all those affected or bereaved, all while keeping costs to a minimum. Further, it is submitted that publicly stating this was the case, while it wasn't, further added to the distress of those affected and families not being supported. In effect, they were being told that they were not affected. Bad enough as it was that many of those who died were not being recognised, the government portrayed that they were.

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Chapter 4 - Ministers, civil servants and government

Introduction

120. The primary duty of government is to protect the population of the state. This is both a legal and moral duty, as government witnesses attested to and as set out in Chapter 1. Lord Norman Fowler, a former Secretary of State for Health, was asked:

> *Q. Now, you've explained how as Secretary of State you were accountable to Parliament for what happened in the NHS. More broadly, would you accept that the Department and, therefore, you as Secretary of State, had a responsibility to ensure, as much as possible, that treatment given through the National Health Service was safe?*
> *A. Yes.*[47]

He also said:

> *I am the Secretary of State and I am responsible for the whole department, and that is as simple as that. And if things go wrong, then I should be blamed for that, or I should take the responsibility for that, rather than personal responsibility, but I should take the political responsibility.*[48]

121. Ensuring safe treatment involves making good, transparent decisions in order to promote patients' health, as defined by the World Health Organisation Constitution. Governments of the time did not do that; they made things worse for patients already unwell from natural causes. Andy Burnham, in his oral evidence, said:

> '*The Department of Health and the bodies for which it is responsible have been grossly negligent of the safety of the haemophilia community in this country.*'[49]

Similarly, Jeremy Hunt was asked by CTI about whether he agreed with Theresa May's view:

> *Q: She described it, as I recall, as "an appalling tragedy which should simply have never happened"; would you agree with that?*
> *A: Yes.*
> *Q: She described thousands of patients being failed. Would you agree with that?*
> *A: Yes.*
> *[...]*
> *Q: She said they had been "denied answers for too long"?*
> *A: Yes*

[47] Tuesday 21 September 2022 - Lord Norman Fowler page 27 lines 18-25
[48] Tuesday 21 September 2022 - Lord Norman Fowler page 12 lines 2-10

> *Q: And that they should "finally get the answers and justice they have spent decades waiting for"?*
> *A: Yes.*[50]

122. As this exchange suggests, the secondary duty of government where things go wrong is to be candid about its failings and then to make amends. Government witnesses to this inquiry unequivocally confirmed this.[51] Andy Burnham said government must 'tell the truth at the first opportunity'.[52] However, having failed to discharge its primary duty, the government did not fulfil its secondary duty either. The truth had to be squeezed out of government by campaigners through litigation and public inquiries. Jeremy Hunt said in his oral evidence:

> *I am afraid that institutions and the State close ranks around a lie, sometimes, and I think that's what has happened in this case.*[53]

123. Why did this happen? One theme that bears emphasising at the outset is that of finance, which runs throughout. Mr Burnham identified the 'fear of financial exposure'[54] as the dominant concern in government reactions to the contaminated blood scandal. He said ministers were 'pressurised against helping people in a desperate situation'.[55] This, rather than the duty to protect its people, motivated the government's response.

> *'I think the real reason why the Department of Health's position was against a public inquiry was because they thought that the costs of any compensation that was decided by a public inquiry would have to be met from the NHS's budget and that was the heart of it.'*[56]

(Thompsons Solicitors propose that compensation costs are not met from the frontline budget[57] – a view we endorse.)

124. This Inquiry has steadily built up a picture of what successive governments knew about the risks they were taking in importing blood products, not requiring them to be heat-treated (again, for financial reasons – untreated products were cheaper) and then evading accountability.

125. As set out in the chapter on the *HIV Haemophilia Litigation*, the government took on the attitude of a defendant asserting that it had done nothing wrong. Its defensiveness was wrong, morally and tactically, and led to a culture that has persisted for the past 40

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[50] Wednesday 27th July 2022- Jeremy Hunt, Page 145
[51] Thursday 14th July - Alan Milburn, pg 202 lines 2-17; Jeremy Hunt,, page 23-25 lines 14-1; Friday 23 September 2022 - Baroness Dawn Primarolo, page 29 lines 3- 16
[52] Friday 15th July 2022 - Andy Burnham page 145 line 10
[53] Wednesday 27th July 2022 - Jeremy Hunt 45- 46 Para 14- 4
[54] Friday 15th July 2022 Andy Burnham Page 28 Line 4
[55] Friday 15th July 2022 - Andy Burnham page 108 lines 13-14
[56] Wednesday 27th July 2022 - Jeremy Hunt Page 127 Para 2- 18
[57] Thompsons' interim submissions, recommendation 8.

years. Even the serving politicians of the day could see that defensiveness would backfire, morally and strategically. In the context of discussing the *HIV Haemophilia Litigation*, David Mellor stated, in his evidence:

> '*[W]hat I always felt right from the beginning, and I think I minuted this quite a lot of months before, is it doesn't matter what happened with the court case, the pressure to do something would continue to mount because the court case was irrelevant to what the public would feel about it. And I just think it was the right thing to do, you know.*'[58]

126. Although the litigation did eventually settle, it took an unusual intervention from the judge (Ognall J), settlement proposals without the claimants knowledge and somewhat less confident legal advice given to the defendants before the Health Secretary and Prime Minister contemplated compromising the claim. When asked about the litigation, William Waldegrave said: 'the crucial information for me was that the Department's lawyers thought we would win the case.'[59] That misses the crucial point.

127. Defensiveness is not what you would hope for in a liberal democracy with a doctrine of ministerial responsibility. The Health Secretary is ultimately responsible to the Prime Minister and to Parliament for the acts and omissions of their department. As Lord Kenneth Clarke said:

> "*In the end the buck stops with you, you're not only the head of everything, you're the last resort, you are the person overall responsible.*"[60]

128. It was not only the community of the infected and affected who were misled, Parliament too was misled on a number of occasions. These include:
    a. in 1983, when Kenneth Clarke said that there was 'no conclusive proof' that AIDS was transmitted by blood products. His contemporaries in government now accept that this was misleading. As Dame Diana Johnson MP asked in 2017:

Was my right hon. Friend shocked, as I was, to learn that in November 1983, the then Health Secretary told Parliament:

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[58] Thursday 19th May 2022 - David Mellor page 165, lines 4 to 11. See also page 166, lines 16 to 23 (noting that even someone who thought that there had been no wrongdoing nevertheless thought responsibility ought to have been accepted for what he termed 'terrible consequences'). As will be clear from the foregoing, we submit that there was wrongdoing.

[59] Tuesday 5th July 2022 - Lord William Waldegrave, pg 40 lines 13-19. He also suggests that the plaintiffs were made to litigate because the government feared that concessions to them would be a slippery slope that led to no-fault compensation. This does not allay Core Participants' suspicion that the plaintiffs were being used merely as pawns in a much larger game. See similarly the second statement of Lord Philip Hunt, paragraph 2.71-2.72.

[60] Tuesday 27 July 2021 - Lord Kenneth Clarke, pg 211 para 2-22. See similarly Matt Hancock, page 98- 96 lines 23- 13; Tuesday 21st September 2022 - Lord Norman Fowler, page 10 line 13– 21.

There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products"?—[Official Report, 14 November 1983; Vol. 48, c. 328W.]

Only months earlier, however, the Department had been preparing a document that stated that AIDS was almost certainly transmitted in such a way, and the Advisory Committee on Dangerous Pathogens had also told of strong circumstantial evidence that the disease was blood-borne. It seems as though there were real issues about what people and Parliament were being told. Ministers must never mislead Parliament, yet clearly the information that was being given to Parliament at the time was not correct.[61]

b. in 2009, when Parliament was misled as to the reasons why the government did not implement recommendation 6(h) of the Archer Inquiry report. Gillian Merron MP told Parliament on 1 July 2009 that the Republic of Ireland paid compensation because it had been found to be at fault, when this was not factually accurate. However, this was the reason proffered by the government to distinguish their position from that of the Irish government. Campaigners brought a judicial review, in which Holman J confirmed the truth.[62] The witness statement of Deborah Mary Webb demonstrates that officials were aware of the true position before the Minister made her statement.[63] However, the information does not appear to have been passed to the Minister before or after the debate. It is submitted that recommendation 6(h) was not implemented because, as Mr Burnham said, it involved expenditure.

c. ten separate occasions between 2016 to 2018, which are identified in two letters from Chris Wormald, Permanent Secretary to the DHSC in 2019.[64] The erroneous statements relate to the assertion in Parliament, in answer to a question triggered by the Penrose Inquiry, that 'all documents up to 1995 are available through the National Archives'. Mr Wormald apologises to two former Ministers because the real position was that only those files *previously deemed relevant* were available. The non-availability of documents and medical records will be discussed further below.

d. and numerous other occasions identified and corrected by campaigners.

129. The government's defensiveness was not just outward-facing. This was not a government that was self-scrutinising. There was a culture of self-justification within the Civil Service. When criticised, internal reviews were self-exculpatory.[65]

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[61] HC Deb, 25 April 2017, c1076.

[62] DHSC0003819_011 at page 12, paragraphs 44 to 45.

[63] Written Statement of Deborah Webb Paragraphs WITN7409001 and 27th May email

[64] WITN1210027. The background to this, and its coming to light, is described in the third witness statement of Jason Jonathan Evans, WITN1210008, paragraphs 51 to 56.

[65] WITN7305001, paragraphs 2.5 and 3.7. The same point can be made about the 'self -sufficiency chronology'.

130. Furthermore, this was not a government that learned from its mistakes. As one former Prime Minister said, government is like an enormous tanker that takes a long time and a lot of effort to turn around.[66] However, accepting the truth of that statement, this was not a government that was receptive even to the checks and balances that the judicial process represents. A later section of this chapter traces the continuing nature of that intractability as it affects the present government's response to Sir Robert Francis's compensation framework.

131. The government's defensiveness and lack of candour was extensive – it covered many issues over many decades. We draw attention to three themes which emerge from the evidence of politicians and officials. We believe these three features contributed significantly to the actions of government that we criticise. They indicate structural problems as well as unhelpful attitudes of individuals. The three features are: **ignorance**, **arrogance** and **dependence** on civil servants. These are by no means the sole causes of government failings, but they are sufficiently persistent and pernicious to be worth dwelling upon. Each of these three are dealt with in turn below. It is worth noting at the start, however, that they are also interconnected: ignorance led to greater dependence on briefings, and arrogance gave no cause to question one's own ignorance. Arrogance may also have been born of ignorance.

Ignorance

132. A number of factors combined to ensure that information was siloed within the hierarchy of government, so that its absence went unnoticed. In turn, this meant that avoidable and unjustifiable delays occurred without accountability, and that egregious decisions were not brought to light.

133. Among the factors that contributed to the general ignorance of government were:

    a. blood policy was merely one area of a large portfolio of responsibilities.[67] This was often (inappropriately) delegated to junior ministers in the House of Commons and/or the Lords minister (whose portfolio spanned the entire range of the DH).[68]
    b. blood policy was not seen as a priority, and was submerged in importance under whatever happened to be the crisis of the day. The evidence of witnesses does not give the impression that anyone felt a strong sense of ownership or responsibility for blood policy decisions – indeed, some witnesses disowned responsibility or blamed others.
    c. there was a high turnover of ministers, so that the pinnacle of the establishment

[66] Monday 27th June 2022 - Sir John Major, page 39, lines 12-13.
[67] Tuesday 21st September 2021 - Lord Norman Fowler, page 17 lines 18-22.
[68] Tuesday 21st September 2021 - Lord Norman Fowler, page 10 line 13 – 21.

effectively had neither experience nor specialist knowledge to draw on. No steps were taken to ameliorate this – for example thorough and accurate briefings upon taking up office.

d. there was deference to the medical part of the dual hierarchy in the Civil Service and/or advisory bodies to government, such that even those with formal responsibility for blood/products assumed somebody else was taking care of it and/or did not challenge the views they were presented with.
e. consequently, there was a great deal of dependence on officials and little scrutiny of their submissions. This point is developed further below, under the heading 'dependence'.
f. exacerbating the dependence was a paucity of input from other sources, such as the voices of constituents or patients (in the case of Lords ministers, who were unelected). Many ministers and officials received information about patients' concerns secondhand,[69] from representations by bodies such as the Haemophilia Society and the trustees of the Alliance House schemes – neither of which has a good track record of acting in patients' interests.
g. ministers had to deal with voluminous paperwork. This is clearly a systemic issue, but the action taken in response to it contributed to ministers' ignorance. The point is not so much that there was inappropriate delegation – as stated at (a) above, in relation to blood policy – there was no real policy of delegation at all. Just the reverse: officials had an unstructured discretion to refer things upwards. This resulted in gaps, lags, and misleading information to ministers.

134. Each of these issues (a) – (g) is developed below, by reference to evidence.

135. The first notable incident of institutional amnesia, for our purposes, occurred with the failure to achieve self-sufficiency. A separate chapter covers the failure to achieve self-sufficiency in depth. It suffices to note in this chapter that the aim of self-sufficiency was announced by Lord David Owen in 1975, but subsequent administrations did not achieve it, all the while proclaiming *de novo* that their government intended to pursue it. As Lord Norman Fowler said, in his evidence:

> *"If David Owen's advice had been taken and we'd gone for self-sufficiency as a nation, then much of the ensuing tragedy, probably not all of it, but much of it, could have been avoided. The advice, you know, broadly speaking, wasn't taken. I mean, had it been taken in 1975, 1976, then the outcome would have been very different indeed."*[70]
> *"I am tempted to say that the idea that -- the principle of self-sufficiency in blood and blood products promulgated by the WHO hasn't been endorsed by successive governments. Well, it might have been endorsed but -- the principle might have been endorsed but, actually, it needed a bit of action on the principle. We needed to take action and we needed to start building. That didn't happen until -- I got there in 1981,*

[69] See e.g. WITN4680008, second statement of Lord Philip Hunt, paragraph 2.8.
[70] Tuesday 21st September 2021 - Lord Norman Fowler page 72 lines 6-17.

it didn't start happening until the following year, in '82. I mean, you know, it was a lengthy process... Too long."[71]

Ten years later, after a change of government, Lord Kenneth Clarke responded to a Parliamentary Question with the words, 'We decided in 1982 that this country should become self-sufficient in blood products.' This statement was ahistorical and misleading.

Self-sufficiency was not achieved by Lord Owen or Lord Clarke's governments. This failure was passed over in silence.

In 2002, Lord Morris said in Parliament:

"Self-sufficiency was not achieved as planned but this was not reported to Parliament, although failure to achieve it meant continued reliance on less safe imports. One is entitled to ask how many people with haemophilia could have been saved from life-threatening viral infection had the policy announced in Parliament been duly implemented. In a letter sent to me on 12th November last, the noble Lord, Lord Hunt, admitted that failure to inform Parliament of this important change of policy in regard to self-sufficiency was never considered by his department's in-house inquiry..."[72]

Above we have highlighted some instances of Parliament being misled through explicit statements. Here, Lord Morris explains how silence on a policy could be equally misleading. This is compounded by the Department's failure to learn lessons in its in-house inquiry.

136. However, the failure to achieve self-sufficiency was only the first in a litany of failures – some larger and some smaller. These instances of nonfeasance and malfeasance are summarised in the conclusion hereto. Turning more generally to the themes that contributed to ignorance of government, the first is that blood policy was dealt with by junior ministers amidst a large portfolio.

137. Caroline Flint's evidence on this is representative.[73] Ms Flint was Parliamentary Under-Secretary of State for Public Health between May 2005 and May 2006, then Minister of State for Public Health from May 2006 to June 2007. She said:

"When you are entering a department, obviously you have got to get up to speed. It can be a completely different portfolio to one you have had before, it may not be something in terms of your own personal work experience that you have any particular knowledge or experience of, so there is then a huge amount of absorbing information, taking on decisions that have been made before but also activities that have been made

[71] Tuesday 21st September 2021 - Lord Norman Fowler page 85 lines 3-15.
[72] Commons Hansard: Hepatitis C. Col. 766, Lord Morris o f Manchester. 12 March 2002.
[73] See similarly Tuesday 21 September 2021 - Lord Norman Fowler page 3 lines 10-15; and page 3-4 lines 23-5.

before. So I do think that the churn of ministers in government from one department to another is not helpful.
Q. And this was your first role in the Health Department. Do you know how you came to be chosen for the role?
A. No.
Q. Did you have any background or context in relation to the Health Department that was seen as particularly of assistance?
A. No.
Q. You have said in your statement that your portfolio as Parliamentary Under-Secretary was the same or very similar to when you were Minister of State. Can you tell us broadly what was within your portfolio?
A. So I covered the public health portfolio, and that would include all those issues around smoking, alcohol, diet, exercise, health inequalities, and so the full range of those areas. I also dealt with drugs and alcohol in terms of addictions. That was something that I covered when I was at the Home Office, so it was one of the areas that I had some experience of before and continued to work with the Home Office on that issue. I also covered contraceptives, fertility, the Health Protection Agency, and a whole number of other things that I put in my statement. And bodies that I worked with as well, external bodies too. And of course in relation to the proceedings today, I also covered blood donor services but also the issues around the Alliance Health Organisations and those who were infected by blood products and their families who were affected by it.
Q. When you started the role in the Department of Health, what sort of briefing did you receive?
A. I can't remember exactly but the usual thing was that you would have a series of different department heads and members of staff coming to see you, giving you maybe a written note but also some oral briefing, and usually it would be a heads up, really, about the areas of policy. As soon as you start in a department you actually have to start work. ... But there's not a structured programme per se in terms of what you do."[74]

Ms Flint is blunt about her lack of knowledge and experience. She describes how she hit the ground running with no structured programme of induction or briefing to ameliorate her inexperience. (A number of Inquiry witnesses, including Alan Milburn[75] and Hazel Blears,[76] have proposed more thorough training and briefings as a remedy.)

138. Frequent turnover not only bred ignorance but also limited effectiveness. Lord Horam explained how a minimum period of time in office was required to make policy and see it through.

> *"Q: There was quite a significant turnover of junior ministers in the Department of Health. Was that something which, looking at it now, you think an advantage or a disadvantage?*

[74] Friday 16th September 2022 - Caroline Flint, page 6 line 20 to page 9 line 8.
[75] Thursday 14th July 2022 - Alan Milburn, pages 205-206 lines 15-1.
[76] Thursday 21st July 2022 - Lord John Reid and Hazel Blears page 142 line 7 to page 147 line 7.

A. A disadvantage. Definitely a disadvantage. I mean, my own feeling, after looking back with hindsight, is that you need about 18 months to really get into the feeling of a department, what the issues are, to get -- to hit your stride, as it were. After that you can be productive. I think that a minimum -- really a minimum should be three years in a department before you can actually make any effect on policy and so forth. And I only had 17 months."[77]

139. In the absence of having a confident grasp on issues, there was a great deal of reliance on briefings and deference to the medical branch of the civil service. The medical branch itself relied heavily on advisory committees, such as the Advisory Committee on the Virological Safety of Blood, which were not sufficiently independent from government to give robust advice. There was an elision of roles, a far cry from the ideal professed by some witnesses that 'advisers advise and ministers decide.' The views of such committees were presented as consensuses, further muting the possibility of challenge.[78] Lord Waldegrave's evidence exemplifies a typical attitude to the Chief Medical Officer:

Q. As a matter of fact, do you recall any occasions during your time as Secretary of State for Health in which you did test or challenge the advice of the Chief Medical Officer?
A. No, I don't. I mean, I do remember the Chief Medical Officer giving me a very alarming account of how he thought HIV/AIDS was going to spread very much faster than others at that time were predicting in heterosexual communities. I would have not contradicted him on that. I think in that -- thank goodness, in that respect, he turned out not to be correct. But I wouldn't have taken upon it myself to have criticised him.[79]

140. Similarly, in his evidence Lord Kenneth Clarke defended his department's actions in relation to the risk of HIV. He said that he knew nothing of a letter from Dr Galbraith of the Public Health Laboratory Service (PHLS) to Dr Ian Field of the DHSS dated 9 May 1983 which recommended the withdrawal of US blood products.

I don't think that ever reached me, I don't think it ever reached -- apparently it didn't reach Simon [Lord Glenarthur, whose portfolio included blood products]. And it was dealt with by the Sub Committee of the Biological Whatsit, who do include extremely distinguished health experts...[80]

141. Lord Clarke blamed the medical advice the department received for the misleading phrase 'no conclusive proof'. He said:

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[77] Wednesday 29th June 2022 - Lord John Horam pg 9 lines 5-18.
[78] Many witnesses conceded that this ought not to have been so. Wednesday 6 July 2022 - Lord William Waldegrave (continued)Wednesday 6th July - Lord William Waldegrave (continued) pg 45 lines 10-15.
[79] Tuesday 5 July 2022 - Lord William WaldegraveTuesday 5th July - Lord William Waldegrave pg 30 lines 3-14;. Baroness Dawn Primarolo made similar comments in relation to other experts: page 92lines 4- 7.
[80] Tuesday 27 July 2022 - Lord Kenneth Clarke pg 214-215 lines 22-6. It is assumed Lord Clarke means the Committee on the Safety of Medicine's Biological Subcommittee.

It was the agreed presumably medical advice by the -- collectively the lot of them that we should use the phrase "there is no conclusive proof" and the ministers carried on using it until we were advised to stop using it.[81]

This is notwithstanding Lord Clarke's assertion that language is not the province of specialists and that the meaning of the phrase should be obvious to all.

Q. Do you accept, Lord Clarke -- I'm going to repeat the question because I'm not sure you've answered it -- that the line to take should have included an express recognition of the likelihood or probability that AIDS could be transmitted through blood or blood products?
A. Not really. It's perfectly bloody obvious that everybody was working on that basis. This is just a drafting argument.[82]

142. It should be noted that other witnesses accepted that the phrase should have been clarified as intending to import that there *was* a clear risk. It goes without saying that this is also our submission. Contrary to Lord Clarke's belief, the phrase is misleading and evidences lack of candour.

143. Dr Walford said about the Galbraith letter:

Q I didn't see… that the paper had been copied, when Dr Galbraith sent it, to anyone in Medicines Division. So I don't know if Medicines Division was aware but I would certainly say that that would have been the place that it should have gone and that obviously, after discussion in the CSMB, ministers should have been told what the outcome was. I haven't found any papers which suggest that they were.
Q Looking at it now, do you think that ministers should perhaps have been told what a leading public health doctor working within the Public Health Laboratory Service was saying to the Department?
A. I think it would be perfectly reasonable to have told them, yes.[83]

144. Lord Glenarthur said:

Looking back on it I think it would have been very useful to have been aware of it. But, you know, so much of this stuff was being dealt with at various levels within the Department by the experts who understood it all in great detail and, looking at this list of professors and others who were involved, they were all, you know, highly qualified in their field. … Looking back on it now, I wish I'd seen this
[…]

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[81] Wednesday 28 July 2022 - Lord Kenneth Clarke pages 30-31 lines 25-4.
[82] Wednesday 28July 2022 - Lord Kenneth Clarke, page 44 lines 6-13
[83] Wednesday 21 July 2022 – Dr Diana Walford page 2 lines 2-11. See also Friday 22 July 2021 - Lord Glenarthur, at pages 169-174. Dr Walford also describes other inefficiencies of the dual hierarchy and mode of working. See e.g. pages 13-14, lines 19 (p13) to 6 (p14);pages 27 – 28 lines 8 (p27) to 11 (p28).

Q: This was the subcommittee on biological products obviously met on a regular occasion, but this was a one-off decision, one of the most significant decisions taken in 1983 regarding blood products. That's what makes it surprising, is it not, that you were blissfully unaware, even that this process was going on?

A: Yes, I was completely unaware.

Q: I detect, I think from your statement, that having now seen it, you don't think you'd have disagreed with it but what I want to suggest to you is that that might be all the more reason for you to have seen what was being said because, if you know that the more radical step of stopping concentrates being imported is not going to be taken, because that's the view of the Committee on Safety of Medicines, you might then have wanted to consider whether there were less radical steps that could be taken to nonetheless minimise the risk and you weren't really put in a position, were you, to be able to do that?

A: No, I wasn't and I was actually always interested in the rather technical aspects, although I'm not in any sense qualified, part of my interest generally in these sorts of things. So I wasn't in a position to comment and I think another thing that surprises me in perhaps general terms, and I may have made this plain in my statement, that I'm surprised that there wasn't a point at which, you know, so many of these things were coming together and coalescing in the minds of officials. Look, at least ministers ought to be aware of some of the competing elements and the real concerns that are being raised, even if it wasn't to make a decision but to say, you ought to be aware, oh Ministers, that these are perilous times in some respects and therefore you ought to be aware of them. But that never actually happened, so far as I can recall.[84]

145. Further, Lord John Patten said, 'I find it very hard to understand why this matter [CSM approval] wasn't submitted to ministers.'[85] Lord Patten also said 'if I saw it, forgive the colourful language, I think I probably would have pressed the panic button' (p89 of Patten transcript). It is submitted that this was exactly what should and could have happened, for the 'panic button' to have been pressed.

146. These concessions beg the question as to why ministers were not aware. And indeed there have been innumerable occasions during government witnesses' evidence where ministers were ignorant of key developments. At least part of the reason must be that there was no structured policy of delegation, but rather the reverse: an expectation that officials would refer matters upward as they saw fit. Here is Lord Glenarthur's evidence on that:

[84] Thursday 22 July - Lord Simon Glenarthur pg 171-172.
[85] Friday 20 May - Lord John Patten, page 93-94, lines 8-8.

Q. You said it was utterly impracticable for ministers to be involved in the level of detail to the extent that officials were and so meant day to day aspects of policy making and implementation of policies were essentially left to officials to get on with.
A. That is broadly correct, yes. The detail involved in so many of these complex areas, and I include all of my portfolio responsibilities were such that there was a substantial team of people dealing with it day by day and if there were important decisions to make, which they needed ministerial approval for, they were brought forward. But it would simply be impractical for a minister to get to that level of detail because the portfolio was so large and the volume of information so large that it was quite difficult to cope with anyway, quite honestly, but if you had to deal with every single detail you would have spent all day doing it and probably all night as well.[86]

147. Many important decisions, such as the introduction of screening tests for HIV and HCV, fell through the cracks in this way. There was a distinct lack of ownership of blood policy as a responsibility, with some witnesses blaming other people for what should have been their own concern. Lord Clarke was asked:

> *'Q. Did you or, to your knowledge, the Department ever ask officials to investigate what other steps could possibly be taken short of the radical step of stopping the importation of concentrates?*
> *A. Well, I think we were told that was the only thing that you could do. That's why everybody had gone so big on self-sufficiency. [...] Bear in mind, I was not directly responsible anyway. I don't know whether Simon was ever taken through possible alternatives or what the doctors have said when you put the possible alternatives to them. [...] I didn't have meetings on blood products and haemophiliacs and -- it wasn't my subject.'*[87]

148. This contradicts Lord Clarke's expressed view that the Secretary of State had ultimate responsibility for the department. Lord Clarke later asserted:

> *'I mean, somewhere in the Department they must have considered whether there was some halfway house, I'd have thought. I don't know.'*[88]

149. Witnesses were asked what structures can best respond to emerging health threats. Lord Clarke said that what is needed is 'a small decision-making team and somebody [] to take clear responsibility for taking decisions, and do what they can to do things and, you know, sometimes step in and really just insist that we've got to take a decision.'[89] Lord Waldegrave likewise noted that effective policy requires a clear strategy and objective. He said: 'if you know what you want to do, you can get it done in government

[86] Thursday 22 July 2021 - Lord Simon Glenarthur pgs 19-20 lines 14-7.
[87] Tuesday 27 July 2022 - Lord Kenneth Clarke pgs 200-201 lines 13-16; see also page 41 lines 12-18 and pgs 211-212, lines 24-2. The problem is not restricted to Lord Clarke. See also: second witness statement of Deborah Mary Webb, paragraph 4.26 (officials in ROI to blame for misinformation to Parliament); Wednesday 13 July 2022 – Rowena Jecock, page 87 lines 9-18 (Lord Warner to blame for misinformation to Parliament)
[88] Tuesday 27 July 2022- Lord Kenneth Clarke page 204 lines 6-9.
[89] Thursday 29 July 2022 - Lord Kenneth Clarke , Q. pg 116 lines 14-19 , A. pg 116-117 lines 24-5.

and blaming the civil servants is a cop-out.'[90] There was never any such leadership for blood policy in government during the material period.[91] However, it is also fair to say that officials did not always brief ministers adequately (or at all) and often applied pressure to ministers. This is discussed under the heading of 'dependence' below.

150. Finally, though not exhaustively, ministers' dependence on briefings for information was exacerbated by a dearth of other sources of information. Jeremy Hunt described his practice of reading letters from patients, and the reaction it received.

> *Q: "It would seem from this that you encountered a degree of resistance from officials both to being provided with letters criticising NHS care in the first place and then to a response that included apologies or acknowledgement of fault; is that right?*
> *A: Yes, I think there is a -- there was -- I think it's changing, actually, but I think there was a very strong institutional nervousness about focusing too much the mistakes that were made in the NHS."*[92]

151. The above paragraphs have focused on structural issues that coalesced to keep ministers ignorant. In the next section of the chapter, the focus is on the uncaring attitudes of some health ministers.

Arrogance

152. Arrogance links to ignorance. Arrogance obscures one's own limitations and inhibits self-reflection about ignorance. The evidence showed that some ministers, having made errors of judgement and having no experience in their roles, nevertheless defended what they did without self-scrutiny or self-awareness.

153. Core Participants have been astonished and hurt by statements from some ministers, delivered during the course of their evidence before this Inquiry. These statements exhibited a staggering lack of understanding of the issues and a lack of empathy for the people whose democratic representatives they once purported to be. The following quotations from Lord Clarke speak for themselves:

> *Q. The Inquiry has heard evidence from both family -- families, patients, clinicians, which it might be said paint a fairly overwhelming picture, of people not having risks drawn to their attention.*
> *A. Well, they must have been fairly switched off.*[93]

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[90] Wednesday 6 July 2022 - Lord William Waldegrave (continued) pg 59 lines 11-17.
[91] See e.g. Thursday 29 July 2022 - Lord Kenneth Clarke pgs 117-118 lines 25-11.
[92] Wednesday 27 July 2022 - Jeremy Hunt page 22- 23 lines 24-7.
[93] Thursday 29 July 2022 - Lord Kenneth Clarke page 185 lines 8-12.

Well, what the difficulty was, as we've seen from our earlier discussions, that we didn't -- couldn't find any way of minimising the risks, short of stopping using American Factor VIII. What possibilities of minimising risks could we have possibly told the haemophiliacs about, apart from if they were homosexual haemophiliacs, which is I'm sure somewhere, do we, you know, try and stick to one partner?[94]

The line to take did not say "blood products don't cause AIDS", it doesn't say that at all. That would be quite wrong, inaccurate and untrue. The meaning, in my opinion, if you give the ordinary meaning of the words, "there's no conclusive proof", and if you look at the sentences round it, it is quite clear we're saying, you know, there's a strong possibility at least that it causes AIDS, and -- but there is, at the moment, no conclusive proof. We might find that -- presumably it implies haemophiliacs are acquiring it in some other way.[95]

Well, the physicians, if they were remotely keeping up to date with things, must have been aware that there was this mounting concern. So they all had specialist doctors who were treating them. They didn't just give themselves Factor VIII. I don't think, I don't know. Personally, I have to admit I don't know how you take Factor VIII. So I'm -- I apologise if you're given a pill which you take home, but they all had highly specialised physicians treating them.[96]

Q. And do we correctly understand from something you said earlier that you were not aware of a treatment called cryoprecipitate?
A. Never heard of it. Is that the treatment that preceded Factor VIII?[97]

154. Lord Clarke is not a lone egregious example. Sir John Major, in the course of asserting the government's sympathy for the suffering of the infected & affected, demonstrated his own misunderstanding of the facts:

I don't think the Government gained very much of the sort of the horror people were facing. I mean, there is no amount of compensation you can give that could actually compensate for what had happened to them. What had happened to them was incredibly bad luck, awful, and it was not something that anybody was unsympathetic to.[98]

155. Arrogance is demonstrated in other ways too. It is demonstrated by a lack of humility – many witnesses did not acknowledge that they could have done anything differently. Lots of witnesses reflected on the effect that this has on a culture of openness in government.[99] It has a chilling effect on a culture of openness. This issue is structural, and goes deeper than questionable comments or personalities. Lord Waldegrave explained:

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[94] ibid., pg 184 lines 7-14.
[95] ibid., pg 31-32 lines 23-9.
[96] ibid., pg 186-187 lines 15-13.
[97] ibid., pg 198 lines 1-5.
[98] Monday 27 June 2022 - Sir John Major, p43 lines 9-15.
[99] See e.g. Monday 27 June 2022 - Sir John Major, pg 171 lines 14-20.

> *I suppose the problem is of any adversarial system -- I don't know whether the same exists in court, but our Parliament is a high court, people say -- that if you say, "I got it wrong" the other side says, "Well you're no use then, are you? You just get things wrong". They very seldom say, "Well done, you've admitted a fault" and it's gone to the next argument. They simply say, "That fellow Waldegrave admitted he got that wrong so he's probably getting this wrong".*[100]

Lord Waldegrave acknowledged that some administrations are able to admit they are wrong and to carry the public with them.

156. Whilst Lord Waldegrave speaks of the difficulties of accepting the consequences of being humble before opposition parties and the electorate, Sir John Major explored the effect of the civil service hierarchy on a culture of openness.

> *So there was a practical case of an independent minded, high quality civil servant saying discreetly to the Government, "You may have got this wrong, it's time to move on". And this is a legitimate role. But it is something that really can only be done by civil servants close to the Prime Minister or the Minister, or very senior civil servants. They can say to ministers, and should, "You have got something wrong".*

157. Although Sir John implies civil servants must be discreet, all the government witnesses testified to the importance of openness and honesty – at least in principle. However, it appeared difficult for many to acknowledge – even with hindsight – that they might have acted differently.[101] Indeed, successive governments during the period seemed to be unable to learn lessons from the judicial process. There are a number of examples of this intransigence. Firstly, Sir John Major is keen to stress that ministers were moved by a moral case for compensation – seemingly untroubled by their unreceptiveness to arguments that the government may be legally liable for failing to implement self-sufficiency.

> *Certainly what was in the mind of the ministers who had discussed it with me, the health ministers, was the growing level of suffering. That was what was moving their minds. Their minds were not moving because they had suddenly been told by the lawyers, "Golly, the Government are liable".* [102]

158. Second, Caroline Flint readily volunteered that, had she known about the judgment in *A v National Blood Authority*, she would not have approved a press release that stated that HCV testing could not have been achieved prior to 1991. Her exchange with the Chairman was as follows:

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[100] Wednesday 6 July 2022 - Lord William Waldegrave (continued), pg 46-47 lines 18-21.
[101] See e.g. Tuesday 27 July 2022 - Lord Clarke, pg 210 lines 1-22 and pg 186 lines 6-14; Monday 27 June 2022 - Sir John Major, pg 192 lines 14-20; Thursday 14 July2022 - Alan Milburn, pg 170 lines 9-12.
[102] Monday 27 June 2022 - Sir John Major, pg 47 lines 15-20.

SIR BRIAN LANGSTAFF: -- and you didn't know about that [judgment] presumably because your officials hadn't told you?
A.I didn't know about the judgment, as far as I'm aware Sir Brian. The briefings that I've obviously looked over in preparation for both my written statement and today and the answers I gave in Parliament and elsewhere were very much sort of a 100 per cent suggesting that there was no testing that could have been done before 1991.
SIR BRIAN LANGSTAFF: If you had known of the judgment and if you had understood, as I just recounted, what it was saying, you wouldn't have written this at all, would you?
A. No, I think it would have had to be qualified in the context of what other tests were there but it was not -and, obviously, during my time in the Department, I did ask questions about different things and you are learning as you go but this was, obviously a position that, both before my time in the Department and since, was used.[103]

159. Thirdly, in terms of quasi-judicial checks and balances, the Department of Health's attitude to inquiries left much to be desired. Not only did it fail to provide witnesses to the Archer Inquiry, it appeared unprepared for the publication of the final report and subsequently failed properly to implement the Archer recommendations. The Public Health Minister at the time, Dawn Primarolo, was dissatisfied with officials' initial summary of the Archer recommendations. In an unusual example of a minister pushing back, she instructed officials to find ways to respond to the report as positively as possible. In the event, the response fell short of full acceptance of the report's recommendations. Baroness Primarolo thought it was unfair to describe officials' response as 'resistant' but rather she believed there was 'institutional inertia' built into the 'whole model' of the Civil Service.[104] In her experience, 'it can be hard to move the Civil Service away from established lines to take and a very cautious approach to setting precedents that will cause difficulties or significant expenditure.'[105] In our submission, the approach of officials such as Liz Woodeson and Rowena Jecock can fairly be termed resistant, even if (in their own minds) they believed they were acting in the public interest.

160. Moreover, governments throughout resisted calls for a public inquiry, even after the coming into force of the Inquiries Act 2005. Lord Philip Hunt says that 'there was a collective thinking across Government in relation to public inquires, and that it is that they were to be generally resisted.'[106] Lord Hunt believes there are good (general) reasons for this. However, it is submitted there was a sense of arrogance in the government's resistance too. Alan Milburn, while endorsing the need for an independent view on whether public inquiries should be held,[107] defended his

[103] Friday 16 September 2022 - Caroline Flint, page 59 line 19 to page 60 line 13.
[104] 23 September 2022 - Baroness Primarolo page 112, line 3 to 14.
[105] ibid.
[106] Second witness statement of Lord Philip Hunt, WITN4680008, para 6.6.

[107] Thursday 14 July 2022 - Alan Milburn pg 201 lines 8-10.

government's decision on the following grounds:

> *'I also think that mainly, and this is obviously a contested position, how that had happened was reasonably well understood. How it had happened was reasonably well understood. Whether it should have been allowed to have happened is a quite different question, but the how question, I think people understand exactly what happened: that people were given blood products that were infected with hepatitis C.* [108]

Despite recognising the history was contested, Alan Milburn still asserted that everything was understood.

161. A fourth example of the department considering itself to be aloof of the judicial process occurred during the HIV Haemophilia Litigation and the application for non-disclosure on grounds of public interest immunity. Having received the order of the court determining that application, officials in the department opted to continue to redact the names of physicians in the documents. The following exchange took place between CTI, Richard Gutowski and the Chairman about this decision:

> *CTI: So, first of all, is it right from these documents that there was a decision taken to continue to anonymise doctors' names, despite the order of the court?*
> *A. I can't remember a decision being taken but if you read Sue Wood's note, that there was clearly discussions that had taken place.*
> *Q. In your own memo there appears that you had that discussions with both Sol C5 and Treasury Solicitor, if we go back?*
> *A. According to that memo, yes, I did.*
> *Q. Do you have any recollection of these –*
> *A. None whatsoever.*
> *SIR BRIAN LANGSTAFF: I mean, the document itself appears to be pretty clear that's what was proposed –*
> *A. Yes.*
> *SIR BRIAN LANGSTAFF: -- that the court says "Disclose the names of the doctors", you say, in this first document we saw on the screen, "We're not going to".*
> *A. The agency clearly had made that decision. As to what -- on what basis or on what level I cannot say, I'm sorry.*
> *SIR BRIAN LANGSTAFF: You were head of the Litigation Unit or involved in the Litigation Unit?*
> *A. I was in -- I* was *the Litigation Unit.*
> *SIR BRIAN LANGSTAFF: So you were responsible for litigation and one would have hoped, perhaps, observing the order of a court?*
> *A. Yes, I take your point.*[109]

162. The third manifestation of the government's arrogance that this chapter will mention is in the dealings of the United Kingdom government and/or the English government with

[108] Thursday 14 July 2022 - Alan Milburn pg 186-187 lines 23-12.
[109] Friday 10 June 2022 - Richard Gutowski, page 16 line 12 to page 17 line 14.

its devolved counterparts. This is particularly seen around the settlement of litigation and the financial support schemes. The impression given is that the government perceived the devolved nations to be junior partners or uppity competitors for public favour. An example of this is the handling of the HIV Haemophilia Litigation settlement, about which Lord Waldegrave says:

> *While I do not recall this issue having prominence, I expect that we could have handled this better, and I include myself in that. Certainly, from the records to which the Inquiry has directed my attention, there would appear to have been little formal involvement of the Scottish and Northern Ireland Offices early in the process. I can only assume that this arose because the English cases were more advanced, and perhaps because of the fast moving nature of the liaison between the Department, the Treasury and No 10 to secure the settlement. I cannot imagine that any conscious decision would have been taken not to involve the Scottish and Northern Ireland Offices. But from the records I have been shown, perhaps we should have involved them earlier, having regard to their own litigation and the plaintiffs involved there...*[110]

163. Lord Reid commented that the contempt was mutual in some quarters:

> *You can see from the papers that there is a suspicion on the part of some officials, particularly in the Treasury, that we don't want the Scottish tail wagging, you know, the English dog, as it were. And you can also see from some of the press coverage in Scotland that when we were working in partnership with the Scottish Parliament on the hep C scheme, the Skipton Fund, that there was accusations: oh, this is a Westminster-controlled area. It was almost the mirror image.*[111]

164. Unfortunately, the bickering among elites was to the detriment of the people of the United Kingdom. The lack of cooperation among the nations meant that the PFC at Liberton was not used to its best capacity, with an impact on self-sufficiency. Furthermore, as set out in our chapter on self-sufficiency, better coordination could have resulted in faster development and roll out of heat-treated products which were being simultaneously researched at BPL and PFC.

165. The final striking emblem of the DH's arrogance was its disconnection with patients and even its contempt for them. Jeremy Hunt put it poignantly when he said:

> *That [i.e. officials dissuading him to look at patients' correspondence] was probably the biggest single thing that made me appreciate that there is a massive institutional reluctance in the NHS to listen to the stories of ordinary people when things have gone wrong. And there is a view -- which I think is changing, in all credit to the NHS, but there was certainly a very strong view that harm to patients is part of the cost of doing business. It's part of what happens.*[112]

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[110] Witness statement of Lord William Waldegrave, WITN5288001, paragraph 4.101.
[111] Thursday 21 July - Lord Reid, page 15, lines 14-23.
[112] Wednesday 27 July 2022 - Jeremy Hunt page 18- 19 lines 20-2.

166. Acceptance of patients' deaths is a theme that recurs among their treating clinicians (see further our chapter below on PUPs). Mr Hunt illustrates how this view permeates the Department of Health itself, into the present day.

167. The faith of the department was very much in the medical profession, as illustrated by Lord Clarke's comments above, and unshakeable. This blind faith permitted substandard clinical practice to continue, largely without intervention from the Chief Medical Officer, in the name of clinical freedom. As Lord Fowler said of one CMO (Henry Yellowlees): 'his interest in his people that he was talking to, you know, tended to be the top medics, and he wasn't really in the public health, general public health.' [113] Unlike individual ministers who might be thought to be genuinely disadvantaged in challenging the views of experts, as laypeople, the CMO had greater expertise. Yet even the CMOs did not take leadership and instruct clinicians in better practice around concentrates.

168. The following section identifies further key themes from the evidence about the relationship between ministers and officials.

Dependence

169. The foregoing paragraphs have outlined the structures which led to ministers relying almost exclusively on officials for all information relevant to policymaking. While Sir John Major thought civil servants should tell ministers when they had gone wrong, he saw that they rarely would. Jeremy Hunt agreed,[114] and ventured two reasons for official reticence:

> *A: The first thing is this desire, human desire, really, to cover up mistakes or to gloss over them, sometimes to protect your colleagues. But, you know, it is a human instinct. But I think there's also, with civil servants, a desire to please their political masters. They're very conscious of the fact that they are civil servants who work for elected officials. So quite a lot of their advice may sometimes subconsciously be what they think their elected masters want to hear. So it may be that the civil servants who were responsible for this area actually did have their own private suspicions that something terrible happened in the 1970s and '80s, but weren't sure whether the politicians would welcome something that would mean billions of pounds of additional liability, so didn't confront us with those facts. It's not for me to make that judgement, it's for you to, obviously with your careful examination of the evidence, to try to understand that. But I think sometimes the problem in our system is that civil servants don't want to confront ministers enough with difficult choices, and they can be too deferential and that may have been a factor here too.*[115]

[113] Tuesday 21 September 2021 - Lord Norman Fowler page 34/35 lines 22 (p34) to 1 (p35)
[114] Wednesday 27 July 2022 - Jeremy Hunt pages 178- 179 lines 20 -5

[115] Monday 27 June 2022 – Sir John Major Page 141-142 lines 17-18

170. Sir John Major added that there is little incentive to reopen past decisions from another administration. He said: 'perhaps governments don't look back quite so carefully at what happened when their opponents were in office, except perhaps to draw attention to the things that go wrong.'[116] This provides an incentive to accept the narratives which the previous administration put forward, repeated by officials to successor governments. An example of this occurring is Lord Philip Hunt who stated to the House of Lords on 26 February 2003 that the government gave "careful consideration and in the end felt that the decision taken by the previous Conservative government was right in relation to the provision of financial assistance."[117] However, there is no evidence that any real consideration or investigation took place. The position appears to be that they adopted the line to take put forward by the civil service without question.

171. Many other witnesses also referred to the pressing concerns of the present being the priority of the government of the day, putting pressure on the desire to investigate historic injustices.

172. Having had experience of the Mid-Staffordshire Inquiry, Mr Hunt had a thesis for how it comes to be that justice delayed is justice denied. He identified a process that leads to entrenchment of falsehoods over successive administrations.

> *What I think is apparent from this letter and the previous briefing [...], suggests exactly the kind of institutional closing of ranks, which I think would have probably happened in stages. I think immediately after it happened, people who were close to the issues might have thought, "Well, perhaps a mistake was made. Perhaps we shouldn't have done that. Perhaps we should have informed people". But then I think the next set of thoughts may well have been -- obviously, I don't know this but I'm speculating, because I think it happened in other areas, many, many other areas -- the next set of thoughts were, "Yes, but these were all good people trying to do their best", and, you know, in those circumstances, we just need to recognise that it wasn't an easy decision. And then the next stage in thinking, which I think is the most flawed of all, but I think may well have been -- I can't say if it was in this case, but was definitely present in many other areas -- was: yes, we were giving it to 2,000 people, and 50 of them were being infected every year, but it was the greatest good of the greatest number and we were helping 1,950 people and, to me, that is fundamentally against what the NHS should stand for, which is the highest standards of safety and care to every single person, as if they were your own mother, father, son or daughter. But I think that you can see that thought process happening in a lot of areas where there were terrible breaches of patient safety, you know, because it is true that no one is trying to do the wrong thing or -- of course, there are one or two bad apples in a system as large as the NHS but, by and large, no one is trying to do the wrong thing. And then what happens is people think, "Well, you know, we need to protect those people who are trying to do the right thing". And then*

[116] Wednesday 27 July 2022 - Jeremy Hunt pages 172 lines 19-25
[117] Second witness statement of Lord Philip Hunt, WITN4680008, para 2.8.

once you get five years on, ten years on, people forget that there was even a moral dilemma, and the account of history changes. So I don't think the officials who wrote that briefing to Anna Soubry would have probably had any understanding of what happened. One might hope -- and that, by the way, was why Andy Burnham, who I know has given evidence, was advised not to meet the Mid Staffs relatives, and something that they are angry about to this day, and I'm sure in retrospect he wishes that he had, but officials said "No, it's not a good use of your time and you'll get drawn into it".[118]

173. Mr Hunt said elsewhere:

> *that briefing is wrong and it shouldn't say that. And I'm afraid it's perhaps an example of what I -- has been described as a kind of memory illusion, but at a departmental level, where the people collectively try to remember things as they would like them to have been, rather than as they actually were. And -- but I think it was a bad briefing for ministers because, at the very least, ministers should be aware, as politicians, that this is contentious and this is disputed by families. But, you know, I'm afraid it tries to suggest the issue is closed when it's not, and it shouldn't have done that.*[119]

174. Mr Hunt did not deny the influence of officials, which he saw as indispensable to the functioning of the system.[120] However, it was not the feature of reliance itself that was problematic, in his view. As well as deference and a desire to please, there were conventions of presentation within government which eliminated dissensus. These include:

a. Presentation of letters to be signed without a full background. As Lord Glenarthur said: '*no letters came with a sort of backing data sheet with "The reason why we've written it like this, Minister, is because", that didn't happen. One had to rely on one's memory and, of course, the volume of correspondence was huge... I read it through, thought it seemed a perfectly reasonable reply, without pulling it to pieces, otherwise we would never have got the letter off.*'[121]

b. A habit of not presenting alternatives – whether these alternatives were contested facts, differences of expert opinion, or different potential courses of action. As Baroness Primarolo said, '*I think this the first note I received from officials from the Archer Inquiry, which has, what -- is reported a year after initially thought it would. I expected options.*'[122] Lord Glenarthur, in retrospect, was troubled by many of the silences in the documentation he received as he

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[118] Wednesday 27 July 2022 - Jeremy, , page 43 line 13 to page 45 line 20.
[119] Wednesday 27 July 2022 - Jeremy Hunt page 38- 39 lines 21- 7. See similarly, page 135 lines 21- 17; page 23- 25 lines 14- 1.
[120] Wednesday 27 July2022 - Jeremy Hunt Page 14-15 lines 16-6
[121] Thursday 22 July 2021 - Lord Simon Glenarthur pg 191-192 lines 24-22. See likewise, Baroness Primarolo: 'I didn't always read the background because I was entitled to expect that a letter replying would do exactly that on my behalf.' Friday 23 September 2022- Baroness Dawn Primarolo page 108 lines 4- 11
[122] Friday 23 September 2022- Baroness Dawn Primarolo page 46 lines 5- 8.

found them to have misled him.[123] A concrete example was the fact that Ministers were not involved by officials in developing, in summer 1983, the policy of continuing to use (less safe) pre-March 1983 plasma.[124]

c. Holding the line and even actively promoting the line. As Baroness Primarolo said: '*even though ministers take policy decisions, there is potentially an inertia, "This is closed, why does she require me to reopen it*?"'[125]

d. Baroness Primarolo was hesitant to say there was anything more than inertia, but Andy Burnham asserted positively that there was resistance. '*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.*'[126]

e. Mr Burnham continued, with reference to a document DHSC0041193_054 discussing the Archer Inquiry which stated: "There is no evidence of any negligence or wrongdoing on the part of the department during the period in question ..." Mr Burnham said: '*That is a false statement. So that's where it starts, with a false statement and, then beneath it you get a series of bullet points piling the pressure, basically -- I'm not making excuses for ministers, by the way, because you are there to resist that pressure, if you believe it is wrong. But you are given a blanket statement of that kind... You got this incorrect line and then a kind of whole heap of financial pressure, reputational pressure, media – why it shouldn't go any further. And, yeah, I think you are absolutely right to ask me to comment on that document. I think it is a very revealing document, and I think it kind of explains why departmental lines can hold, even if they are inaccurate, for much longer than they should.*'[127]

175. Although Mr Burnham did not wish to make excuses for ministers who did not resist pressures, structural flaws meant this was not possible with every issue. Lord

[123] Thursday 22 July 2021 - Lord Simon Glenarthur see e.g. transcript 22.7.21 at pages 8 and 176-177.
[124] ibid., p.79.
[125] Friday 23 September 2022 - Baroness Dawn Primarolo page 114- 115 lines 14- 4
[126] Friday 15 July 2022 - Andy Burnham, page 27- 28 lines 25- 20
[127] Friday 15 July 2022 - Andy Burnham, page 33 lines 4- 16 and page 34 line 11- 19

Glenarthur, for example, described the totalising effect of dependence on briefings:[128] He was asked:

> *Q: Beyond the civil servants, whether in the private office or the medical hierarchy or the administrative hierarchy, did you have access to any other particular sources of information or advice about the matters that fell within your ministerial responsibilities or was it very much dependent upon what the officials within the Department provided to you?*
> *A: It was -- I had no external information at all. It was entirely from within the Department. I mean, I might have had the odd chat with people who were interested, for example in the House of Lords, where there are a number of doctors, but they were just, you know, informal discussions, as one was bound to have in a collegial setting like that, but nothing serious.*
> *Q: You have referred already to there being a number of expert bodies and the Inquiry knows, and again Dr Walford cast some further light on this, there were a myriad of working parties, committees and the like, arguably often with overlapping responsibilities, throughout this period. Did you ever have any direct dealings with those committees or working parties?*
> *A: Not that I can recall.*[129]

176. The views of committees were rarely presented with differences of opinion retained in the minutes. Add this to the reliance of ministers on civil servants, and the picture is one of a government with few outside influences. Unsurprisingly, witnesses univocally accepted that ideas could get entrenched in government.[130] Both officials (such as Rowena Jecock)[131] and ministers (including John Major[132]) concluded that the civil service is the corporate memory of a department. Ms Jecock readily accepted that this placed a higher burden on officials to provide full and accurate briefings.[133]

177. Alan Milburn added, '*I do think this is where the role of the Civil Service, in the end, it is what it is described on the tin, it is a permanent Civil Service. It is not a coincidence that the official leader of the department is called the permanent secretary, unlike the ministers who come and go. So, at the heart of what the Civil Service should be doing is really embedding that question around how lessons can be learnt. And again, I don't think that is probably sufficiently embedded in what is expected of civil servants, and so maybe that is something, in terms of the Civil Service code, that one could think about.*'[134] It is for this reason that we recommend there be a civil service duty of candour.

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[128] See also Friday 23 September 2022 - Baroness Dawn Primarolo, page 41 lines 17- 22; Friday 15 July - Andy Burnham, page 9 lines 6 -14
129 Thursday 22 July 2021 - Lord Glenarthur p12.
130 Wednesday 27 July 2022 - Jeremy Hunt, page 135 lines 21- 17
131 Rowena Jecock 13.7.22 transcript p.27
132 Wednesday 13 July 2022 - John Major, p 172 lines 1-8.
133 Wednesday 13 July 2022 - Rowena Jecock p.27
[134] Thursday 14 July 2022 - Alan Milburn Pg 203 lines 8-19

178. The gravest problem in all of this was encapsulated by Jeremy Hunt. He said:

> *I think the groupthink that I found most troubling was this idea that harming and killing some people is inevitable in modern healthcare systems: it's just going to happen, it's the price of doing business. [...] the result of that kind of groupthink, that this was going to happen anyway, there's nothing that could have been done, is that you don't then have a proper examination as to whether things could have been done differently.*[135]

179. The nub of the problem, as identified by Mr Hunt, was that the Department of Health had become the antithesis of its ideal as a body whose primary duty was to safeguard the population of the state and promote their complete physical, mental and social well-being – in the words of the World Health Organisation.

Inadequate leadership and alacrity from Chief Medical Officers

180. This section will necessarily be brief because the Inquiry was unable to hear directly from Sir Henry Yellowlees or Sir Donald Acheson. The documentary record does not make clear which correspondence and/or briefings were personally seen by the CMO.

181. We have above criticised the CMO for not taking leadership in stopping or limiting the prescription of factor concentrates. Although in Dr Acheson's statement to the BSE Inquiry,[136] Dr Acheson refutes the suggestion that he had any power of direction (calling himself a mere adviser), it is clear that the CMO could and did write 'Dear Doctor' letters. However, it does not appear that he took a hand in advising on the use of factor concentrates. Furthermore, the CMO could and did advise government albeit, we say, ineffectually in response to the infected blood scandal. In particular we highlight two incidents. The first is the use of the United Kingdom as a 'soft target' or testing ground for contaminated US commercial concentrates. The second is the CMO's lack of urgency in the government's response to AIDS.

182. As to the first matter, a letter to Dr Yellowlees dated 25 November 1975 tells him: "The general gist of Mr. Gillard's inquiries seems to rest on the premise that the American pharmaceutical industry is sending material to the United Kingdom which is so unsafe as to be unacceptable in the U.S."[137] Despite receiving this letter, the CMO appeared entirely ineffectual[138] in preventing the UK from becoming a "soft target" for trials of

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[135] Wednesday 27 July 2022 - Jeremy Hunt page 143 lines 17- 22; Page 144- 145 lines 16- 3.

[136] MHRA0011433, para 14.

[137] DHSC0100001_036 Theodore Cooper, M.D., Assistant Secretary for Health)

[138] A more oblique reference appears in an earlier letter to BPL: "They mention the possibility of undert aking clinical trials in this country of new preparations of human blood and seemed to hint that such trials might be done here more easily than in the USA…" (National Archives File: MH 168/143- Visit of Mr. Sydney M. Pugh (Cutter International) and Mr Carroll E. Jones (Cutter Laboratories Overseas Corporation) to Blood Products Laboratory, 9 March 1978.)

concentrates which would not have been permitted in the USA due to FDA rules.

183. As to the second matter, the CMO's actions at the advent of AIDS, it is submitted that the CMO was aware of the existence of AIDS in 1982 and very likely at least several years before. His annual report from 1982 suggests AIDS has been a phenomenon for the last four years,[139] which may well refer to the 1979 CDC in Atlanta noting cases of immune deficiency. If the CMO did not know about AIDS then it is submitted that he should have, as the most senior medical adviser on public health matters. A letter from Dr Gunson in June 1983 to the CMO certainly makes mention of it.[140] Although Lord Clarke blamed the medical advisers for the line that there was 'no conclusive proof' that blood products transmitted HIV, the CMO's 1983 Annual Report, published at the end of 1984, said: *"The cause remains unknown, but is likely to be a viral agent transmitted by sexual contact, transfusion of blood and certain blood products.*"

184. The CMO does not appear to have been consulted about the line on conclusive proof. If he had sight of the letter dated 9 May 1983 to the Principal Medical Officer from Dr Galbraith saying all US blood products should be withdrawn,[141] he took no action. He was told by Dr Gunson that '*there is, in my view, no alternative to the continuation of this policy [use of US plasma] in the short term.'* What he made of this, if anything, and what Dr Gunson meant by 'short term', can only be speculated at. However, products derived from US plasma continued in use.

185. Although Lord Fowler believes that had the CMO at the time of Dr Galbraith's letter (Dr Yellowlees) 'taken a grip of this thing now, then … we might have had a better picture.'[142] He further said: 'I think that if Donald Acheson had been Chief Medical Officer then, and not a couple of years later, I think more action would have been taken.' However, this is not the view of the infected and affected. Review of the CMO's annual reports demonstrates that it was not until 1985 that crucial steps were taken including distribution of information leaflets, development of a screening test, development of heat treatment; and the ongoing work to redevelop the BPL, with the aim of achieving self sufficiency. (Even at this time, there is no mention of NANB hepatitis.)

186. Although Dr Acheson insists to Lord Clarke that both heat treatment and screening are needed, this is in 1985. The evidence of Dr Richard Tedder is that the Principal Medical Officer was dismissive of his approach to the DHSS in early 1983 stressing the need to research this emerging disease. His evidence to the Penrose Inquiry was that: 'We were told this was really not any of our business and it was not going to be a problem and go away and stop rocking the boat.'[143] Regardless of the actions of the CMO, therefore,

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[139] DHSC0007004 p.62-63.
[140] NHBT0001067
[141] CBLA0000043_040
[142] Tuesday 21 September - Lord Norman Fowler page 137 lines 10-15
[143] Thursday 13 October 2-22 - Professor Richard Tedder, page 46 line 2 to page 50 line 5.

the response of the PMO was seriously misguided. The precautionary principle should have been paramount in the decision-making of government and civil servants. Dr Peter Foster in a letter dated 29 September 1983 said: "*I would like to comment on the letter from Lord Glenarthur Arthur to Clive Jenkins. I found the letter surprisingly complacent about the blood products situation and there are number of points to take up.*"

187. Dr Tedder's evidence describes immense delays in evaluating and introducing HIV testing. Indeed, it appears that Sir Donald Acheson eventually shared Professor Tedder's frustration that more had not been done. In a letter to Sir Kenneth Stowe, the Permanent Secretary at the DHSS, dated 3 October 1986 he said: '*From the medical point of view, the Government's response has been inadequate and is now substantially less to educate the public than some other European countries.'*[144] Lord Clarke was asked,

> *Q. Did you ever ask, in your time as Minister for Health, what other countries were doing?*
> *A. No, I don't think I ever did because I wasn't the minister responsible for this, but I was having -- with hindsight it might have been a good idea to have asked.*[145]

188. As recognised by both Sir Donald and Lord Clarke, the response of the medical stream of the Civil Service was inadequate.

Lack of candour

189. There are diverse illustrations of the government's lack of candour over the years, some of which are itemised in this section. Others, including its actions surrounding disclosure and waiver in the *HIV Haemophilia Litigation*, have been touched on above – and are dealt with in more depth elsewhere.

190. Jeremy Hunt, Baroness Primarolo and Lord Warner all identified the problem of a department marking its own homework.

a. Mr Hunt said: 'I became aware that I couldn't ask the Department to do these inquiries because that would be like asking them to mark their own homework. So you had to ask someone trusted from outside to look into the issue.'[146]

b. Lord Warner says in his witness statement that as the people who lost and destroyed documents were departmental civil servants they had an incentive to resist both a review and a public inquiry.[147]

c. Baroness Primarolo said in her witness statement, 'reflecting on these events, I question whether the whole model needs to be reviewed. It was certainly not

[144] DHSC0007008
[145] Wednesday 28 July 2022 - Lord Kenneth Clarke, pg 41 lines 12-18
[146] Wednesday 27 July 2022 - Jeremy Hunt page 139- 140 lines 20- 2.
[147] WITN7501001 Para §5.63

ideal to be expected to make the judgement on whether to have a public inquiry into historical events as the Minister for the Department said to have been most involved in the past, whose officials had conducted their own internal reports which had not supported the need for an inquiry. In some cases there may be a role for external assessment for an independent review to help decide whether a full public inquiry is commissioned but I recognise that there are difficulties and that this may be seen to delegate a decision for which the responsibility lies with the Government.'[148]

191. The government did not publicise, nor did it follow, the Council of Europe's guidance in 1983.

192. A lack of candour can also be seen in the response to legitimate reporting on infected blood issues.

a. A May 1983 Mail on Sunday article – entitled 'Hospitals using killer blood' – was aggressively responded to. Dr Peter Jones, on behalf of the UKHCDO, condemned the article 5 days later and complained to the Press Council. This ultimately had effect of shutting down the story. Dr Jones furnished the Press Council with material to lead it to conclude that the story was 'extravagant and alarmist … unacceptably sensational.' Yet both the UKHCDO and the government had reason to suspect that AIDS was a real and imminent threat to public health. This article would have invigorated frank and open discussion of the risks and benefits of blood/products. It would have assisted in keeping patients informed for purposes of consent.

   i. Why close it down? One reason may been fear of panic, but anxiety was reasonable and would have allowed people to protect themselves.
   ii. Another reason was perhaps a fear of criticism or litigation. However, the truth will out, as it did in *HIV Litigation*, and now more fully 40 years later when it looks all the more shameful to have hidden it, and to have let people suffer in the meantime. Mr Hunt traced the toxic and ossifying effect on a public institution of uniting around a lie for decades.

b. An example of this toxic effect was canvassed in the evidence of Baroness Primarolo. She was shown a "Media Handling Plan" which set out tactics to accompany the Government's publication of its response to the Archer Inquiry.[149] The insincerity of the government's response is exposed by the paragraph which states:

[148] WITN5494001, para 5.25.
[149] DHSC0041219_124

'Many of the individuals affected by contaminated blood and blood products believe that insufficient action has been taken by successive governments. In responding to the Archer Inquiry, Press Office recommends that you, Dawn Primarolo, agree to accept carefully chosen interviews if necessary. This will help show that this is a serious issue that has been carefully considered.'

193. Furthermore, as the calls for a public inquiry got louder, the government constantly peddled the line that everything reasonable had been done and all relevant information was already in the public domain so there was nothing to be gained from an Inquiry. A crass example of this was the "self-sufficiency chronology" which was published in an attempt to show that everything reasonably necessary had been done. It was subsequently discredited and withdrawn. Its publication attempts to add credence to the government's silence before Parliament, alluded to by Lord Morris of Manchester, when self-sufficiency was not achieved as planned. It is very telling that the publication makes little to no mention of what effect self-sufficiency would have had in respect of HIV infection and focuses almost entirely on Hepatitis. It is submitted that the reason the publication avoids addressing the effect of self-sufficiency and HIV is because the authors knew, as is widely known, that self-sufficiency would have dramatically reduced the scale of HIV infections among people with haemophilia.

194. As the Public Health Administration experts observed, the phenomenon of ministers defending the indefensible shows that the Nolan principles are not working.

Plus ça change? The present government's approach to compensation

195. This brings us up to the present day. The community of the infected and affected, despite all the loss and hardship they have suffered, had hoped that this Inquiry would bring change. Unconscionably, however, at the time of submitting this draft, the government has not announced when and how it will implement the recommendations of Sir Robert Francis. Indeed, Jeremy Quin stated in the House of Commons on 15 December 2022 that he was unable to commit to a timetable. He said:

'Sir Robert recognised in his study that the Government could not give in advance a commitment on the exact shape that redress will take. Our comprehensive response must await the final report of the infected blood inquiry.'[150]

196. In Matt Hancock's evidence, on 21 May 2021, Mr Hancock was asked:

MS RICHARDS: Do you agree with the view expressed by the Paymaster General that action on financial support and compensation was long overdue?

[150] Commons Hansard: Infected Blood Inquiry Col. 1251, Jeremy Quin, 15 December 2022.

MR HANCOCK: I think that resolving this problem, this whole tragedy and all that it's left behind, is long overdue, yes.
MS RICHARDS: And resolving this tragedy includes taking action on financial support?
MR HANCOCK: Well, I'm very glad that since this letter was sent we have been able to take action to resolve matters in terms of financial support with respect to parity and that's -- and I'm really pleased that we've been able to do. And then when it comes to the wider question and compensation, as we've discussed, I think the appropriate thing to do is to respect the results of the Inquiry and ... the Sir Robert Francis Report...[151]

197. Unfortunately, despite acknowledging that the resolution to this tragedy is long overdue, the government has produced no tangible outcomes eighteen months later – other than making interim payments to those identified in Sir Brian Langstaff's interim report.

198. A pattern has been established by recent administrations of responding late and opportunistically to this Inquiry. For example, parity / levelling up of the financial support schemes was announced the day before Mr Hancock's evidence.

199. Some beneficial steps (in healthcare, specialist psychiatric support in the devolved nations, the resumption of tracing undiagnosed HCV sufferers) have only happened since and because of this Inquiry. It is only since this Inquiry – and the public attention it attracted and press coverage – that anything positive has happened. Credit is owed to all the infected and affected campaigners and to the Inquiry team itself for working and uncovering material.

200. The Paymaster General received Sir Robert's report on 14 March 2022. On 22 March, Michael Ellis (Minister for the Cabinet Office and Paymaster General) confirmed in response to a Written Question from Dame Diana Johnson MP of the APPG:

"It is my intention to publish Sir Robert Francis' study alongside the Government's response. Before I am able to do so, you will understand that work must be undertaken within Government to formalise our response. That work is already underway. I recognise how important it is for the Inquiry and its core participants to have sufficient time to consider the study before Sir Robert gives evidence to the Inquiry. It is my intention to publish the study alongside the Government's response as soon as possible."

201. On 27 April 2022, the government reaffirmed its "intention to publish the Study and the Government response, in time for the Inquiry and its core participants to consider them before Sir Robert gives evidence to the Inquiry." The report was published in the second week of June 2022, on 7 June – i.e. three months after it was received – and did so only because Sir Robert was due to give evidence on 11 July.

[151] Friday 21 May 2021 – Matt Hancockpages 174, line 1- 20.

202. However, despite Mr Ellis taking time to consider the government's response prior to publication, the government does not yet have a response. Core Participants had only four weeks to consider their response prior to Sir Robert's evidence.

203. Sir Robert Francis' understanding, as outlined in his oral evidence, was that "It was always intended I think that the Government would take time to consider the report and publish a response at the same time as they published the report. [152]

204. On 20 June, Mr Ellis said: "The Government is considering Sir Robert's recommendations and it is most important that the government is ableto reflect upon Sir Robert's evidence and the evidence of others to the Inquiry as part of that consideration."

205. Sir Robert was unable to give an explanation for this when asked by CTI during his oral evidence:

> *Q: So it appears that, as between the end of April and this date in June, the Government's position has shifted from publishing the response as well as your study in time for you to give evidence to simply publishing your study. Have you had discussions with Cabinet Office or anyone else in Government that would throw any light on why the Government has decided to take that course?*
>
> *A: No, the only meeting I've had with Mr Ellis was on the day I handed in the report, at which point, obviously, he had nothing to say about it, apart from thanking us.*[153]

206. By 30 June, there is a further (unsustainable) justification for delay:

> *"I would like to emphasise that there is a great deal of complexity to the issues covered in Sir Robert's study. At present, officials from across Government are conducting a thorough analysis of the report and its recommendations; that analysis requires careful and diligent work given the very many factors that must be taken into account. I should note that Sir Robert is due to give evidence to the Inquiry on 11 and 12 July. Following his appearance at the Inquiry, officials will also need to factor in his oral evidence as well as the recall evidence of others appearing at the Inquiry.*

It is not clear who these others appearing at the Inquiry are, nor what light they could bring to bear. In any event, the Inquiry has now concluded hearing evidence, without the government producing a response.

207. The government broke its express promise (by letter from the Paymaster General to the APPG dated 27.4.22) that it would respond before Sir Robert gave his evidence.

a. This is to treat the infected and affected with contempt. Despite platitudes, actions speak louder than words.

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[152] Monday 11 July 2022 Page 14 Line 20 - 23

[153] Monday 11 July 2022 – Sir Robert Francis QC Page 15 Lines 17- 25 and Page 16 Line 1

b. It prevented Core Participants engaging in scrutiny and public discussion about the scheme in the Inquiry forum, and to date in Parliament.

c. It denied the Chairman and CTI the chance to scrutinise the government's proposal to see how it matches up with what they, as an Inquiry panel, have heard and learned about the needs of this community.

d. As a result, time and (public) money was spent probing Sir Robert on the finer details of a scheme that is hypothetical.

208. There was a subsequent revised promise to deliver the government response before the conclusion of the Inquiry. None has been forthcoming before the deadline for the parties' final submissions. Thus it is not even a case of parties aiming at a moving target, the government simply has not given CPs a target at all. More importantly, as x are dying every week, that will be x lives lost, x families shattered, before anything approaching justice is done. Moreover, those figures are only in relation to those infected whom we know will die, let alone those ineligible for any support, such as bereaved parents, who will not live to see the outcome. The dying are not even being given the comfort of knowing their family will be provided for under the details of a scheme, even if their demise precedes the payment.

209. In late November, *"a spokesman"* told Caroline Wheeler of the *Sunday Times* (article 27.11.22): *"While this is a complex process, we remain committed to publishing details on the compensation framework before the inquiry concludes. We will also consider and respond to any recommendations relating to compensation in the inquiry's final report."* This adds nothing substantive, except that the response will be published before the inquiry concludes – with no indication as to how long before, nor what the timescale anticipated by government for the final report is.

210. During the most recent discussion in the House of Commons, on Thursday 15 December 2022, the day before the deadline for parties' final submissions, Mr Quin gave a statement that included the following:

> *I recognise that, tragically, we continue to see victims of infected blood die prematurely, and I also recognise that time is of the essence. […]*
>
> *The Government had intended to publish a response alongside the study itself, ahead of Sir Robert's evidence to Sir Brian Langstaff's inquiry. However, as the then Paymaster General explained, the sheer complexity and wide range of factors revealed in Sir Robert's excellent work meant that when the study was published by the Government on 7 June, it was not possible to publish a comprehensive response. The Government remained absolutely committed to using the study to prepare for the outcome of the Langstaff inquiry, and that is still the case. […]*

It is my intention over the coming months to update the House on progress and, where it is possible, to provide greater clarity on the Government's response to Sir Robert's recommendations prior to Sir Brian's report being published.

In the meantime, I wish to make clear one critical answer to a recommendation posed by Sir Robert. In the first recommendation of his study, Sir Robert sets out that there is in his view a moral case for compensation to be paid. The Government accept that recommendation. There is a moral case for the payment of compensation. We have made that clear in our actions with the payment of interim compensation. I now want to make it equally clear on the Floor of the House. […][154]

211. The Shadow Minister, Florence Eshalomi, responded:

I thank the Minister for the statement, which is welcome but long overdue. It is very disappointing that the Government did not find time for an oral statement in the House earlier this year when they published Sir Robert's report. Ministers were dragged kicking and screaming to publish the report when it was leaked. That has been the pattern throughout this long painful process and it seems no different today.

Victims of the contaminated blood scandal will be watching today with great interest. Heartbreakingly, many of those infected have not lived to see today's exchanges and the prospect of proper justice at the end of the inquiry.[…]

In a recent Westminster Hall debate, the Minister's colleague, the Parliamentary Secretary, Cabinet Office, the hon. Member for Brentwood and Ongar (Alex Burghart), gave a frankly insulting response on the subject. He dodged the question and failed to give any certainty about the timeline for payment or the publication of the Government's response to the report, which they have had for more than eight months. Victims will not accept empty gestures. It seems to families that the plan changes with every announcement.

Can the Minister make a promise to the House today to publish a timetable for the compensation framework for those affected by the infected blood scandal? What plans does he have to work in partnership with the infected blood community to develop the compensation framework for those affected? When will he end the Government's silence on the other 18 recommendations that have gone ignored? How will the Minister make sure that everyone who wants to respond to the proposals has the opportunity to do so? Rather than sporadic updates without any substance, will the Minister commit to more regular updates on progress and the direction of travel on this heartbreaking issue, ahead of the report next summer?[155]

[154] Commons Hansard: Infected Blood Inquiry Col. 1250, Jeremy Quin, 15 December 2022.
[155] Commons Hansard: Infected Blood Inquiry Col. 1251 -2, Florence Eshalomi, 15 December 2022.

212. Mr Quin replied,

> *I cannot commit to a timetable. The reason is that I do not want to say anything in this House that we cannot meet.*[156]

Conclusion

213. As Jeremy Hunt saw, the Department of Health became the antithesis of what it set out to be. '*There is a view sometimes in medicine that you do something for the greatest good for the greatest number, and there's going to be consequences for some unlucky souls along the way. Personally, I think that's completely wrong and not consistent with the values of the NHS, but that's that.*'[157]

214. The paragraphs above identified some key themes that beleaguered government during the relevant period. Today's government has given the community of infected and affected little hope that things have changed.

215. Both ministers and officials used lines to take stubbornly and defensively. There was little independent scrutiny of lines to take on the part of either. MPs generally took on faith what the civil servants said; the civil servants took on faith what the files said (even from a different administration). This created a vicious circle of repeated untruths. In this case, as Jeremy Hunt said,

> *'the Government didn't have a -- or the State, is perhaps a more accurate phrase, including the Civil Service, didn't have an open mind to this issue. They basically had decided that the State in the 1970s and '80s had done the best it could in the circumstances: a very sad thing had happened; compensation had been put in place; matter closed.'*[158]

216. Whilst the above deals mainly with causes and themes, the chapter will close with a summary of factual conclusions that the Chairman is invited to lay at the door of the government.

- Allowing untreated large-pool factor concentrates to be distributed through the NHS.
- Failing to adhere to the World Health Organisation resolution of 1975.
- Failing to achieve self-sufficiency and then to own up to this failure.
- Issuing circulars and memoranda concerning the arrangements for the purchase and import of commercially-produced Factor VIII which, once issued, went out across the United Kingdom to regional health authorities and RTCs.

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[156] Commons Hansard: Infected Blood Inquiry Col. 1252, Jeremy Quin, 15 December 2022.
[157] Wednesday 27 July 2022 - Jeremy Hunt page 171- 172 lines 5- 3.
[158] Wednesday 27 July 2022 - Jeremy Hunt page 43

- Failing to make any adequate enquiries into the manufacture of (or to properly regulate) commercial concentrates which were being supplied into the UK.
- Allowing economic concerns and the priorities of private pharmaceutical industry to override patient safety. We endorse the conclusion of Lord Peter Archer in the Inquiry Report of 23 February 2009, where it was stated that: "Commercial priorities should never again override the interests of public health".
- Failing to adhere to the Council of Europe recommendations of May 1983 on the use of coagulation factors and AIDS, that concentrates prepared from large plasma pools should be avoided except where such a product was specifically indicated for medical reasons.
- Allowing the UK to become over-reliant on imported blood products.
- Reacting too slowly and without decisive steps to early indications of the AIDS epidemic, and over-reliance on published medical papers and a group of experts who were not sufficiently independent.
- over-reliance on the widely disseminated line that there was "***no conclusive evidence***".
- Failing to take preventative steps over Non-A non-B hepatitis (NANBH) and hepatitis B in blood products throughout the 1970s which had the knock-on effect of exposing users of blood products to AIDS (because HIV is more heat-sensitive than hepatitis viruses and measures put in place for hepatitis would have protected against HIV).
- Failing to timeously introduce proper screening of UK-produced blood products.
- Suppressing legitimate press criticism. Long-term methodical undermining of campaigners who were simply trying to get to the truth.
- Non-receptivity to judicial scrutiny and quasi-judicial scrutiny.
- Failing to implement the recommendations of the Ross Report (Report of The Expert Group on Financial and Other Support) in March 2003, and instead ushering in a hastily devised national scheme, the Skipton Fund, which was inadequate.
- failing to timeously introduce ALT testing and HBc (hepatitis B core) screening
- failure on the part of the CSM to insist on limitations being placed on the type of source donations origination from within the USA.
- Accepting US material which was so unsafe it was deemed to be unacceptable in the United States itself.

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Chapter 5 - Clinicians

Introduction

217. We include this Chapter conscious that in his Statement of Approach, the Chair has not specifically asked for submissions in respect of clinicians, and at §12 of that Statement of Approach he indicated that he had well in mind the evidence he had received from the clinicians.

218. We have elsewhere in these submissions on behalf of our Core Participants set out what we invite the Chair to conclude in respect of:
    (a) the involvement of clinicians in issues of knowledge and consent;
    (b) the use of factor concentrates as against the continuing use of cryoprecipitate;
    (c) the involvement of clinicians and UKHCDO in what occurred in Lord Mayor Treloar School;
    (d) the testing and treatment of PUPs; and
    (e) consent, communication and information-sharing.

219. We anticipate that the Chair will not find it helpful for us to go through every clinician, haemophilia centre and hospital offering our views on whether any given clinician, or the treatment undertaken there, was in our view good, bad or indifferent. That would involve recitation back to the Chair of what amounted to several months of detailed evidence.

220. We therefore below make first a series of general observations, standing back from the totality of the evidence the Inquiry has received in respect of clinicians and the UKHCDO, and invite the Chair to consider it. We then make a series of limited, specific observations on a limited number of points which we hope will be of assistance to the Chair.

Good and poor practice

221. It will have been obvious to anyone who listened to the evidence of the various haemophilia clinicians, and read and heard the presentations about the various haemophilia centres, that there was good practice and poor practice across different centres and individuals at the material time. We use the term "good practice" in a relative sense, remaining of the view at all times that untreated Factor concentrates should never have been in use.

    (a) There were some centres (albeit relatively few) where there was a consistent picture of the clinicians being well-trained; attending conferences; keeping up to date with clinical literature on haematology and also on associated disciplines

such as hepatology; receiving and reading the minutes of the UKHCDO; complying swiftly with guidance (questionable though it often was); keeping patients off concentrates as much as possible and using them only in cases of irrefutable and unavoidable clinical need; considering all other forms of treatment ahead of concentrates; explaining their treatment approach to patients; preferring UK concentrate to imported commercial large pool concentrate if it had to be used at all; understanding the risks of viral transmission through blood products; explaining those risks so far as possible to patients; operating batch dedication so far as was possible, etc.

(b) We submit that those centres and clinicians were keeping up with acceptable standards and practices if all those steps were taken.

(c) There were some where that was tragically not the case, and where the combination of some or all of those shortcomings was – without a shadow of doubt – directly causal of the infection, illness and the death of numerous patients.

222. The Inquiry cannot determine questions of civil or criminal liability. But it can (and we say should) identify hospitals and clinicians where things fell short of what might reasonably have been expected, and where treatment and policies could be described as woefully inadequate, unacceptable or substandard.

223. There is no bar to the Inquiry recording (as we say it should, for example in respect of the treatment of children at Alder Hey) that other experienced clinicians who were contemporaneously invited to review what happened there and produce expert reports for the purposes of anticipated litigation, were unsparing in describing what happened there as "negligent".

224. The Chair is likely already to have well in mind the differences in approach between various hospitals and clinicians. He has already indicated for example during the presentation on Alder Hay that he was struck by the differences in approach between it and the not-too-distant centre at Sheffield in terms of how the patients were treated and how that translated so starkly and inexcusably differently into levels of infection, and fatal infection, in each centre.

225. Other Core Participants with a particular focus on Wales and on Northern Ireland[159] are likely to make particular submissions in respect of the actions of Professor Bloom and Dr Mayne. We will almost certainly agree with and endorse what they say.

226. We have chosen to focus specifically on Lord Mayor Treloar School in Hampshire. We invite the Chair to consider that many of the conclusions we invite him to make in respect

[159] Those represented by Watkins & Gunn, and Mr Williams KC

of Treloars can be extrapolated to other centres and to the practices which took place in them.

Knowledge and benchmarks against which clinicians might be considered

227. We submit that the precautionary principle ought to have been uppermost in clinicians' minds at the material time.

228. In respect of their attitude towards and use of factor concentrates and the risks of hepatitis, the Chair will be familiar with the literature, so we simply repeat in summary our submission that it was known since at least the 1940s that there were hepatic viruses in blood and therefore inevitably, with increased risk, in pooled blood products. It was known then that serum hepatitis could be fatal. When HAV and HBV had been identified, it was still known that another form of hepatitis remained. There was no reason at all to consider that it would be any less severe in the long-term than HAV or HBV would be, if unchecked. As such, it ought to have been considered at all material times that it could have serious and long-term consequences. It did not become any more potent when named HCV rather than NANB – it ought always have been understood to be a disease with serious and long-term consequences.

229. When it became clear at about the time of Dr Biggs' letter in 1967 (to which we refer in our chapter on self-sufficiency) that US commercial companies were going to be at the forefront of producing pooled plasma factor concentrates, it ought to have been immediately apparent that they bore a considerable risk of transmitting hepatitis and should have been avoided.

230. We note that even in his 1967 paper referred to in our previous 'Myths and Lies' chapter, Professor Bloom expressed concern that cryoprecipitate might involve treatment with more donors than fresh frozen plasma, and so gave rise to a greater risk of hepatitis. We rhetorically ask how did this obvious risk come to be forgotten when he later endorsed the use of large-pool concentrates? [RLIT0001514_0009]

231. And by the late 1970s material which the Chair has already been taken to in presentations (including but not limited to Prof Preston's research and publication in the lancet on 16.9.78) drove home the point that NANB was a serious condition. In his oral evidence, Professor Preston said:

> *"Our state of knowledge was that in 1978, non-A, Non-B Hepatitis was associated with a broad spectrum of chronic liver disease, including cirrhosis"*

232. From at least that date, that knowledge ought to have informed clinicians' choice of treatment and (as we say in a previous chapter) they ought to have preferred cryoprecipitate over concentrates until the NANB risks could be eliminated.

233. By 1980 [PRSE0003946] the UKHCDs noted that some pathologists would not carry out post mortems on haemophiliac patients because of the possible risk of hepatitis.

234. By 1980 [PRSE0003946] the UKHCDs discussed the relative risks of hepatitis in large (3,500) pool sizes at Elstree and small (500) at Oxford and Professor Bloom was wondering whether cryoprecipitate might be a better product for mild haemophiliacs. Dr Craske agreed and suggested that NHS product was better than commercial product because of the screening of donors and the regular donor panels in the UK … considering it likely there would be a higher incidence of hepatitis then in the UK volunteer blood donors.

235. Dr Tedder's evidence that it was well known in the 1970s that using large quantities of blood would certainly lead to hepatic infection (then known to be HBV but also known that there were others). And that it was understood that HBV was a serious illness which may in the future cause severe liver illness and that it could be transmitted by blood. His evidence was that virologists never assumed that the initial limited severity of NANB meant that it would have no long-term effect *"virologists would always be nervous about any persistent infection."*

236. Similarly but later, clinicians ought to have been aware of the developing state of knowledge of HIV from the US medical and disease centre reporting, media articles, the Heathrow Airport meeting, the Galbraith letter, the Council of Europe's draft recommendation and the many other events and publications which the Chair is familiar with.

237. When UKHCDO eventually came to issue guidance in May 1983 about keeping children, previously untreated patients and mild and moderate haemophiliacs off concentrates, there can have been no conceivable excuse not to do so.

Responsibility

238. As set out in our introductory chapter and in our chapter dealing with Government, we invite the chair to conclude that ultimate responsibility for shortcomings in clinical practice at the material time devolves onto the Secretary of State for Health, and therefore rests with the Government.

Why did clinicians allow imported large pool concentrates to be used?

239. We suggest that the answer might lie in the unique nature of haemophilia, the unusual position that a group of self-selecting experts in that condition formed themselves into what was effectively a "club" determining for themselves national strategy in their

specialist area and in part in the fact (as we mention in an earlier chapter under trust) that unlike other areas of medicine these were not patients who were seen once for a momentary condition and then discharged, these were patients who were destined to spend their lives in regular contact with their clinicians, engendering a close relationship of trust, but also making them an ideal cohort for study *en masse* which may have led to losing sight of the particular duties owed to each individual patient. All too often, the pursuit of science surpassed care.

240. We invite the Chair to consider that the UKHCDO became in effect a close group of fellow-clinicians, not particularly open to outside opinion or dissenting view, which saw themselves as a body of specialist, intellectual clinicians with a vocation to treat a whole cohort / big group, for the benefit of science and medicine as a whole.

241. Perhaps being, wrongly, carried away with believing they were involved in ground-breaking and life-saving new discoveries and treatments with concentrates, they therefore became blind to their weaknesses, unwilling to see their risk (choosing to ignore or dispute the early research about the serious longer-term risks of NANB). And subsequently were unwilling to accept that they had been wrong.

242. They lost their way in over-stating the benefits of treatment (see the evidence Dr Lee, who remains defensive of what they did and even now appears to believe it was life-saving, when the papers and data the Inquiry has suggest that the major gains in life expectancy in fact came earlier from cryoprecipitate. It is noted that Dr Lee's book published in 1986 "Blood Product Therapy in Haemophilia – Historic Papers", spanning hundreds of pages and sponsored by Alpha, begins detailing the history of blood product published papers in 1906, but, besides Poole's original paper announcing a method to manufacture Cryo, contains no other papers regarding Cryo or its use at all).

243. They confused and conflated the big picture which they felt they had a duty to solve with the individual interests and wellbeing of their own individual patients.

244. They therefore put what they saw to be the interests of the whole group of patients (or perhaps the interest of their own scientific research and credibility) above the interests of the individual patients.

245. One striking example of this was the UKHCDO's concerted response (through Dr Jones in Newcastle) to the Mail on Sunday's May 1983 *"Hospitals using killer blood"* article – which was to denigrate it and complain to the Press Council that is was sensationalist. Yet at the same time knowing or strongly suspecting that the concerns expressed in it were real and credible.

246. Also striking is their conflation of *incidence* with *risk* – again evincing an unwillingness to recognise the true picture.

247. The notes of the Heathrow Airport meeting of January 1983 show that they were being told at the same time that Immuno were very close to having a product which they believed would not transmit NANB, and that there was developing concern that HIV was virally transmitted through blood. But despite the obvious implications of that information, they chose not to pause the use of concentrates and revert (even temporarily) to cryoprecipitate. It may have been wishful thinking that the concerns were untrue, it may have been a desire still to see their patients have home prophylactic therapy, it may have been fear of being seen to change their minds or to simply make their jobs easier. But equally there were no steps taken to apprise patients themselves of the information the clinicians had just received; the paternalistic approach of the clinicians deciding what was right for what they perceived to be "their" cohort of patients continued.

Retrospective justification

248. One specific example of the retrospective justification of the approach taken by clinicians of maintaining patients on concentrates can be seen in Dr Mannucci.

249. In 2003, he published "AIDS, hepatitis and hemophilia in the 1980s", presenting it as an authoritative account of the contaminated blood scandal, the paper was published in the Journal of Thrombosis and Haemostasis and received attention from haemophilia doctors worldwide [WITN0644071].

250. Core to Mannucci's article is the argument that NANB was not considered a serious condition in the early 1980s - a key plank relied on to justify the use of untreated FVIII.

251. Mannucci's 2003 paper has been referred to in IBI hearings, including during the oral evidence of Prof Christine Lee. [20th October 2020 p103 of transcript].

252. Prof Lee used Mannucci's paper to argue that NANB was considered benign in the early 1980s.

253. The assertion that Mannucci's 2003 paper proves NANB was thought to be benign in the early 1980s should be rejected.

    (a) Mannucci altered the data found in his original 1982 report [PRSE0003351] in his 2003 paper.
    (b) In the 2003 paper, Mannucci writes *"A prospective biopsy study was undertaken by me with the hepatologists Colombo and Rizzetto in **10 hemophiliacs** with non-A, non-B chronic Hepatitis followed up for more than 6 years. The study, published in 1982, demonstrated **no case of progression towards cirrhosis or hepatocellular carcinoma**."*
    (c) However, Mannucci's original 1982 report says there were *"**11 patients** included in this study"*. Not **10**.

(d) The 11th patient, who is removed from existence in Manucci's 2003 paper, is referred to in the 1982 paper: *"One patient with active cirrhosis died of liver failure during the follow-up period."*.

(e) Mannucci's 2003 paper stating that there was *"no case of progression towards cirrhosis"* is inconsistent with the 1982 paper stating *"One patient with active cirrhosis died of liver failure"*.

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Chapter 6 - Lord Mayor Treloar School & College, Hampshire

254. A focus of the Inquiry's evidence has been on HIV infections at the school, which given the scale of former pupils' demise, is understandable. There were contemporaneous deaths when the deceased were pupils at the school, and shortly after leaving. A significant proportion of pupils' lives were tragically lost.

255. The Inquiry has had the benefit of reading the statements of former pupils and their families, hearing devastating witness testimony, together with a detailed Presentation by Counsel over the course of a week. This submission is not intended to duplicate that evidence which is burned into the memories of all those who heard and lived it.

256. Those who have passed should not be forgotten – a memorial should be placed at the school. Former pupils have had to take the lead on supporting each other, as the school has looked the other way. There remain significant ongoing physical and psychological issues for the infected and co-infected survivors, as well as their affected.

The Pupils' Dilemma - Excited to attend a new chapter with specialist support

257. The objective of LMT: from *1908* was to provide "*consistent sustained education, in an environment where medical needs were met on site, with minimal disruption*"[160]. A worthy ambition. In 1948 the NHS took over the medical centre, 'The Lord Mayor Treloar Hospital'. Haemophiliac boys attended the school and centre from 1956 onwards, including those with Factor VIII, Factor IX and VW deficits.

258. The education of many haemophiliac boys suffered as a result of time spent in hospital, treating bleeds and missing school. Therefore, having the opportunity to go to a school with others who suffered with the same disease and be able to receive treatment on site was seen by many as a fantastic opportunity.

259. Requests to attend the school, were made to both the Headmaster and the Haemophilia Centre Director. They came from local authorities, 'home' treating clinicians, and other Haemophilia Centres. A parent reports receiving an invitation 'out of the blue' for a haemophiliac boy who was getting on fine at his local school, and now queries the motive for such.[161] The diverse range of applicant routes suggests there was likely to have been liaison over admissions, between educational staff and clinical staff, regarding a prospective pupil's suitability and medical needs.

260. As LMT was also a boarding school, many of the children were away from their homes and families, often from an early age. Like many children, the pupils at LMT were naïve

[160] HSOC0022908 – Haemophilia Society Bulletin, 1981, Sister Turk article, p.4 etc.
[161] GRO-A, mother of GRO-A WITN 1428001, §8

and innocent. However, unlike other children, some had to suffer haemophilia, before the heavy burden of infectious and often fatal diseases were imposed on them.

261. They have been told all their lives (up until this Inquiry's evidence), that this '*was an unavoidable accident*'. The reality uncovered now shows otherwise. Those who had haemophilia relied on the adults around them, trusted the adults around them – the school staff and the clinical staff. They believed what they were told; and did not question those in authority.

262. The pupils were first and foremost dependent on the Headteacher (Mr. MacPherson), and his staff, their Housemasters, and other adults at the school for their pastoral welfare. All legitimately expected the staff to act *'in loco parentis'*, with full responsibilities and obligations, to act as if the parents of the children, including appraising themselves of the pupils' medical welfare.

263. The pupils trusted and believed the medical clinicians treating them, and again had no reason or capacity to doubt either clinicians or their teachers. The pupils' position was one of dependent boarders, reliant on the professionalism of the teachers and clinicians.

264. The school's obligation – educational and clinical - was to provide medical care, in the best interests of the children, it was not to assist the interests or research, of other parties, clinicians or pharmaceutical companies. As well as a Headmaster and Housemasters, LMT employed: nurses; physiotherapists; speech therapists; occupational therapists, and a College Medical Officer. Such were separate from the NHS Hospital and Haemophilia Centre. They too owed duties: legal and moral, to the children they cared for.

265. Over the relevant period, the Medical Officer, Dr. Pat Tomlinson, confirms in her statement[162] that the '*Haemophilia Centre operated independently of the medical decision-making being made by her and her team'*; and she had no part to play in any haemophilia or treatment issues for haemophiliac boys. There is suggestion of some input by her in one of the protocols for studies. Thus, her evidence was that the Haemophilia Centre appears to have been a law unto itself, despite the majority of its patients being pupils at the school, reliant on the school to oversee their holistic welfare.

Research and Clinical Trials

266. Former pupils strongly feel they were identified as a '*research or testing commodity*' for haemophilia doctors and pharmaceutical companies; and targeted for product research. They deny that either they or their parents, were given the opportunity to provide informed consent for such, and often had no knowledge of it occurring.

[162] WITN5578001, §16

267. Correspondence in September 1967 identified reference being made to a grant having been obtained to establish '*a research unit for the study of the treatment of certain aspects of haemophilia*'[163]. The comments of the School Warden in that letter are indicative of the school's knowledge, that medical research was a feature moving forwards, together with the school's and clinicians' perception of the haemophiliac boys attending the school and a potential for establishing research cohorts:

"... there are nearly 40 haemophiliacs in the college, and we have long felt that they provide an opportunity for research, which should not be missed ... The project has the enthusiastic support of the Haemophilia Society and will be carried out with the closest possible co-operation of the Oxford Haemophilia Centre, Medical Research Council Laboratory ... The proposed study ... will deal with three aspects of the treatment... (1) Treatment of acute joint and muscle haemorrhages with plasma preparations: "pool" factor VIII rich cryoprecipitate ... This investigation will be extended ... to embrace ... regular, precautionary injections of factor VIII concentrate..".

268. Dr Rainsford was a Research Fellow appointed at LMT Hospital in 1968. He introduced a 'Treatment Research protocol', when setting up the coagulation laboratory in 1968.[164] After inception of the Haemophilia Centre in 1972, and transfer to the LMT school in 1978/9, it is questioned why similar protocols on *specific product use* and/or *specific to each pupil* were not apparently devised or adhered to?

269. Another letter sent to Mr. and Mrs. Cuffley, dated 14th February 1969[165], also from the School Warden, confirmed a grant had been obtained to appoint Dr. Rainsford to the College's staff, along with a laboratory for his use. He was to be "… *concerned with the welfare of boys suffering haemophilia ... and will co-operate with and advise staff of the Treloar Hospital regarding their treatment ... Dr. Rainsford will work under the direction of Dr. Rosemary Biggs of the Oxford Haemophilia Centre ...*"

270. This grant was extended in 1971[166] to allow Dr Rainsford to remain employed by the college, it being anticipated '…. *Dr Rainsford will stay in the locality of Lord Mayor Treloar College and will continue to work at the Centre for the next two years in the capacity of Clinical Assistant and Honorary Consultant in Haemophilia. During this extension of his work, Dr. Rainsford will support the Centre, complete his present research projects, and give assistance to the new Research Fellow.*

The present arrangements at the College are particularly suitable for a specific type of research into haemophilia and other coagulation disorders, namely the study of the relationship between laboratory findings and close day to day clinical observations. It is the only establishment in the United Kingdom which can provide the opportunity and

[163] Letter to Mr. & MRs. CUFFLEY from the College Warden, Sept'1967 [WITN 7547002].

[164] Transcript, LMOT presentation, 21-6-2021, p.28-29

[165] WITN 7547002

[166] SWCX0000003_008 at page 2

the facilities for extensive clinical trials of various kinds of treatment which cannot at present be conducted anywhere else'

271. The grants obtained with the College Trustees' knowledge, and a research unit was set up for the study of '*certain aspects of Haemophilia and closely related conditions*'[167]. The Treloar Haemophilia Centre was then formed in 1972; and after previously working under Dr. Rainsford, Dr. Aronstam became the Haemophilia Director in 1977, and moved the Centre into the School. [168]

272. The first of a series of hepatitis studies of haemophiliac boys is detailed by the Inquiry as occurring over the period of Summer 1970 to Summer 1973. The purpose was to consider how the patterns of critical illness correlated with frequency of transfusion to 54 boys, and to consider the presence of serum hepatitis in the blood and blood products with which they were treated.[169]

273. In addition, in the mid 1970s, an application relating to funding Dr. Kirk as a research fellow at the Centre made specific references to studying at LMT '*the complication of (commercial concentrates) treatment...*' and "*... the danger of contracting the blood-borne viruses causing hepatitis is also increased. The residence of these boys in one place provides an ideal opportunity to study this ...*" [170]

274. A letter sent to the Medical Research Council on 10th January 1973 confirms the DHSS as paying the costs of the drugs for a *'Trial of Factor VIII concentrates at Lord Mayor Treloar College'*[171]. At the UKHCDO meeting held in October 1972[172], it was noted that such trial had been previously opposed by various other Haemophilia Centres (on ethical and practical grounds), with Dr. Biggs stating '*perhaps the only place where it could be done would be at Lord Mayor Treloar College*'.

275. Immuno and Hyland commercial concentrate products were proposed for that trial, with NHS products initially rejected. The meeting minuted that '*... co-operation of Haemophilia Centre Directors would be required wherever possible to obtain parents' consent for boys in the trial ...*' Later documents indicate the 'home' treating clinicians would be responsible for obtaining the required parental consent, not the trial clinicians at LMT[173].

276. As noted by the Inquiry, protocols for this trial did not inform participants of possible risks associated with receiving more concentrates than required for 'on demand'

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[167] WITN 7547002
[168] Transcript, LMOT presentation, 21-6-2021, p.29-30
[169] HHFT0000053_001 & HHFT0000332.
[170] AMRE0000011_006
[171] MRCO0000065_013
[172] HCDO0001015
[173] DHSC0100026_147

treatments, with possibly enhanced risks of infection with hepatitis viruses other than HBV[174].

277. The trial commenced in the summer of 1973, ending in January 1975. A paper was sent for publishing to the British Journal of Haematology[175] in July 1975, essentially stating prophylactic therapy works, reducing overall bleeding by 15% with a 73% increase in the use of therapeutic materials.
It is submitted that on any analysis, the risks of increased infection, and increased material use would not justify a 15% reduction in bleeding.

278. At a Haemophilia Centres Directors' meeting in September 1975[176], Dr. Kirk at LMT proposed: studies on the incidence of hepatitis, in haemophilia patients receiving therapeutic material of known types: cryoprecipitate, Kryobulin and Elstree Factor VIII, be conducted at three locations, including LMT. Under the research protocol[177], patients were to be kept on one product for research purposes; and the same batch where possible, as he recognised that as at 1975, other, as yet unknown viruses caused post-transfusion hepatitis.
The Inquiry rightly questioned[178] why such approach was not the baseline approach to be adopted at the school in ALL Administrations of therapeutic treatments, if it was recognised it was safer for the pupils / patients to do so in a study.

279. The stated purpose of the proposed study was to ascertain "*Does the administration of factor VIII concentrates, to haemophiliacs on regular replacement therapy, significantly increase the incidence of transfusion hepatitis*?'. HCDO discussion of the protocol noted the increased probability of infected donors was greater with commercial factor VIII, than with NHS Factor VIII, as such was derived from larger pool sizes (2,000 to 6,000 compared with 500-750). The Protocol itself referred to Prince's article which suggested a tenfold increase in the level of risk.

280. At LMT under that 1975 Trial, the 'subjects' or 45 pupils comprised: cryoprecipitate (21 boys); Kryobulin (8 boys); Hemofil (6 boys); Profilate (1 boy); Elstree F8 (4 boys) Factor IX (5 boys). The Inquiry identified countless examples of interactions between LMT and the home Haemophilia Centres about the study[179], but no records providing any detailed information to the patients or parents is apparent. Insofar as any information was being provided, parental replies suggest limited information was forthcoming, with oblique references to 'other substances'[180]

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[174] Transcript, LMOT presentation, 25-6-2021, p.92-93
[175] NHBT0000091_036
[176] OXUH0003735
[177] CBLA0000312
[178] Transcript, LMOT presentation, 25-6-2021, p.128, ln 9-11
[179] Transcript, LMOT presentation, 25-6-2021, p.130+
[180] TREL0000147_018, TREL0000070_027, etc

281. It is submitted those 45 pupils were subjected to a study, seeking to test the wilful transfer of an infectious disease, NANBH, which duly infected those identified as being given commercial concentrate products. Several were noted as suffering chronic active hepatitis and chronic liver disease (15 out of 45 boys as at April 1978)[181]

282. The Inquiry investigated further 1977trials at the school of prophylactic treatments, building on the previous trial that ended in 1975; undertaken during 1976-1977, with findings presented to the Haemophilia Centre Directors in January 1977[182]. Concerns were expressed over 'large scale use' of prophylactic treatments. Those findings were later published[183].

283. All the LMT trials involved between 5 and 15 boys each, and entailed cryoprecipitate, commercial and NHS Factor VIII products, administered without restriction. This was the case, despite earlier acknowledgement that limiting exposure to one type of product or batch was perceived as a safer practice, and undertaken as knowledge of increasing chronic infections from concentrate use was emerging.

284. Trials were also undertaken to make direct comparisons on the efficacy of competing commercial products – Armour and Hemofil[184]. Informed patient consent was required under the protocol, but there is no evidence of what pupils/parents were to be told, or that they were even so informed. The Inquiry has highlighted a 'generic' consent form produced by Dr. Aronstam[185] which does not identify any specific product, any risks, nor any rights of the patient.

285. A meeting on the 28-3-1979, seeking funding to move the Haemophilia Centre on school grounds), minuted Dr. Aronstam, who:
'…. *emphasised* ***the necessity for research as the concentration of haemophiliacs found at Treloar's is unique within Britain*** *…. The need for continuous monitoring of the levels of Factor VIII given to haemophiliacs in order to compare the relative effectiveness of different dosage levels … the benefits of intensive prophylaxis and the effectiveness of DDAVP in the treatment of mild haemophilia should be further investigated…'.*

286. It is also clear from that meeting, that Dr. Aronstam regarded the cohort of haemophiliac boys at the college, as a '*unique*' opportunity for research and clinical trials, a view which other clinicians recognised over many years. Later examples include:
    a) Dr. Painter (Clinical Officer at LMT 1977/78) w/s, p.9 – refers to the boys '*enrolled in the hepatitis study*'[186].

[181] CBLA0000756
[182] PRSE0002268
[183] RLIT0000093
[184] HHFT0001201_004
[185] TREL0000012_113, TREL0000108_158
[186] WITN5277001

b) A letter dated 10-5-1979 from Dr Craske to Dr Aronstam, requests feedback on a study of NHS Factor Concentrates and the incidence of patient hepatitis, which was nearing the end of its first year. He made proposals for a second year of study[187].

287. It is apparent that pharmaceutical companies were also benefitting from research at LMT. Many core participants were shocked to hear:

(i) Pharma companies were also providing grants to the College to fund research[188], with the 'Acknowledgments' in a written report including Armour Pharmaceutical for funding it; and

(ii) they were involved in setting out the protocols for research being conducted at LMT[189], as well as reimbursing costs incurred upon receipt of an invoice, when research funds were exhausted. T

Armour were not alone. Minutes of a Cutter Laboratories Board meeting in December 1980 record Cutter looking into '*providing some form of financial support for a research fellowship to Dr. Aronstam'*, after its representatives made promises to that effect, to try and boost their sales[190]

288. In addition to the above, UKHCDO figures for 1980[191] confirm LMT use of Speywood's Humanate product for the first time. Adrian Goodyear[192] states that in September 198, 50 haemophiliac boys were chosen for an 8-month trial on US Speywood products, including him. He recalled different coloured bottles were noted by the boys, and he recalls mild adverse reactions post-injections.[193] There was no prior discussion.

289. Mr Goodyear understands all 50 in the trial were infected with HIV[194] along with an additional 6 more who joined it. He considers LMT '*was a gift of an establishment for the pharmaceutical companies to try out their products, whilst knowing little boys and young adults were being maimed and harmed en masse*' (§43 of his witness statement).

290. It is not proposed to repeat all the various studies undertaken at LMT, including those on inhibitors, DDAVP, etc. It is submitted that all these trials confirm the former pupils' perception, that they were utilised in studies for the effect of treatments on their own health. The school's / clinicians' first duties should have been to treat their pupils / patients with appropriate and suitable therapeutic treatments, not to pursue research.

291. Such trials also indicate probable collusion among the clinicians to ensure a sham '*consent*' for the research: full risks were never explained or documented to parents or pupils; 'ethical' concerns with some studies that led several Haemophilia Centres

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[187] HHFT0000916_003
[188] RLIT0000104
[189] HHFT0001201_003
[190] BAYP0000021_063
[191] HCDO0001388
[192] §34 of w/s & Transcript – Adrian Goodyear, 5-6-2019, p. 65, ln 22 and WITN1243001
[193] WITN1243001 §32-34 & Transcript – Adrian Goodyear, 5-6-2019, p. 67/68
[194] Transcript – Adrian Goodyear, 5-6-2019, p. 68-9, ln 20-5

declining participation were not particularised. The approach under the Hippocratic oath is to 'not do any harm'. It is submitted, the administration of known higher risk products, likely to induce disease, was doing harm when safer less riskier products and processes were available.

292. Their own studies and research had specifically recognised the greater risks of infection from commercial products, mixed products, and different batches, but LMT provided these as its standard treatment anyway, both before and after those trials. Pupils not enrolled in trials were still being given multiple products during the currency of select product trials, before all were reverted back to multiple products and batches.

293. Furthermore, it was ruthlessly deemed appropriate to undertake studies on children from aged 7 or 11 upwards, in this 'unique' cohort environment of LMT, using toxic commercial concentrates. They were vulnerable and dependent, and behind it all, pharmaceutical companies benefitted whilst clinicians sought to enhance reputations.

294. Such evidence fuelled the surviving pupils' reflection or perception their treatment was a form of research for others, rather than for their own best interests. Despite suggestions to the contrary, it is clear that neither they, nor their parents, ever gave informed consent to any research, let alone were ever informed of the risks.

295. Whilst grateful for the investigations undertaken by the Inquiry, the evidence heard has rocked the surviving infected and affected to the core. Child ignorance of the events surrounding their treatment has been shattered by the truth, and the actual occurrences of the trials and research that was occurring.

296. In his book (1985)[195], Dr. Aronstam confirmed he was collecting research data on the boys from 1977, and detailed the different forms of prophylaxis administered at the college. Contrary to assertions in his book, it is submitted he did not let the patient decide on treatment. It is apparent prophylactic treatment was a habitual feature for LMT's pupils, and had been from an early stage, as evidenced by Dr. Arblaster's request on the 19th August 1972[196], for funding from the DHSS for '*a research grant for a prophylactic trial in haemophilia*'.

297. Examples confirming this penchant for prophylactic treatment are found in the testimony of: Richard Warwick – '*...they were crazy about prophylactics at Treloars ...*'[197] [referring to Mr Warwick's treatment notes in 1982, with every line recording '*Factorate prophylactic*'[198]]. Adrian Goodyear corroborates factor concentrates were regularly given prophylactically: '*there was plenty of it'*.[199]

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[195] RLIT0000666_106
[196] DHSC0100026_146
[197] Transcript R. Warwick - 20-7-2019, p.67, ln 18-25)
[198] WITN1592023
[199] Transcript – Adrian Goodyear, 5-6-2019, p.70

298. Such witnesses now question – with some support on the evidence – '*Was this treatment approach necessary*?' It is submitted that it was not, and that research was an influencing factor.

299. None of the former pupil witnesses identify any discussions with them, their housemasters, teachers, or their parents, as to the risks associated with their treatments. This accords with the Inquiry Team's investigations.[200] If anything, pupils felt they were told by clinical staff, that they 'had to take the treatments to avoid the risk of brain bleeds'; and such was necessary.

300. This is hardly the suggested '*collaborative approach*' touched upon by the Chair, when referring to Dr. Aronstam's (1985) claims in his book.[201] Furthermore, any reliance placed upon Dr Aronstam's assertion at paragraph 136 of his Thesis, that '*consent was obtained from the parents and the boys themselves'*[202] must now be wholly discounted.

LMT Knowledge of the risks of infection from factor concentrates and treatment choices

301. The incidence of hepatitis is documented at LMT from as early as 1969[203]. The Inquiry identified outbreaks of hepatitis infections at the school in 1974, and 1975, following treatment with a Hemofil batch and other concentrates.

302. Clinicians at LMT attended UKHCDO meetings, where issues of hepatitis were regularly ventilated. Reports of NANBH were linked to Kryobulin concentrate use in January 1976[204], with raised liver tests noted as increasingly common in the boys who had been jaundiced in January 1978[205]. The Clinicians were patently aware of the risks associated with concentrates.

303. During haemophilia treatments at LMT, the incidence of Hepatitis as a transmitted viral infection was considered and accepted as '*the norm*'. Former pupils' stated evidence is that '*we'd all go yellow*'[206] and pupils would '*regularly*' develop jaundice.[207] Despite general medical knowledge at that time concerning: Serum Hepatitis (HBV) and NANBH (later HCV); the school and its medical staff accepted hepatitis would occur from use of factor products, frequently adopting an attitude stating *'Don't worry about it, it's just yellow'* and that it was insignificant.[208]

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[200] Transcript, LMOT presentation, 25-6-2021, p.35+.
[201] Transcript, LMOT presentation, 25-6-2021, p.7
[202] (TREL0000517_0155
[203] TREL0000382
[204] TREL0000070_056
[205] TREL0000100_096
[206] Transcript – Adrian Goodyear, 5-6-2019, p. 62, ln 4-5.
[207] Transcript – Adrian Goodyear, 5-6-2019, p. 76, ln 15-16.
[208] See further statements of Nick Sainsbury [WITN1800001] & Witness WITN3224001.

304. Given the known risks of potentially viral hepatitis, it is considered somewhat surprising that the following issues were also apparently overlooked (or not discussed) by the School or its Clinicians, including:
   (a) Whether or not the clinicians should treat every bleed, and what alternative treatment therapies to blood products may have been available, e.g., aspiration and rest.
   (b) Identification and communication of the risks associated with the products being utilised/deployed, and whether such was justifiable.
   (c) whether only cryoprecipitate should have been routinely used (with smaller donor pool sizes, and reduced risks of hepatitis and later HTLVIII).
   (d) If the prophylactic treatment regime should have been applied across the board at all, and/or in light of the personal circumstances of each pupil, or considering the risks accompanying overuse of concentrates.
   (e) The use of alternative products (when available), which were known to be safer, e.g., DDAVP.
   (f) Restricting use of factor 8 concentrates being administered to individual patients, to: specific products; commercial / NHS sources only; and specific batches within those products.

305. There were no formal liaison or discussions documented or recorded, as occurring between pastoral and medical staff, regarding any of the foregoing issues; nor were contributions ever invited from the children's parents. In fact, from the evidence the Inquiry has heard from Parents and pupils alike, the opposite was true[209], and it is submitted that the clinicians were permitted to act in an unfettered manner, encouraging pupils to attend the 'Fridge room' alone, to select and mix (or pick up) their Factor concentrates, to learn how to administer their own injections[210] under the guise of teaching independence.

306. As stated, Dr. Aronstam was the treating haemophilia Consultant at LMT from the 1970s. In 1981 he submitted his thesis (the "Thesis")[211] to the University of Southampton, on the study of LMT haemophiliacs between 1973-1977, and such confirms his knowledge of the risks of transmission of HAV, HBV and NANBH, through the use of plasma therapy.

    He writes:

> [p.77] '*…but the risk increased markedly with the introduction of pooled concentrated preparations of factor VIII…*' and '*… fraction AHF prepared from large donor pools carried a higher risk than cryoprecipitate …*'

    whilst noting that NANBH was [p.79]

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[209] Transcript 23/06/21 pg 69 para 20-22
[210] Transcript – Adrian Goodyear, 5-6-2019, p. 59, ln 6-8.
[211] 'Bleeding Episodes in Severely Affected Adolescent Haemophiliacsand their Management with Replacement therapy' - TREL0000517_001

'..as likely to progress to chronic hepatitis as the Hepatitis B variety ....' and *'... at present about half of all severely affected haemophiliacs have persistently abnormal liver function tests and more than half of these will have histological evidence of serious chronic liver disease ...'*.

307. The Inquiry has also highlighted from his thesis [page_086] '*…As preparations of factor VIII became more freely available, so reports of undesirable side effects became more and more frequent, culminating in the realisation that widespread parenchymal liver disease appeared to be a direct consequence of transfusion therapy ..*".

308. Dr. Aronstam's thesis concluded [p.79/80] " *...The addition of a further chronic disabling disease to the lot of patients already suffering from severe haemophilia, is a therapeutic catastrophe and will be a major concern to those concerned with transfusion therapy of haemophiliacs for some time to come.*'

309. It is submitted Dr. Aronstam did *not* heed his own warning, in those or the ensuing years. He was advised by Dr. Craske in October 1979, to keep patients on the same single products – NHS or Kryobulin[212]– where possible as such was deemed safe. This was ignored.

310. The evidence indicates that after attending a conference in 1980, Dr. Aronstam was aware of the safety benefits of viral inactivation, from using heat-treated Behring factor concentrates, and tried to manufacture his own version at the school in 1982[213]. He did not obtain, manufacture, or administer such inactivated treatments despite his knowledge in 1980, which was a missed opportunity for his pupil patients.

311. Significantly, Dr. Aronstam was also one of the many clinicians attending the Heathrow Airport Hotel meeting with Immuno representatives, on 24th January 1983[214]. Immuno informed the meeting of their trial products which were providing good results on viral inactivation.

312. At that meeting, it is minuted that in relation to NANBH, and ongoing clinical trials of concentrates: Dr. Hill and Prof Hardisty had "… *pointed out the ethical difficulties of using newly diagnosed children as first candidates in the trial. This is* ***because children may be safer on cryoprecipitate*** *because of the possible toxic effects ...*". It was stated '***Young children could not be used for trials*** *as neither they nor their parents could give consent*', and that tests to date had identified '*NANBH as the main problem'* (§7).

313. In relation to the emergence of AIDS, Dr. Craske is minuted as summarising the known information: it had an incubation period of 6 months to 2 years; a 45% mortality rate (as

[212] HHFT0000909
[213] Transcript – Adrian Goodyear, 5-6-2019, p. 63/64
[214] see PRSE0002647, list of attendees at 004; and DHSC0001800

at December 1982); and 10 haemophiliacs had been infected following prolonged treatment with factor concentrate, with 5 deaths (including one as young as 7 years old). Those infected included a transfused 20-month baby (in San Francisco), who had gone on to develop AIDS. It was noted '*there may be a barrage of viruses being transmitted'*, including NANBH.

314. The Clinicians discussed Desforges' *New England Journal of Medicine* article (13-1-1983)[215] commenting on the discovery of concentrates, the associated risks of liver disease, hepatitis, and infections known to include AIDS, and that '*treating haemophiliacs with factor VIII preparations may exact a high cost*' (indeed a fatal one). It was noted patients '*treated with commercial concentrates of factor VIII appeared more likely than those receiving cryoprecipitate to have abnormalities of T-cell subpopulations.*'

315. The article compared exposures of one-donor pools (cryoprecipitate) to that of 2,000 to 5,000 donors in commercial concentrates pools. The fact that haemophiliacs were at risk of AIDS '*is becoming clear*', and if '*use of cryoprecipitate will minimize this risk, current home-infusion program needs to be revisited*'. It concluded '*Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself*'. Nevertheless, Professor Bloom's meeting summary proposed further trials in the UK to obtain a licence, including that *'... (d) The material could then be used on* ***newly diagnosed children***.' [emphasis added]

316. Similar matters were ventilated at the UK Reference Centre Directors meeting of 14th February 1983[216], which Dr. Aronstam also attended. Such noted that patients in the UK who had received US concentrates might be at risk. It appears that LMT then began looking for signs of AIDS and/or Aid Related Complex (A.R.C) in its pupils[217].

317. Somewhat remarkably, despite Dr. Aronstam's established knowledge since the 1980 conference, and attendances at the Heathrow and UK Reference Centre Directors meeting in 1983, UKHCDO figures for LMT's use of cryoprecipitate in 1982/1983 – see below - was essentially 'zero'[218]; with the majority of LMT pupils still being treated with multiple commercial concentrate products. The figures indicate a rate of x2½ commercial products to NHS products in 1983.

318. It is submitted Dr. Aronstam did not revert to using cryoprecipitate at precisely the time when any objective assessment of the situation would have expected such. Nor did he secure virally inactivated treatment products, despite being aware of their existence and where to obtain them from.

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[215] PRSE0002410
[216] HCDO0000411
[217] TREL0000267_028
[218] HCDO0001686

319. Furthermore, as regards Haemophilia B pupils, it is queried why the school was even importing commercial Factor IX products, when the UK was effectively self-sufficient in such? There is no logical justification or basis for such, as pointed out by a concerned parent, Robert Nicholls to Dr Wasseff.

320. Further, it was noted by the Chair[219] that in March 1983, Heat-Treated Hemofil concentrate had been licensed in the USA, and was potentially accessible in the UK on a 'named patient' basis. One questions why, after attending the 1980 conference; being aware of the benefits of virally inactivated products, attending the meeting at Heathrow and the Reference Centre Directors meeting, ANY Haemophilia clinician would continue to import and use, non-heat-treated concentrates, on children or any patients?

321. Contracts with pharmaceutical companies should not have been entered to distribute potentially fatal treatments. If cryoprecipitate was discounted for its (albeit much lower) infection risks or other perceived (disputed) disadvantages, a viable alternative was licensed by the FDA from March 1983 which was safer than the ongoing use of non-heat treated products. If they had to import anything, they ought to have imported a safer product, even if on a 'named patient' basis, to reduce risk and safeguard pupil welfare.

322. It is recalled that a Public Health Laboratory report (10-9-1984)[220] identified a series of batch numbers, related to the Bristol & Cardiff AIDS cases, which included an Armour infected batch R6511. This batch was distributed at LMT: [*Richard Warwick linked this batch to his LMT medical notes, showing he received it on: 29-6-1978, 28-9-1978*[221]]. At no stage did he receive any 'lookback notification' in connection with that batch.

323. There is no evidence demonstrating that Dr Aronstam: medically liaised with the pupils and their parents; gave any information of the risks associated with the various treatments being administered; sought to reduce risk by reverting to cryoprecipitate; or demanded heat treated treatments from 1980 onwards. He appears to have carried on as he had always had, knowing of the risks to the boys. This was without any checks, balances, or adequate supervision by the school, its Headmaster, trustees, school's CMO, or any of the staff employed to safeguard the welfare and pastoral needs of the boys.

324. Evidence of Dr. Aronstam's policy towards treatments was identified by the Inquiry, in his thesis, as being (in relation to the most prevalent elbow bleeds) '*to treat these bleeds vigorously*'[222] This reflected a practice of increasing use of concentrate materials, identified in UKHCDO figures.

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[219] Transcript, LMOT presentation, 21-6-2021, p.78, ln 6-13

[220] WITN1592026

[221] Transcript 20-06-2019, p.70-72, ln 20-22 & WITN1592-026 & -051)
, p.70-72, ln 20-22 & WITN1592-026 & -051)

[222] TREL0000517, page 113

325. The Inquiry has forensically considered LMT's UKHCDO returns from 1976 onwards[223] which demonstrated that over the ensuing years:

(a) a significantly reduced use of cryoprecipitate, becoming virtually zero in 1982[224] and 1983 (i.e., *when approaching the peak of contaminated products, and as medical knowledge of HIV/AIDS was developing*) which is staggering.

(b) a substantially increased use of commercial concentrate products and suppliers from 1976 onwards.

(c) increasing use of NHS concentrates, but such still being significantly less than the level of commercial products (generally at around 1:4).

(d) the vast majority of individual pupil patients received multiple manufacturers' factor concentrates – frequently from 3 or 4 manufacturers in any given year. Those restricted to a single manufacturer were the minority, tended to be older out-patients, and did not receive what is described as '*the full platter*'[225].

(e) There was no attempt to restrict pupils to a designated batch from one specific manufacturer either, within one type of product. Instead, increased exposures to increased number of donors was rampant, with a consequential exponentially increased risk of infection from contamination.

326. This forensic examination confirmed the former pupils' witness testimony, that they were frequently given a range of different concentrate products without explanation. The Inquiry highlighted two 9-year-old children, who received (all in 1979): Factorate, Koate, and Hemofil products; with the other: Elstree F8, Koate, Hemofil and Kryobulin products[226]. An almost identical pattern of multiple products will be found in the random selection of medical notes for any pupil at the school, into the mid 1980s.

327. In as much as there is evidence of any policy criteria for product selection, the evidence indicates Dr. Aronstam's priority was '***convenience*** *of administration*'[227] with Hemofil "*the preferred option because it went into solution more quickly that the others*". Thus, product safety, or the best interests of the patient is not identified as a primary or any concern for him.

328. Further, when home clinicians proposed restricting pupil's treatment to NHS products only, Dr. Aronstam did not comply. Instead, he continued administering commercial concentrates[228] in increasing proportionate rates over the years.

329. Evidence of Dr Aronstam's justification for his range of product use is recorded as a desire *not* to confine the boys to a single type of concentrate due to '*difficulties we*

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[223] Transcript, LMOT presentation, 21-6-2021, p.48+
[224] HCDO0001590
[225] Transcript, LMOT presentation, 21-6-2021, p.57
[226] Transcript, LMOT presentation, 21-6-2021, p.60
[227] Transcript, LMOT presentation, 23-6-2021, p.127 (ln 4-14), p.128 (ln 14-17) & IPSN0000331_008 Transcript, 23-6-2021, p.129 (ln 9-13), & WITN5277001 p.9
[228] Transcript, LMOT presentation, 23-6-2021, p 137- TREL0000175_090 & TREL0000036_004

experience in supplying replacement material for 55 severe haemophiliacs'[229] : Dr. Aronstam's letter to Dr. Swinburne, dated 23-4-1979, concerning Richard Warwick's treatment] affirming the aforesaid *convenience* criteria selection. Although the 'convenience of administration', mentioned above might conceivably be thought to benefit the patient in addition to LMT, the convenience of procurement mentioned in this letter to Dr Swinburne is the convenience of the institution alone. Giving patients unsafe product was thus rationalised to a fellow clinician on the mere grounds that it would have (allegedly) been more difficult for LMT to procure safer product. Even taken at face value, this is a poor reason for exposing children to fatal diseases.

330. The Chair queried how similar sized Haemophilia Centres appeared able to obtain, and maintain, use of concentrate products when LMT were unable to do so? It was highlighted that although there may be more severe haemophiliacs at LMT, its distinctive feature was it was predominately a child patient centre (*and thus PUPS*)[230] which may have influenced matters. Such echoes Dr. Aronstam's minuted comments in the 28-3-1979 meeting (detailed above).

331. The Inquiry's forensic product analysis also identifies that non-factor concentrate treatments, such as cryoprecipitate and DDAVP, became unusual, then exceptional; and allocation of specific batches or products, to specific pupils to attempt to reduce risk, rarely featured in the treatment programmes[231]. Such would have been easy control measures to implement.

332. The Inquiry noted[232] an absence of any explanation for the approach that was adopted and deemed it most likely to be an 'administration' decision by the Treloar's centre.[233] Such is in keeping with Dr. Aronstam's general approach to haemophilia treatment during his tenure.

333. The Inquiry heard witness evidence that in or about 1991 Dr. Aronstam blamed pupil infections with HIV on 'PHLS'; for not implementing use of heat-treated products, he claimed to have previously requested/suggested[234]; and that he was racked with guilt according to the boys, declaring '*We f...#..d up!*'.[235]

The School staff - Where were they?

334. Although some generic consent forms for various medical procedures[236] were obtained, the **school's staff** ought to have informed themselves as to what was happening medically

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[229] WITN1592011
[230] Transcript, LMOT presentation, 23-6-2021, p.134-135
[231] Transcript, LMOT presentation, 21-6-2021, p.71
[232] Transcript, LMOT presentation, 23-6-2021, p.135-136
[233] Transcript, LMOT presentation, 23-6-2021, p.136
[234] §30/31 of w/s & Transcript – Adrian Goodyear, 5-6-2019, p. 75-76
[235] WITN1243001 - § 47, §56. Transcript – Adrian Goodyear, 5-6-2019, p. 75/76.
[236] Transcript, Mr. MacPherson, 24-6-2021, p. 83, ln 8-25

– how and what the children were being treated with – and to question clinicians, to discuss and/or update parents at home.

335. The school's prospectus states '*The Regional Haemophilia Centre has been situated at the Upper school since 1978, and there is a close liaison between the Director and the College Staff over the education and care of the boys suffering from haemophilia*'[237] (our emphasis). The evidence shows this was not the case. There was neither close liaison nor compassionate care in respect of their medical treatment.

336. The staff's failure to engage with the pupils' haemophiliac welfare left those children defenceless, and prone to the whims of the clinical staff and external influences and/or collusion with pharmaceutical companies. The clinicians had one eye on research, whereas the pupils were a vulnerable, captive, cohort of patients, unsullied by excesses of adult lifestyles, and untested by treatments in all other respects. Clinicians and pharmaceutical companies recognised their uniqueness; and exploited it. It should have been the function of the school staff to act as a barrier to this, and to ensure what was best for the children.

337. The school's Headteacher, Mr. Macpherson, did not ensure any scrutiny or supervision occurred at all. The pupils were left without advocates. Instead, from the top down, the Head '*left all medical matters solely to the doctor*' and did not involve himself [238]. This was wilfully turning a blind eye, and a dereliction of moral and legal duty.

338. It is striking, and telling, that when it became known the boys were infected, the Headteacher avoided involvement in their pastoral welfare. In evidence, he stated he had no apparent knowledge of how the boys were being informed of their HIV diagnosis [239]; and agreed that looking back, it was: badly handled; horrific; and any pastoral care should have involved the housemaster/mistress for each boy; as well as their parents being (more) involved.[240] Mr. Scott, a housemaster, confirmed he was not involved in the process of informing the boys either[241]. It is submitted that there was a distinct lack of leadership on the part of Mr. Macpherson.

339. As the infections became known, the headmaster states he was unsure how exactly his pupils were to be informed; and whether specific staff were designated to act *in loco parentis* at any meetings to inform the boys of their infectious status and disease.[242] This led to various approaches being adopted, with some told individually, others in a group of their peers, but overall, a haphazard mechanism was implemented without any meaningful support.

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[237] WITN5561002 at page 2
[238] Transcript, Mr. MacPherson, 24-6-2021, p. 83, ln 10-22; and p.94, ln7-9.
[239] Transcript, Mr. MacPherson, 24-6-2021, p. 92, ln 17-24
[240] Transcript, Mr. MacPherson, 24-6-2021, p. 93, ln 1-17
[241] Transcript, LMOT presentation, 25-6-2021, p.11 and WITN5314001
[242] Transcript, Mr. MacPherson, 24-6-2021, p. 84, ln 14-22.

340. There was no joined up approach between the school, clinicians, and parents to the boys' HIV infections. The earliest reference identified by the Inquiry team for such, appears to be minutes of a Governing Body meeting from February 1986, setting out a 3-stage approach to be followed upon diagnosis of AIDS[243] –. This is somewhat late in the day, and at a time when the Governing Board were perhaps more concerned with media attention and adverse publicity.

341. Assertions of availability of counsellors at the school (by Mr. Macpherson and his secretary, Ms. Burton) is not something any former pupils recognise or recall. The Inquiry identifies no specific HIV counselling as being provided, and at its height only a broader counselling service available to all pupils as a matter of generality.[244] Mr. Scott confirmed that staff were not trained to offer pupils psychological support with HIV.[245] Dr. Aronstam's report to the Area Region in 1986, stated he and a nursing sister '*had done it all up to now*' belying any suggestion of the Headmaster that specialist HIV counselling had been provided to the boys by the school[246]. It is submitted this did not occur, in keeping with former pupils' recollections, and the research by the Inquiry team.[247]

342. It is apparent non-clinical staff took a back seat, did not ask questions, nor involve themselves to act as 'pupil advocates' looking after the best interests of the children for whom they had responsibility. This was a gross dereliction of legal and moral duty, an unacceptable abrogation of responsibility by the school, its senior staff, and clinicians.

343. By way of contrast, previously, in January 1978, the Headmaster banned football on medical grounds, being deemed by him as detrimental to haemophiliacs' health.[248] However, when it came to medical treatment, there was no similar interest, investment, or involvement by staff in the boys' welfare. Nor was there any consideration of all treatment options.

344. Furthermore, school employee Dr. Tomlinson's letter to parents was contradicted by Dr. Aronstam's report to the Health Authority, and instead played down the effects and consequences of AIDS and HIV infection.[249]

345. In any event, there was a review every term, involving house staff with pastoral responsibility, to discuss a pupil's haemophilia welfare and treatment should have been a minimum requirement. Staff ought to have been enquiring about treatments and ensured they were consulted; or questioned why they were not being consulted. There were no

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[243] TREL0000365
[244] Transcript, LMOT presentation, 25-6-2021, p.12
[245] WITN5314001, page 8, §41
[246] HHFT0001073
[247] Transcript, LMOT presentation, 25-6-2021, p.26
[248] Transcript, Mr. MacPherson, 24-6-2021, p. 88, ln 8-17; p.92, ln 4-5.
[249] Transcript, LMOT presentation, 25-6-2021, p.24 , RLIT0000663

reviews conducted with: the boys, clinical practitioners, pastoral housemasters, and parents. Instead, the school staff simply did not engage, leaving haemophilia clinicians to act unfettered, unquestioned, and unchallenged – despite obvious dialogue and communications occurring in many other aspects of school life, and pupil welfare.

346. The parents trusted the school staff, its clinicians and the medical services provided, to care for their children. They had no reasons not to do so; and were grateful their boys were receiving specialist medical care and a private education at a boarding school. They believed their sons had a much sought-after place, at a ground-breaking school.

347. There was little communication with them on medical matters. Meetings or other interactions did not occur to discuss testing, proposed treatments, side effects, and potential long-term consequences. This was affirmed by the evidence of one of many parents. Testimony was heard from John Peach, concerning the treatments administered to his two sons at the school, and the lack of communication, which undermines any bold assertions of consent being provided to any clinical action[250].

348. The Inquiry team's investigations confirm an absence of any meeting notes being recorded, relaying diagnosis communication, counselling and/or parents being informed.[251] A medical summary was sent to 'home' clinicians, and sometimes (albeit rarely) sent home to parents at the end of a term or year, but it did not identify prospective treatment pathways. It is submitted that any information provided was after-the-event, brief, and could not have amounted to consent, let alone informed consent, to ratify the steps taken.

The Consequences

349. HIV / HCV Infections prematurely killed, and stunted young lives, their careers, job opportunities and relationships. There has been the decimation of a generation, childhoods lost, friendships damaged and early death when just entering adulthood. Of one group of 5 boys, informed together of their HIV status, we have heard only 1 survives today.[252] There are lost careers[253], loves, families, and lost optimism for the future.

350. The school was flooded with US Pharmaceutical 'freebies' in 1983/84. Pens, stationery, backpacks, even watches, were provided as incentives for product use.[254] Witnesses said it '*was like being groomed by the pedlars of death*'.[255]

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[250] Transcript – John Peach, 22-06-2021, p68, In 3-5
[251] Transcript, LMOT presentation, 25-6-2021, p.37
[252] Transcript – Adrian Goodyear, 5-6-2019, p. 88, ln 4-9
[253] Transcript – Adrian Goodyear, 5-6-2019, p. 111, ln 11-14; p.112, ln 1-10: inability to go on a world music tour due to HIV & Insurance
[254] Transcript – Adrian Goodyear, 5-6-2019, p. 72-73
[255] Transcript – Adrian Goodyear, 5-6-2019, p. 73-74

351. There have been shocking figures of former pupils' demise: '*73 children from LMOT, known to have died from infection, 16 remain*'.[256] However, they are still dying. It is understood that the latest figures *(from Adrian Goodyear – not in evidence)* are: 122 former pupils attended the school since the introduction of concentrate therapy between 1970–1987: 32 are still living (26.23%); 87 have sadly passed away (73.31%); with 3 'presently unknown' whereabouts today. That figure of 87 includes: 72 [not 73] (59.02%) who have died from HIV/AIDS or Hepatitis.

352. Their illnesses swept the infected victims to the margins of society. Former pupils who survived feel guilty for doing so[257]; and have endured years of pain from their original haemophilia; along with epileptic attacks, fatigue, brain fog, itchy skin, irritability, mental anxiety, anguish, stigma, shame, and isolation – all from being infected and/or co-infected from simply going to school, when wholly dependent on that school and its associated clinicians, who were meant to look after them

Psychological damage: Unsurprisingly there has been a lot to process

353. Not only did/do the consequences impact on their lives, but also the lives of their families. Families have been torn asunder through death and/or alienation from children as a psychological response to infection. Parents have been deprived of their offspring, adult children, grandchildren, and future generations.[258] Excited young boys were sent off to school, many returned infected, and subsequently died from their treatment.

354. Whilst this group has been one of the closest and most supportive of each other, by reason of their common bonds and years of communal suffering –they often refer to each other as an 'extended family' – they have collectively endured the ongoing trauma of burying friends, peers, and wondering if they will be next. The Inquiry has shed light on what was going on in the adult world behind their school days – the days meant to be 'the best days of your life' which has been a difficult for process for them, albeit necessary.

355. A heavy burden for many, is 'survivor guilt', allied to feelings of isolation outside of this group. The strong bond they have arises from a unity, dignity, compassion, and support for each other, all bourne put of having had to live through this tragedy. Many feel they were exploited, or groomed into a research cohort, with their hopes and aspirations stolen from them.

356. This was not assisted when the tragedy began to unfold. The method of informing the boys of their HIV seropositive status, was unacceptable. There was no plan or consideration, with boys lined up and told '*you have it, you don't, you do, ... etc'*.[259] When communicating the fact of infection, the boys were told they had 2 -3 years left to

[256] Transcript – Adrian Goodyear, 5-6-2019, p. 99, ln 22-24.
[257] Transcript - Richard Warwick, 20-6-2019, p.98, ln 1+; Adrian Goodyear, 5-6-2019, p. 108, ln 7-9
[258] John PEACH's sons Transcript – John Peach, 22-06-2021 p91, In 1-17
[259] Transcript – Adrian Goodyear, 5-6-2019, p. 83, ln 5-12.

live. This was described as being a '*lockdown on every emotional, physical, and psychological level in every kind of relationship and we were just kids*'.[260]

357. It is evident Dr. Aronstam knew the pupils were HIV+, long before the boys were told. Contrast the accounts of Dr. Aronstam in Summer 1984 at his home, with May 1985 when boys were beginning to be told.[261]

358. Parents were not notified in advance of the communication of illnesses. Many were denied the opportunity to support their children at a crucial moment.

359. Doctors misled parents when asked as to prognosis – such as Dr Waseff to Mrs. Goodyear.[262] It was felt '*the Treloars Centre should have picked up the phone, communicated in some way the genuine truth*' to the parents.[263] Some staff were very supportive, with two members acting as *'surrogate guardians'* to a pupil to extricate him from care, when his relationship with his adoptive mother broke down because of his infections.[264]

360. Boys were stigmatized within the school (before society's greater stigma ensued upon leaving) – e.g. (i) being quizzed by some teachers on their HIV status, when teachers had been told not to ask the pupils; (ii) a 6 inch rule enforced to keep them distanced in lessons, being enforced up to 10pm at night; and they '*were made to feel diseased*' were '*isolated*'.[265]

361. The names of deceased children were read out at assemblies[266]; a haematologist doctor in Basingstoke whom they were sent to stated they did not '*know how lucky you are to have free treatment for your haemophilia*' when confirming their HIV illnesses; and made them feel '*they were the problem*' and '*like a walking disease'*.[267]

362. Many boys concluded after receiving their diagnosis that there was little or no point in life. Adolescents went off the rails, stopped trying hard at education, or pursuing their dreams.[268] A hope in a future was taken from them. Multiple infections precluded the possibility of a 'normal' life, which haemophiliacs were entitled to otherwise expect.

363. They lost their 'potential'.[269] They were left with uncertainties, e.g., housing, employment, relationships, families.[270] Society's stigma of them exacerbated matters.

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[260] Transcript – Adrian Goodyear, 5-6-2019, p. 93, ln 11-13.
[261] Transcript – Adrian Goodyear, Summer 1984 drinks at his home, cf May 1985 when told- p. 79-81, cf 81-82
[262] Transcript – Adrian Goodyear, 5-6-2019, p. 90, ln 15-17.
[263] WITN1243001, - §59.
[264] Transcript – Adrian Goodyear, 5-6-2019, p. 90/91.
[265] Transcript – Adrian Goodyear, 5-6-2019, p. 86-87
[266] Transcript – Adrian Goodyear, 5-6-2019, p. 79, ln 20-22
[267] Transcript – Adrian Goodyear, 5-6-2019, p. 101-102
[268] Transcript – Adrian Goodyear, 5-6-2019, p. 93/94
[269] Transcript – Adrian Goodyear, 5-6-2019, p. 115, ln 5-25
[270] Transcript – Adrian Goodyear, 5-6-2019, p. 114/115

All witnesses gave examples of this leading to them becoming isolated. They were consigned to the fringes of society, disadvantaged in applications for work; mortgages, insurance, healthcare, whilst being desperately sick, exhausted, and enduring the symptoms of their infected illnesses, feeling fearful about both their own futures and those of their families.

364. Very limited counselling was offered at LMT, if any. Any counselling available was generic in nature. Further, when some was later offered (as this was to occur in the very place where they were told they had been infected and were going to die) pupils did not consider it beneficial.[271] This offering was unacceptable, inappropriate, and insensitive.

365. Despite HCV levels dropping to 'non-detectable' (loosely called 'cleared') some of those infected fear the HCV may recur, with potentially fatal consequences.[272]

366. It is apparent from these foregoing that there is still a place for counselling for the surviving pupils from LMT, and those affected.

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[271] Transcript – Adrian Goodyear, 5-6-2019, p. 110, ln 5-12.
[272] Transcript – Adrian Goodyear, 5-6-2019, p. 108-109

Chapter 7 - HIV litigation

Introduction

367. *'A Government which takes upon itself the role of public provider of medical advice and clinical services is in a very different position to any commercial organisation. It is clearly arguable that their duty to innocent citizens who suffer injury under the aegis of such treatment has a moral dimension to it which should distinguish their assessment of their position from the criteria to be adopted by other defendants of a corporate character. Government owes a duty wider than to its shareholders or insurers. It should also mean that the public may be entitled to expect from Government an appraisal of their position which is not confined solely to legal principles to be found in the law of negligence, or problems of proof.'*

Sir Harry Henry Ognall 26th June 1990

368. *'No one could doubt the sincerity of the efforts of those in the Department to protect and to assist the plaintiffs as patients in the National Health Service, but on the pleaded case grave errors of judgment were made. Even if there was no grave error of judgment it appears to be not in dispute that there was in fact a failure to protect the plaintiffs from the danger of using blood products, whether imported or supplied in this country, which were infected'.*

Ralph Gibson L.J. 20 September 1990

369. To some extent the way in which the litigation was conducted by the defendant is a reflection of prevailing attitudes at the time, but when examined more closely concern must be had at a number of individual issues which this Inquiry has sought to examine in more detail, not least among them being openness/candour and cover up. In short the Government was to become confused as to the extent of its duty to fully and properly advise and inform the public and eventually chose to protect its position by an improper reliance on alleged litigation privilege.

Parties, issues, settlement, cover-up

370. What was to become known as the HIV Litigation occupied the court between 1989 and 1991 when about 960 plus claimants, largely Haemophiliacs (including wives, partners and children) took on a slew of defendants (over 200), primarily the Department of Health. The main allegations were the Department's failure to achieve self-sufficiency in the supply of blood products, the delay in the implementation of heat treatment and the resultant failure to respond properly to the AIDS crisis. Following what was in any sense a remarkable intervention by the managing judge (see 1 above) and a brief trip to

the Court of Appeal on the issue of public interest immunity (see 2 above), the case was effectively settled in the December of 1990, although the settlement was not to be approved by the court for some months, until the late Spring of 1991.

371. Group litigation at this level and on this scale was a relatively new development at the time and led to polarisation and victimisation. All be it, with, to some extent, the benefit of 2022 hindsight, it is clear that the issues between the parties called out for resolution without litigation and that it was wholly wrong in principle for the Government and civil service to force a seriously ill cohort of people infected through the fault of the state to take on litigation of this magnitude and then whilst ignoring a glaringly obvious conflict of interest, (the role of the Department of Health in being the potentially culpable defendant and for all practical purposes the party conducting and directing the litigation) push the claimants to the point where settlement was forced upon them.

372. In the words of Mark Mildred:-

> *'many considered the length of time taken from the beginning of the case to settlement of the claims was excessive and that, if the Government had intended to settle the claims, this could have been achieved in a much faster and less adversarial way'.*[273]

Litigation tactics

373. It is still unclear whether and if so to what extent reliance on public interest immunity was in fact justified. Mark Mildred had this to say:-

> *'Andrew Collins, the highly respected Leading Counsel for the Central Defendants, told Mr Justice Rougier that it was his duty, rather than a choice, to apply for a Public Interest Immunity ("P11") Certificate. Even so I regarded the application as highly tactical. It seemed to me that, if the application was successful, documents that would have shed clear light on how and why self-sufficiency in blood products was delayed so long would not be before the Court'.* [274]

374. The timing of and the manner in which the settlement was eventually announced, were both to prove critical.

375. It is now clear that settlement was announced by the Government before the claimants had in fact agreed to it and possibly more importantly before they had adequate opportunity to give full consideration to the significance and importance of the

[273] WITN5258003 at page 26
[274] WITN5258003 at page 12

documents that had recently been made available to them following the Court of Appeal decision on public interest immunity.

376. GRO-D

377. GRO-D

378. GRO-D

379. He was, however, too late, the settlement was announced later that day.

380. Mark Mildred had this to say:-

> *'I could understand why the Government, having suffered criticism for failing to settle the claims, wanted to extract maximum public relations benefit from the eventual settlement. I do not know whether they thought an immediate announcement would bounce the claimants into believing that they had to accept the terms. I thought the announcement was highly discourteous to the claimants and their advisers, disingenuous as they knew claimants had not agreed to the terms and foolishly premature as the claimants might have rejected those terms. By that stage 2 or 3 of my clients were dying every week and at least those without dependents might in fact have felt insulted, rather than vindicated by the offer. The Government knew that it needed virtually all claimants to accept the offer to avert the prospect of a trial and that public funding of the claim being ended for those who refused and wanted to carry on to trial would be a public relations disaster.*

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275 276 GRO-D

Now as then I consider this was a striking misjudgement by an insensitive public relations machine'.[277]

381. The evidence now available makes it clear that at a very early stage, a policy decision was made which was to be adhered to for the next 30 years. That policy was based on a fear of a no-fault compensation precedent. Superimposed on this was advice given to Government ministers time and again by the Department of Health that:-

    a. No one was at fault.

    b. The patients had received the best possible treatment in line with the standard of care at the time. The evidence demonstrates now that this was simply not true, however once the line had been taken, it was never broken.

382. We now know that this was simply not true, however once the line had been taken it was never broken.

383. On the contrary the theme was to be developed by the Government to a point where the only logical and reasonable conclusion which could be drawn from the public statements which were made was that it was pre-ordained destiny for the victims to become infected with HIV and suffer as they did.

384. Appearing on BBC Television on 2nd October 1990 Kenneth Clarke said that he saw no

    … 'very strong common sense case' against the health service because ... 'it was nobody's fault that this tragedy had occurred' – [278]

385. Six days later Mr Clarke told BBC Radio 4

    …. 'they were given the best treatment possible and in the then state of medical knowledge they don't actually, in my opinion, have a claim' [279]

386. However, behind the scenes on 23rd October we have evidence of concern and in turn, coverup. Just two weeks later, Mr Clarke is quoted as saying

    ….. 'some of the cases against the health authorities were very strong and were in fact straightforward medical negligence cases'[280].

387. The draft confidential memo dated 26th November 1990 from A Edwards to Chief Secretary re HIV Haemophiliacs Litigation evaluating possible reactions to a proposed settlement states:-

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[277] WITN5258003 at page 19
[278] https://www.newspapers.com/clip/27091872/theguardian/
[279] DHSC0002472_078
[280] HMTR0000002_002

> *' I understand from DH that there are more than 500 sufferers who might in principle have contracted the virus after the stage at which hospitals might reasonably have been expected to use different forms of treatment'.*[281]

388. Meanwhile the public relations machine was to roll on and a draft Conservative MP circular read

> ….. '*The Government does not believe that the measures taken and treatment provided for haemophiliacs were negligent or out of line with the state of medical knowledge*'[282]

389. In breach of its very clear obligation to do so, none of the Governments very clear concerns was ever communicated to the claimants or otherwise the public at large.

390. By now matters were moving on and on 4th December 1990, just 7 days before (and whilst the claimant's legal team were still poring over the documents which has recently been disclosed following the court of appeal ruling on PII) the Government would unilaterally announce settlement, Justin Fenwick KC had advised

> …… '*As to whether or not there had been actual negligence in the early years on the question of self sufficiency [he pointed out that] certainly 'there are some terrible gaps'* [he said] there was obviously quite a lot of neglect.

391. In giving oral evidence to the Inquiry on 9th June 2022 Mr Fenwick said

> *'so I think –'terrible gaps' and 'neglect' I think is a reference to gaps in the record'.*

392. Given a gap of over 30 years it is virtually inevitable that people's recollection of events will vary, although Mr Fenwick's explanation and his recollection of events must be put into context with the internal note referred to at paragraph 10 above. The internal note says, inter alia 'In terms of self sufficiency the crucial period is the turn of 1974/1975 through to 1982. The overwhelming impression left by a reading of these documents is of bureaucracy, inertia, fragmentation, inconsistency, inadequate/inappropriate expertise and, above all, a lack of 'Grip' by the civil servants charged with achieving self-sufficiency. There was no material shift in policy during the life of the Labour administration. The documents establish that civil servants within the Department were well aware of the increased incidence of hepatitis attaching to commercial as contrasted with NHS concentrate. In a draft submission to ministers prepared by Dr Diana Walford (a civil servant) dated December 1979 she advised:- 'certain blood products notably Factor VIII and Albumin solutions are also manufactured commercially albeit not in the U.K.… Moreover products derived from paid donor plasma are known to carry a tenfold

[281] HMTR0000002_009

[282] https://drive.google.com/file/d/1PA_82HRiiQ14syhbVEPgQQI3xS0EyuRw/view?usp=sharing

increase in the risk of transmitting hepatitis over the risk from products derived from voluntary donations'

393. The Claimants should and could have been treated differently. A fair result could have been achieved without any prejudice to the Government's position.

394. Over and above the Department of Health taking on the role of judge and jury, it also sought to control the evidence. Again, Mark Mildred says:-

> *'The community of experts in haemophilia care in the UK was small and close. I remember when I was first instructed I was introduced by a medical friend to a Centre Director who agreed to see me and make a statement about how everything worked. He then wrote to cancel, saying that all specialists had been told not to speak to the claimants' legal team. Whatever the rights and wrongs of this it made the task of developing good expert evidence for the Court very difficult. I cannot now remember from whom we obtained evidence on haemophilia care. In many product liability cases expert evidence could be obtained from abroad but in this case the 13 specific NHS context would have rendered such evidence less helpful, although we had no option but to approach experts from abroad in some disciplines'.*[283]

395. The 'litigation waiver' which was eventually included in the terms of the settlement was to become an ongoing bone of contention as the years went by.

396. Mark Mildred says :-

> *'There are a number of views as to precisely how and why and when this came into existence.*

397. He also says:-

> *'I agree with the suggestion that Hepatitis C (then known as Non A-Non B and undetectable by any test until at least summer 1990, if not later) was thought to be of far less consequence than infection with HIV. Although I was not involved when the shape of the case against the Central Defendants was decided I would have taken the same view that infection with hepatitis virus was not a worthwhile separate head of general damages in the context of these claims and adding such a claim would have generated more problems in relation to breach of duty and causation'.*[284]

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[283] WITN5258003 at page 13

[284] WITN5258003 at page 22

398. Essentially his position is that if the claimants had known that many would have gone on to live longer lives and if they had known of the damage caused by HCV he might had regarded HCV as a Head of Damages and the merits been assessed very differently. They did not and it is obvious whilst trotting out a sanitised version of events that it did, the Department of Health never made this clear to the claimants/and or their advisors.

Conclusion

399. Mark Mildred concludes:-

> *'I hope that, should there be a similar therapeutic disaster in the future, a solution can be found that saves very significantly on the time, the expenditure that did not benefit the claimants, and the suffering and distress involved in the HIV Litigation'.*[285]

400. Rupert Jackson said:

> *... 'It is unfortunate that the Government of the day did not face up to its moral responsibility in the same way that the present Government has'.*[286]

401. Whether the present Government has, or will do, still remains to be seen.

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[285] WITN5258003 at page 27

[286] WITN7202001 [4.1]

Chapter 8 - Self-sufficiency and in particular when and how it might have been achieved

402. As is our approach elsewhere in these submissions, we do not begin to try to summarise all the evidence the Inquiry heard, to repeat the immensely detailed presentations prepared by CTI, or to duplicate chronologies or timelines the Inquiry already has well in mind.

403. In respect of self-sufficiency, we point out that here, as in other areas, the Inquiry has been able to make progress and gain an understanding of events which was denied to or CPs for far too long by lack of candour on the part of government.

404. The question raised by the Inquiry – *when and how might self-sufficiency have been achieved* – necessarily involves consideration of a counterfactual situation.

405. That situation requires consideration of *when* the importance of self-sufficiency was recognised and of *what self-sufficiency is* (or ought to have been understood to have been). That *'when'* matters, because it identifies when government ought to have started taking positive steps to achieve it. The *what* matters, because in the counterfactual scenario it should <u>not</u> have been understood to mean simply the provision (or over-provision) without limitation on a prophylactic basis of as much factor concentrate as any clinician wanted to prescribe, or any patient wanted to take.

406. We need not here spell out the underlying premise of our submissions, namely that self-sufficiency ought to have been achieved as early as possible. This much ought to have been patently clear to all concerned, and indeed it was recognised belatedly by various actors – as detailed in the next section below.

(i) What self-sufficiency should have been

407. Stepping back and taking an overview of all the evidence the Inquiry heard, it is apparent that through the 1970s and early 1980s there was a drive to provide as much factor concentrate as possible. In part, this was due to the business and marketing efforts of pharmaceutical companies which stood to make (and did make) very substantial profits from their sale. In part it was due to clinicians, whose enthusiasm for being able to deliver what were believed to be (on the part of *some* clinicians, we must charitably assume) transformational products to patients blinded them to the risks of those products. Perhaps, in part, it was due to demands from patients who had been told that factor concentrates were miracle products, without having been told of the

risks associated with them. Regardless of the reasons for which it occurred, it was felt that this perceived level of "need" (which the Inquiry knows was reported by UKHCDO clinicians to be rising year-on-year) was legitimate, desirable, unstoppable and had to be met – whether by domestic production or by importing commercial products.

408. That is an instance of the tail wagging the dog. In the counterfactual scenario, we submit:

(a) Clinicians (and government) ought to have appreciated that *all* pooled factor concentrate carried a significantly higher risk of harm through viral infection than single-donor cryoprecipitate.

(b) They ought to have appreciated that (as we set out elsewhere and the Inquiry already well knows) commercial factor products made in the US carried a *very significantly higher* risk of harm than small-pool UK factor concentrates because of the nature of the donors and the pool sizes, which were inherent features of the commercialisation of blood and the scale of the manufacturing processes adopted in the US to maximise yield and profit.

(c) They ought to have known that the viral risks included what was then known as NANB hepatitis which (as we set out elsewhere) should not even then have been assumed to have been a modest, mild, transient or short-term condition. No other hepatic virus was simply mild and transient; why should this one be assumed to be? As a general statement, noted by the Expert Report on Fractionation: *"Since the beginning of plasma fractionation, there was a concern that existing and new emerging blood-borne pathogens may enter the blood supply and threaten the safety of plasma products."*[287] Since the beginning of fractionation, therefore, there were no grounds for complacency and every reason to adopt a precautionary principle.

(d) See also in this regard Dr Savidge's evidence to the Archer Inquiry[288]:

> Savidge: So you have a failure to implement self-sufficiency, which essentially was a mixture of safety and finance, to try to bring them together to make haemophilia care a little bit more cost-effective and safer, from a European perspective point of view for harmonisation. That failed in essence, and then **it became pretty clear, towards the end of the 70s**, that non-A/non-B hepatitis, as it was called then, was not merely just a biochemical abnormality that a few chemistry departments picked up. **It did have clinical impact, but not in the short-term necessarily, in the longer term, and that all concentrates made from large donor pools had a similar rate of infectivity. That is 100 per cent on first exposure.** So it is pretty straightforward. [...] group of individuals, who are quite happy to say that, you know: we just measure it with blood tests and the blood tests stay the same, so we just think it is a little bit of inflammation

[287] *Report to the Infected Blood Inquiry: Fractionation* [EXPG0000044 at page 25], page 19.
[288] ARCH0000011 at page 115 to ARCH0000011 at page 117

of blood tests from the liver. So--called transaminitis, which has no clinical connotation and which is merely a figment of a few people's imagination. So, by the time the histology data started coming through and **by the time children started developing cirrhosis of the liver**, perhaps it was a little bit more than inflammation of blood tests. So **I think the majority of responsible physicians and people treating these patients knew by the end of the 70s -- in fact pretty closely about 78 I think tipped it -- that large donor pool concentrates, whether it be for Factor B or Factor 9 were the cause of non-A/non-B hepatitis**. Nobody knew what the agent was but they assumed it was an infective disorder; it came from an infection. And as time moved on, it became proven that was the case.

THE CHAIRMAN: And by that time, was it suspected that would be conveyed through blood, through large pool --

Savidge: Very much so and that is the simple reason why 99.9 per cent of producers of commercial Factor 8 and Factor 9 in the world then started to invest money in their research and development departments to clean up their blood products.

THE CHAIRMAN: By the end of the 70s?

Savidge: At the end of the 70s, in fact the first product that was produced to go into patients was produced in Germany in 1978...

(our emphasis)

(e) Even without foreseeing HIV specifically, clinicians, regulators, officials and ministers ought to have considered that there could be other as-yet-unrecognised blood-borne viruses, the risk of transmission of which would also inevitably be magnified by larger pool sizes.

(f) They ought to have approached the use of this new medical product, particularly the version of it manufactured commercially in the US, cautiously and with the precautionary principle firmly in mind.

(g) They ought to have known (as we set out in detail elsewhere) that cryoprecipitate was significantly safer and cheaper while still efficacious, suitable for home treatment and able to be used prophylactically. And that the UK was already self-sufficient (or could readily be) in cryoprecipitate as it could be easily produced, and with greater yield, from plasma.

(h) They ought to have either not used factor concentrates at all unless and until such time as the viral risks of NANB could be eliminated or ought to have reserved their use for clear and truly exceptional cases of clinical need. Instead (as we set out elsewhere) clinicians became carried away with providing what they asserted to be life-changing treatment having inexplicably allowed themselves to become blinded to the obvious and basic risks from such treatment (when made in large pools, with poor donor selection and without viral inactivation, as it then was).

(i) Patients ought to have had the risks of pooled factor concentrates as against the relative safety of cryoprecipitate clearly explained to them.

(j) That appreciation of the true picture and true risk would have significantly

dampened patient demand for large-pool commercial concentrates.

(k) That, in itself, may well have led to increasing patient (and thereby clinical) pressure on government to accelerate and increase small-pool concentrate manufacture in the UK and/or have led to increasing patient and clinical pressure to accelerate work on viral inactivation.

(l) Factor concentrates should have been prescribed only as and when truly mandated clinically.

(ii) When the importance of self-sufficiency ought to have been recognised

409. In 1967 Dr Rosemary Biggs, respected doctor at the Oxford Haematology Centre, wrote to the then-CMO, Dr Godber (letter 22.8.67[289]). She pointed out that the UK had pioneered factor concentrate treatment, that there was a shortage of it in England and world-wide, that it was likely that US companies would shortly begin production and sale, that their products would be expensive and that everything should be done to expedite the manufacture of these fractions in England, and to accelerate the new fractionation buildings in Elstree and Edinburgh. She considered that having pioneered the treatment, the UK had the personnel who knew how to make the products and had enough plasma. Although expressed as a financial argument, her warnings about the intrusion of US companies must – to anyone with any clinical knowledge, such as a CMO – have been understood to include concerns over the viral safety of the products, given what was then already known about the process of commercial blood donation, collection and pooling in the US. It is possible to infer that she may have framed her argument as a financial one believing that this was the language the government would have understood and been influenced by.

410. This was the first *"call to arms"* to improve UK facilities and to retain control of production and treatment which had been pioneered here. Hers was not a radical view and was not gainsaid. We say this represents the state of clinical and scientific knowledge at that time, and shows the knowledge which government had (through the CMO and the DHSS). There had been consideration of self-sufficiency in Scotland from 1962/3 (see below) and there is no reason why the same had not occurred in England. The importance and urgency of self-sufficiency in England ought therefore have been recognised from (and steps taken from), at the very latest, 1967.

411. Dr Cash said that Scotland had been thinking of self-sufficiency since 1962/3 and planning their fractionation plant since 1968[290]. In consequence, they were able to open their plant in 1975.

412. By March 1969 factor concentrate (UK-produced small-pool concentrate) was being

[289] DHSC0100025_062

[290] Transcript of Interview, May 1990 at SBTS0000053_055

supplied to Treloars. Its benefits were apparent. By then, at the latest, the importance of self-sufficiency ought to have been urgently recognised.

413. In 1970 Professor Richard Titmuss' book "The Gift Relationship"[291] was published, starkly contrasting the UK and US approaches to blood donation. He considered not only the ethical and sociological aspects but also the dangers of transmitting disease. It was widely read. There is no evidence of it being considered to be contentious in the UK; on the contrary numerous witnesses from whom the Inquiry has heard have spoken of being influenced by the book and agreeing with his views[292].

414. It was not until 1973 that the Expert Group on the Treatment of Haemophilia was set up comprising clinicians and representatives of the DHSS. It first met on 20.3.73.[293] It noted that the preferred treatments were those with more purified products, then considered to be cryoprecipitate and concentrate. The risks of hepatitis from larger pool concentrates were noted. It was noted that life-saving surgery had been able to be undertaken for some time using therapeutic agents already available, but that concentrates might now improve quality of life. Against the background that two commercial products were already being imported, it was agreed that there was "*a pressing need to seek ways of increasing UK production with the intention of reducing and as soon as possible ending purchase from foreign sources*." It was essential that production and distribution of the therapeutic agents should be considered as a UK exercise with close co-operation between England, Wales, Northern Ireland and Scotland to co-ordinate and optimise blood collection and transport, fractionation and distribution. From this we draw three points:

(a) The importance of ensuring viral safety was clearly recognised by 1973; the undesirability of commercial, large-pool products, particularly from the US; and the need for co-operation and co-ordination within and across the entire UK.

(b) But this was already six years too late. None of this was new or radical thinking in 1973. It was all, already, accepted wisdom.

(c) This expert group should have been set up, and its recommendations made, six years earlier, in response to Dr Biggs' letter.

415. An article in the BMJ dated 27th July 1974, entitled 'Blood Donors and the Transfusion Service'[294] identified the beginning an NHS reliance on overseas donor products. It stated that this trend was neither *'inevitable, desirable or necessary'*; would prove a serious drain on the financial resources of the NHS over the next 10 years; and the cost would be distinctly less, if undertaken by the NHS. Evidence indicated there was no shortage of voluntary donors in Britain, but the problem was one of management or

[291] Department of Social Policy, LSE

[292] See e.g. Statement of the Rt Hon Lord David Owen (WITN0663001 at page 2, at paragraph 5 et seq), Baroness Virginia Bottomley (transcript 28.6.22), Dr David Bevan (WITN4106001 page 51, and letter to Independent 12.4.91 UHMB000000_064_0001), statement of Hugh Tunstall Pedoe (para 24), and others

[293] PRSE0004706

[294] DHSC0100024_126

administrative inadequacies. The article highlighted that since the 1950s, there had been *'no effective planning'*, with regional and protein fractionation centres lacking staff, accommodation, equipment, and basic organizational units to do the job. Medical staff were frequently geographically isolated from the care of patients. It called for an '*urgent appraisal (for the first time) of a national policy for the procurement and eventual distribution'* of blood by the DHSS.

416. In May 1975 the World Health Assembly of the WHO passed resolution 28.72[295] which noted:

(a) the increasing use of blood and blood products;

(b) the increasing activities of private firms;

(c) the desirability of national blood transfusion services based on voluntary and nonremunerated donations;

(d) the higher risk of disease when products are obtained from paid rather than voluntary donors;

and which urged member states to:

(e) promote national blood services based on voluntary nonremunerated donation; and

(f) enact effective legislation **and take other actions necessary to protect and promote the health of recipients of blood and blood products** (our emphasis).

417. The evidence of Lord Owen established that in his time as Health Minister (1974 - 1976):

(a) The case for self-sufficiency was already understood to be both on economic grounds and on grounds of patient safety / health – see also his written answer to parliament on 22.1.75.[296]

(b) The significance of the WHO report of 21.7.52[297] – almost 20 years previously – was appreciated. It considered how to minimise risks of serum hepatitis, the importance of donor selection, pool size and viral inactivation.

(c) He thought that no doctor could have been unaware from 1972 of the risks of blood products.

(d) He thought it well-known that paid blood donors would not answer honestly about their viral risk, but that in the UK – when sought – the number of voluntary donors rose (so plasma resources for UK manufacture would not be a problem).

(e) He would have let private pharmaceutical companies become involved in or run BPL as an agency – the private sector working in partnership with government.

(f) He said that he could not control the health authorities other than by money but gave no cogent reason why he did not in fact try to control them by money,

[295] WITN1055190
[296] LDOW0000032
[297] RLIT0000215

alternatively re-structure them.

(g) We note that, in his oral evidence:

(i) his view was that the medical profession failed patients by not telling them risks and that politicians failed them by not delivering self-sufficiency;

(ii) he considered that the UK should have pursued self-sufficiency (on the same rationale) earlier;

(iii) he agreed with the BMJ editorial (para 14 above) that the 'shortage' allowing pharma companies in was due to poor administration, poor organisation and underfunding.

418. In 1976 the BMJ published a paper by Professor Cash[298] in which he predicted rising future demand, identified the greater yield from plasma of cryoprecipitate than factor, and stated that *"undue delay now [in investing in BTS and re-appraising their function] may be a serious error of judgement."*

419. Plans to utilise the full capacity of the Protein Fractionation Centre ('PFC') in Edinburgh to supply concentrate to be distributed to all parts of the UK (or at least beyond Scotland, to northern England/Wales) were envisaged when PFC was originally designed. A 24/7 shift system to provide products would have assisted or eased the burden on BPL/FPL. This was again considered in March 1977 by the DHSS & SHHD after PFC's construction[299] but not pursued.

(a) It would have been practicable, as was shown by the 3-week trial of producing albumin on a 24/7 basis.

(b) In his evidence to this Inquiry, Dr Robert Perry (Quality Control Inspector and then Director of PFC from 1984-2003), could not say why there was no enthusiasm for this on the part of government.[300] Nor could he confidently say why plasma collected in Northern Ireland was not fractionated by PFC prior to 1981.[301] He stated: "*As with most endeavours of this type, increased scale creates greater efficiency. So, I think PFC always felt, certainly during the 1970s and 1980s, that it would benefit not only PFC but the UK as a whole to have a more equitable split of plasma to supply to both PFC and BPL.*"[302]

(c) He was asked by Counsel to the Inquiry: *"It might be said that the failure to use PFC's fractionating capacity more fully, so as to fractionate plasma from England and Wales, was a lost opportunity for the UK as a whole. Would you agree with that?*" [303] Dr Perry responded: "*I think from my perspective, yes, it was. **Yes**. I think others might disagree and might say the correct solution was*

[298] PRSE0003425
[299] WITN3530081
[300] Transcript of evidence 31/03/22 [INQY1000183], at page 60, line 5.
[301] Transcript of evidence 31/03/22 INQY1000183], at pages 111-112, lines 25 and 1-18.
[302] Transcript of evidence 31/03/22 [INQY1000183], at pages 56-57, lines 24-25 and 1-4.
[303] Transcript of evidence 31/03/22 [INQY1000183], at page 111, lines 4-24.

the solution we had then, which was to rebuild BPL for the whole of England and Wales. But I think a joint approach to providing the capacity for fractionating products for the UK would have been more quickly met and more efficiently met by a joint approach. And I think it would have been more secure as well. As it was, BPL were processing at least 90% of the plasma for the UK and the PFC was only producing 10%. Now, in any sensible organisation you wouldn't have that imbalance. You would say: in order to secure the long-term security of supply, or at least a minimum level, something closer to a 50/50 split would be appropriate."[304]

(d) It is unfortunate that the government of the day was not a 'sensible organisation' (see further paragraphs 20 and 22 below, along with our submissions on the organisation of the Blood Transfusion Services).

420. By 1977 the DoH Working Group on Trends in Demand for Blood Products considered (Dr Lane) that '*during the next 4 years the problems of technology and plant must be resolved*' with a need for '*changing the Department's attitude to free spending on expensive commercial imported alternatives to NBTS-produced therapeutic fractions and serological reagents*'[305] and, later, that a review of the relationships between BPL and the RTCs, as well as between BPL advisory management and the DoH, along with closer integration between the RTCs and Central Laboratories was required.[306]

421. Even leaving aside patient safety, with each year that had gone by there had been an increasingly clear and obvious economic case for self-sufficiency, given the high costs of importing commercial products into the UK to fill increasing gaps in supply. This had grown to £2m p.a. in 1979.[307] In 1980, £4m p.a. was quoted in a parliamentary debate.[308]

422. By the date of the House of Commons debate in December 1980,[309] the government was well aware of the risks of hepatic infections which were said (erroneously, as we explain above) to be occasional, minor and inevitable, the risks of commercialisation, and the risks of imported products from non-voluntary donors. However the government said that self-sufficiency in factor concentrates was a *long-term aim* (and queried whether clinicians were using too much). This was nothing new – all these points had been made and understood since 1967, so describing self-sufficiency as a long-term aim was misleading at best, and effectively admitting failure to date. In the debate there were references to under-investment and diffuse administration causing BPL to fall behind current technology and being unable to keep up with demand; to the disparate organisation of the system with 15 RTCs under the controls of the RHAs

[304] ibid.
[305] DHSC0001318 at page 12
[306] DHSC0001318 at page 30
[307] DHSC0002313_010
[308] NHBT0006435_007
[309] NHBT0006435_007

(rather than centrally), to the known risks from using pooled commercial donations; and to the need for a single unified structure. Again, none of this was new in 1980; these issues had all been evident since the late 1960s.

423. By June 1981 the Advisory Committee for the NBTS – Working Party to Advise on Plasma Supplies for Self Sufficiency in Blood Products in England & Wales[310] was suggesting increased use of plasmapheresis. Authors included Drs Gunson, Walford and Smith. They noted that small pool products (cryoprecipitate) reduced the exposure to larger numbers of donors, and thus lessened the risk of hepatitis transmission. They recommended that the best method to collect what they identified as a shortfall in plasma requirements was by plasmapheresis. They noted that a trial had been conducted at Leeds RTC, that it was considered that recruitment of donors for plasmapheresis '*should not prove insuperable if resources are made available*' and that despite initial outlay costs and annual costs '*the overall savings are clearly demonstrated.*' We contend that these conclusions were correct, but should have been reached many years sooner.

(iii) Retrospective view

424. Dr Cash, writing in the BMJ in September 1987[311] was succinct, accurate and correct in his analysis of what had gone wrong.

(a) He referred back to an article by Dr Biggs in 1977 wherein she was concerned about rising demand in UK for Factor VIII, high cost of commercial products and higher risks of transmitting viruses from commercial products than from voluntary donations. (Of course, she was right in 1977, but had been saying the same thing since 1967, as we observe above).

(b) Dr Cash pointed out the massive rise in commercial concentrate use in England from 1977 to 1985 (whereas he said in Scotland there was no use of commercial concentrate by 1985).

(c) He referred to the *sustained failure* over last 2 decades of NBTS to meet the demands of the NHS for factor concentrates and other blood products.

(d) He identified inappropriate use of blood: over-use leading to over-exposure of patients to iatrogenic hazards.

(e) The RTCs had no voice in the management of BPL Elstree.

(f) His view was that NBTS was a fragmented and disorganised shambles – it was possible to have severe shortages in one place while 10 miles away another RHA might be dismantling its blood collection programme because of sustained excess.

(g) There had been what he described as a remarkable failure by politicians of all colours over past 25 years – lack of interest, vision and commitment.

[310] DHSC0002207_040
[311] PRSE0000598

(h) Years of neglect of BPL had eventually led to investment but, even then, with the wrong focus.

(i) There would still be problems with cross-charging schemes between BPL and RHAs.

(j) The 'gift relationship' had been lost. *"Current trends which view the voluntary blood donor as a source of marketable commodities need to be challenged and debated."*

425. In his 1990 transcript of interview[312], Professor Cash:

(a) Referred back to his own 1976 paper in the BMJ[313] in which he predicted rising future demand, identified the greater yield from plasma of cryoprecipitate than Factor VIII, and stated that *"undue delay now [in investing in BTS and re-appraising their function] may be a serious error of judgement."*

(b) Emphasised that minimising the exposure of patients to concentrates was because safety was paramount.

(c) Referred back to his 1987 article and reiterated that what had been needed was an integrated BTS removed from RHA funding and managed by a new and separate health authority that included BPL.

(d) Commented that even the creation of an NBTS Directorate in 1988, as a move towards integration, was flawed as there were no effective management arrangements between it and the RTCs.

(e) Was critical of BPL having hidden behind Crown Immunity to be able to lag behind current technology and advances.

(f) Observed that Scotland would have had the capacity to run a 24/7 shift system at PFL (thanks to CSVM technology) to assist with national self-sufficiency but that there was no appetite from England to take this offer up.

(g) Was of the view that the necessary managerial infrastructure to respond to Dr Owen's £0.5m investment was not at the time in place in England (against which he contrasts Scotland, which had a national, co-ordinated service, centrally funded, which could plan ahead).

(h) Was disappointed with the quality of deliberations of the DoH BTS Advisory Committee (on which he sat as an observer).

(i) Concurred that US imported products between 1972 and 1982 were *"dirty blood, a sewer of viruses"* (while observing that that language was a little "theatrical").

(j) Recognised that paying blood donors was *"an incentive to lie."*

(k) Was critical of commercial blood product manufacturers, and of the influence they were able gain over the Haemophilia Society and the World Federation of Haemophilia.

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[312] SBTS0000053_055

[313] *supra*

426. The statement of Peter Wormald (formerly Under Secretary in the DoH with responsibility for BTS) dated 4.11.22[314] is illuminating.

(a) He did not recall (para 3.2) self-sufficiency being discussed in the 1960s and his assumption at the time was that BPL had the capacity to satisfy the demand for blood products, given sufficient raw materials. He was told by Dr William Maycock the Director of BPL that the voluntary donor principle was important because *"blood from paid donors was considered to carry a greater risk of infection, specifically hepatitis."*

(b) By 1978 (para 3.3) when he returned, it had been agreed between the English and Scottish Departmental officials (in 1973 in the context of a joint steering Committee) that the UK should aim for self-sufficiency in blood and blood products. But as far as he is aware no detailed planning had been done as to the production levels which would be needed to attain full self-sufficiency or how BPL might increase production, nor had the resources required been estimated.

(c) His minute of 10.4.81 to the Minister of State[315] refers to two principal reasons for "early rebuilding" of BPL: the unsatisfactory nature of the current buildings and the *"potential benefits from replacing expensive and in the case of Factor VIII relatively dangerous (hepatitis) imported blood products by our own products"* In explaining his comment about the *"relatively dangerous"* nature of blood products he goes on to explain in para 24.4 that *"It was common currency amongst my medical colleagues that imported blood products carried a* ***much higher*** *risk of transmitting infections particularly hepatitis."* (our emphasis)

(d) Although he misses the crucial aspect of what self-sufficiency should mean, at para 56.2 he correctly identifies that the requirements to implement self-sufficiency (however defined) would be *"(i) accurate forecasts of need/demand; (ii) sufficient supplies of plasma of satisfactory quality; (iii) sufficient fractionation capacity, skilfully and efficiently run; and (iv) efficient distribution systems."* He observes (with some caveats) that bringing the whole NBTS under central management would have given a real chance significant improvement, but offers no cogent explanation for why what was not earlier contemplated.

(iv) Conclusions we invite the Inquiry to reach

427. On our primary counterfactual case, self-sufficiency (as we say it should have been defined) could and should have been achieved by not long after Dr Biggs' 1967 letter, and certainly by the early 1970s at the latest.

428. Contrary to this, and giving rise to obvious risk, the chart at INQY0000336_0042 shows that clinical demand for concentrates was allowed to rise almost without control, and

[314] WITN6934001
[315] DHSC0002315_049

throughout the period from the early 1970s to 1982, the use of cryoprecipitate dropped, and the use of commercial concentrates rose.

429. On the events which in fact occurred, there was no clarity over what self-sufficiency meant. Concepts of need, demand, and what patients wanted were not defined. As such, it was inevitable that the goalposts would move and no coherent policy could be pursued. A central policy ought to have been devised and implemented by the DoH which was, directly or indirectly, funding the RTCs, RHAs, BPL / PFL / PFC and was – ultimately – responsible for each.

430. Criticisms of what in fact occurred can probably be categorised under three heads:
   (a) insufficient forward planning;
   (b) insufficient financial investment (whether directly or through collaboration with industry);
   (c) failure to introduce central oversight, control and responsibility (within which we include failure to co-ordinate between BPL and the NBTS, between the RHAs and between England and Scotland).

431. For the combination of those three reasons, progress towards self-sufficiency (however defined) was woefully and unacceptably slow.
   (a) There was a lack of any meaningful or realistic financial investment in the manufacturing infrastructure in England, particularly when compared with Scotland's planned approach. It ought to have been immediately obvious that Lord Owen's £0.5m would never be enough, and greater funds should have been committed sooner.
   (b) Any suggestion that there was insufficient money to invest to achieve self-sufficiency could be tested against the increasing sums which were in fact spent each year on the purchase of commercial concentrate instead. There was significant lack of foresight on this.
   (c) Rebuffing the approaches of private industry from as early as 1975[316] to work with the government on the refurbishment and then the operation of BPL was a lost opportunity. Significantly greater control over manufacturing processes, pool sizes and donor selection (together giving control over viral risk) would have been achievable by a joint venture in the UK than was the case when purchasing commercial concentrates from US pharmaceutical companies. We note that civil servants in the DoH effectively "parked" this possible collaboration and failed to resurrect it even after the change of government and political direction after the 1979 election.
   (d) There was a manifest and critical lack of co-ordination within England and between England and Scotland. There was also a lack of proper forward planning.

[316] DHSC0002179_082

(e) The pro-rata system (by which each area received back in factor concentrate only the amount which represented the proportion of total plasma which it had sent for processing) ought immediately have been appreciated to be system which would produce manifest unfairness and skew supply and provision. It ought to have been seen as a system which would obviously and inevitably lead to needy areas being short of UK-manufactured concentrate and obliged (if they were to meet perceived need) to purchase US commercial products.

(f) The Scottish facility (PFL Liberton) was specified and built to be able to work 24/7 to process plasma from Scotland and the north of England. Unjustifiably, it was then used only for Scotland. The engineering and facilities were in place but were unused. Scottish spare capacity could and should have been used to support English production and meet overall national need. Working time and funding issues should have been tackled and overcome.

(g) Dr Cash was correct in his retrospective analysis of what went wrong.

(h) Dr Perry was right when at §§48-52 of his evidence he referred to there not having been a UK-wide approach and describing this in his oral evidence as "a lost opportunity".

(i) Dr Smith referred in his statement to coming from Edinburgh to Oxford in 1975 and being shocked by the lack of appetite for self-sufficiency at a national level, but having found a good example of how it could be achieved locally in the "virtuous triangle" between the Oxford RTC, PFL in Oxford and the Oxford Haemophilia Centre. He described it as a "worked example of commitment and co-ordination" and could see no reason why that could not have been replicated more widely in England and Wales.[317] He also considered that if government had listened to what was being said before 1978, the 5-year programme of rebuilding BPL could have begun in or before 1978, could have been completed by 1983, and that safe products before 1983 would have prevented HIV infections and made a material difference to HCV infections.[318] (We note that in his first Penrose statement, Dr Smith suggested that fractionators thought it likely – ahead of haemophilia clinicians – that AIDS was caused by a blood-borne virus.)

(j) The "14 fiefdoms" of separate RTCs did not produce a cohesive blood transfusion service, and ought to have been changed far sooner.

(k) Dr Walford's oral evidence[319] establishes that by the time she joined Med SEB in [c1973] there was no policy in place for achieving self-sufficiency within any particular time frame, and she agreed[320] that there was no adequate planning, co-ordination or finance for it from the outset, and no over-arching plan in order to achieve it.

432. The refurbishment of BPL simply took far too long, as set out in the witness evidence

[317] WITN3433001 at p.57
[318] WITN3433001 at p60, In 170
[319] Transcript for 19.7.22 p.151
[320] Transcript for 20.7.21 p.2

of Lord Norman Fowler.[321]

433. The earlier use of Crown Immunity to justify the poor facilities at BPL was inexcusable. Why should that ever have been thought appropriate, and why put up with those conditions and/or level of productivity in the first place?

434. Even leaving aside the economic and safety arguments, there is a quite separate argument (Titmuss, *supra*) that it would have been morally better to have achieved controlled self-sufficiency than to purchase commoditised blood products. This underscores the point our CPs make that their lives were simply not thought valuable enough by government in either economic or moral terms.

435. We adopt the point made by the Chair to the public health administration experts[322] (with which they agreed) that there was a critical failure in the missed opportunity to create a national blood service, or at least one in England and a complementary one in Scotland which would jointly provide for Wales and Northern Ireland too. There was instead a system of local areas and serious underfunding of the English facility, plasma in England was sourced from the regions and that fell within regional budgets. But the production facility was not financed directly by the regions, even though it served the regions. Unhelpfully (we say perversely), Dr Lane's view at the time was that it was wrong for regional English money to be spent to collect plasma to send to Scotland to produce product for England, even though the development of that facility in Scotland was what the DoH had already financed. There was a breakdown in working relations between the Scottish and English bodies. There was therefore a shortage of available NHS product (which all knew to be safer for the patient / consumer) in England and Wales. So English clinicians imported substantial amounts of factor concentrate from the US.

436. Ultimately, all these criticisms fall onto the shoulders of the DoH. Per Lord Glenarthur: 'the Secretary of State for Health was ultimately responsible for that treatment'[323]

[return to index]

[321] Tuesday 21 September - Lord Norman Fowler page 72 lines 6-17; page 72 – 73 lines 18 (72) – 10 (73); page 76 lines 1-9; page 76 lines 10-16; page 85 lines 3-15; page 87 lines 12-22
[322] During their evidence on 4.10.22 locate reference in the transcript
[323] Transcript 23-07-21 Lord Glenarthur p163, In 15-17

Chapter 9 - Viral inactivation and in particular whether and how more could or should have been attempted earlier

437. By the 1940s, the problem of viral infections, in particular hepatitis, in blood and blood products was well known[324]. As early as 1903, Hepatitis and potential infectivity routes had been described[325]. It became known that hepatitis (or liver inflammation) is an illness that can be transmitted by transfusion.

438. The IBI has heard[326] how serum hepatitis (being a multitude of hepatitis viruses) was known to be potentially fatal with hepatic damage to the liver, and without liver function, life is not possible. By no means was hepatitis, of any form, something to be taken lightly.

439. By 1944, a method to heat-treat Albumin had been found, to inactivate any viruses.[327] It is of note that the authors of the above 1956 paper stated: *"The use of human albumin as a therapeutic agent makes it essential that every precaution should be taken to prevent the possible transmission of virus infection."*

440. As per the discussion between the chair and Dr Foster[328], in order to heat treat albumin, a stabiliser was required, and it was known that: *"at least with some proteins, that the presence of a stabiliser might be important. The question then was finding an appropriate stabiliser".*

441. There was a failure by both UK & US manufacturers of FVIII to invest proper time and resources into finding an appropriate stabiliser, before distributing products for patient use. In effect, the known safety step was skipped over.

442. The IBI has not received or encountered any evidence to suggest that in the late 1960s or 1970s, substantial, if any, efforts were made to find a stabiliser for FVIII. It is submitted this is because such efforts did not take place.

443. It is also submitted that it was cheaper, at least in the short term, for manufacturers to forego this crucial Research & Development exercise; and err on the side of risk.

444. Forsaking a safety step of heat-treatment known since the mid-1940s was critical to events ensuing in the following years. Indeed, by taking this safety step in relation to Albumin and

[324] IBI presentation 0n 23-9-2020, p5
[325] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1431013/pdf/annsurg01018 0052.pdf
[326] IBI presentation 0n 23-9-2020, p16
[327] A good summary is found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1199867/pdf/biochemj00848 0080.pdf
[328] Transcript – 25-3-2022, INQY1000198, page 102, ln 7-15

Plasminogen, the infected blood products scandal did not extend to those products. It would have done had those products not been subject to heat-treatment.

445. As is apparent, from the 1940s onwards the level of knowledge of the severity of serum hepatitis steadily increased. Two forms of Hepatitis were initially identified: **Serum hepatitis** (HBV) or 'Australian Antigen' in 1964 (Blumberg & Others); known to be transmissible by serum or plasma; and **Infectious Hepatitis** (HAV) identified in 1973 (Feinstone & Others); known to be transmitted by oral and faecal routes.

446. Tests to screen HBV infected blood were pioneered in 1971; and introduced across the UK in December 1972. Tests for HAV were introduced shortly thereafter in 1974. In 1975, it was known that an agent/s other than HAV and HBV also caused post-transfusion hepatitis, as identified by Dr. Alter, NIH, in Maryland, USA, and termed '**NANBH'.** At all times it was known that exposure to these agents could result in severe illness and death.

447. In *A & Others v NBA & Velindre NHS Trust*[329], Burton J found [§99+]: that following the introduction of screening for HBV, NANBH was responsible for most, if not all, infections of blood by hepatitis; and that in the 1970s and 1980s, infection by NANBH was '*the major complication*' in blood transfusion.

448. The UK was among the countries that erred on the side of risk, with regard to inactivation and/or eradication of Hepatitis in Factor concentrates. This approach shaped what was to happen in subsequent years, not just in relation to NANBH, but also HTLV-III (HIV) and AIDS.

449. Insufficient time, effort and resources were deployed in attempting to inactivate or eradicate viruses from blood and blood products. Instead, a line was promulgated that Hepatitis was a transitory illness, with initial minor symptoms, jaundice, and few long-term effects.

450. Such mentality shaped the approach and attitudes of those nationally engaged in: collecting, manufacturing, and administering therapeutic treatments, in what transpired to be an

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[329] *A & Others (x6) v NBA & Velindre NHS Trust* [2001] 3 ALL ER 289, Burton J
The claim was brought under the CPA 1987, which came into effect on the 1 -3-1988, without retrospective effect.
Also, all claims pertaining to PTH infections after 1-4-1991 were settled. By the parties (90:10) on the basis it was conceded that anti-HCV tests should have been introduced by then. Thus, the claim concerned only infections between 1-3-1988 and 1-4-1991. The parties agreed the incidence of HCV in transfusions was between 1%-3% [pg. 19, §(x).] Mr. J Burton determined infected blood was a product within the CPA, but one which was 'non-standard' or inferior to a standard product (ie blood that was not infected), and its' deficiency or harmful characteristic was the cause of the material injury or damage. His Lordship also concluded blood was not the type of product '*which by its very nature carries a risk and which has been presented as such* ', and that consumers expected blood presented to them to be 100% clean; and would not have had any knowledge that it may be infected with hepatitis. [pg. 29, §55].

adverse way. This was to the detriment of those receiving blood and blood product transfusions.

451. At the centre, was the falsehood of '*only minimal harmful side effects of hepatitis*' from which a patient seemed to recover. If suitable efforts were undertaken to address hepatitis through existing inactivation methods, and research variations thereof, this would have had an advantageous impact of preventing the spread of HTLV-3/HIV.

452. The approach was in contrast to a number of other countries, including:

(a) Behringwerke in Germany, who focused on viral inactivation much sooner due to the risk of Hepatitis. The Germany Blood Inquiry[330] recorded: *"Prof. Klaus Schimpf reported during his witness hearing, that in lectures before 1981 he had pointed out the risk of hepatitis in haemophiliacs. Dr Heimburger from Behringwerke was also present at one of these lectures. It was agreed in the discussion that the most threatening side effect for haemophiliacs was hepatitis transmission. Dr Heimburger then said, according to Schimpf, that he would promise him that he would do something. According to Prof. Klaus Schimpf, the pasteurized "Factor VIII HS Behring" preparation came out a short time later, in 1981."*

(b) In Finland, the decision was taken to not to use Factor concentrates until they were virally inactivated, specifically due to the risk of Hepatitis. They stated: "*the large-pool preparation was not introduced to clinical use because of the increased risk of viral infection, i.e. hepatitis*" [331]

453. It is submitted that the UK should not have distributed FVIII for patient use until inactivating heat-treatment was possible, as Finland had.

454. It is submitted heat-treatment would have been possible by the mid-1970s, had efforts been made to find a suitable stabiliser from the outset. It is submitted that if, for any reason, work to find a stabiliser and/or heat-treatment of FVIII sooner could not have been undertaken, and heat-treated products not provided sooner, the approach adopted in Finland should have been taken.

455. As submitted above, erring on the side of risk acceptance, or an approach of apathy towards inactivation or eradication of NABH, shaped what then happened in the ensuing years. Dr Smith confirmed this position in his statement[332], noting that not only inactivation research was required earlier, but also redevelopment of BPL ought to have started in 1978 rather than 1982, to have made a difference.

[330] https://dserver.bundestag.de/btd/12/085/1208591.pdf at page 118
[331] RLIT0000469
[332] WITN3433001, at §170.

456. Furthermore, only when the pandemic of HTLV-III (HIV) emerged, and the potential scale of tragedy was materialising, did such act as a fillip to those collecting, manufacturing, and administering therapeutic treatment to actively pursue inactivation. Dr Tedder, the virologst, stated in evidence[333] that the pattern of disease observed in HIV was similar to that seen previously in HBV, in homosexuals and drug users, which led to the conclusion of there being a transmissible agent in operation. This view was widely shared by counterparts in the US - CDC and elsewhere.

457. Dr. Mark WINTER's evidence in October 2020 confirmed his perspective as a haemophilia clinician:

a) He was aware of the various studies into NANBH in 1978/79, including Professor Preston's in Sheffield.[334] Professor Preston had undertaken liver biopsies. This was a '*key moment*' for all haemophilia clinicians; and '*blew out of the water*' the idea that '*there was nothing to worry about'*. The conclusion was now that most patients had very significant chronic liver disease, including chronic active hepatitis and cirrhosis, despite appearing symptomless/having a mild form of virus[335].
b) He describes such as '*one of the great sea change moments in history*' when he expected every haemophilia doctor to say '*all the rules have changed on this one, and chronic liver disease is a major clinical problem in haemophilia*'.
c) Against this was a backdrop of: (i) the self-sufficiency initiative having stalled; (ii) no progress being made in 1977/78, as they still imported significant amounts of FVIII; and (iii) Elstree – BPL – being heavily criticised due to the state of the building, facilities, and safety risks.

Thus, he would have expected the UKHCDO to pressurise the Department of Health about the need to address NANBH, as a condition which was now seen as severe.

Viral Inactivation Processes

458. Heat treatment of viruses was recognised as an effective sterilisation method. The mechanism deployed could vary according to temperature, pressure during heating, and the solvents used. In fractionation, two processes are generally used:

a) inactivation (killing the virus – HIV, HCV) precluding the virus from infecting cells and multiplying; and
b) efficient removal of the virus (clearance – HCV).

459. Given the increasing knowledge of viral infection, it is submitted that in the 1970s, large-pool factor concentrates should not have been licensed for use until they had been subject to at least one form of viral inactivation or pasteurisation, thought to reduce or remove the

[333] Transcript – Dr Tedder, 13-10-2022, p. 38/39
[334] [RLIT0000175]
[335] Transcript – Dr. Winter, 1-10-2020, p.58/9

risk of virus transmission. It is apparent from the following that viral inactivation, removal and/or stabilisation of products was not pursued early enough by US/UK manufacturers. Products should not have been imported nor licensed by the medical regulatory authorities until they had done so.

460. Three basic inactivation strategies were utilised, predominately by commercial organisations:

1) Heating in a solution – pasteurisation.
2) Dry heating materials.
3) Vapour (or steam) treatment – wet heating.

These have been considered by the Inquiry. However, inactivation through use of solvent detergents is also a technique that has been touched upon, but not considered in any great detail, in particular the work of Dr. Edward Shanbrom. Each are considered below.

Pasteurisiation and the Behringwerke AG 'wet' heat-treatment process

461. In 1980/81, (following research studies from 1977), Heimburger et al identified a method of pasteurised heating of Factor VIII for 10 hours at 60°C, with glucose and glycine, with factor VIII components separated by precipitation. Such was manufactured in Germany and licensed in 1981 under the name of Haemate HS / Haemate P; and was produced by Behringwerke.

462. Successful trials of 155 patients were carried out, from February 1979 to December 1986. The evidence indicates that such was presented in a conference in 1980, which haemophilia clinicians from the UK attended[336].

463. In September 1988, all patients tested for HIV were found to be negative; and none of the haemophilia patients tested positive for hepatitis, or post-transfusion seroconversion for hepatitis.

464. However, Haemate HS had a low yield (8% of the initial plasma); and thus required larger volumes of plasma. Further refinements were made to increase its stability and yield in 1988.

465. Cutter / Miles Inc, applied for a FDA license for its pasteurised factor VIII product in August 1983, which was granted in January 1984. Alpha Therapeutics applied for an FDA

[336] Transcript – Adrian Goodyear, 5-6-2019, p. 63/64

license for its wet heat / pasteurised factor VIII product in December 1982, which was granted in February 1984.

466. Thus, it is submitted a heat-treated, pasteurised inactivation product (Haemate HS / Haemate P) was potentially available (subject to availability), to clinicians in the UK on a 'named patient' basis from 1979 onwards; and licensed in Germany for purchase and importation from 1981.

467. Similar alternative therapeutic treatments were potentially available, subject to availability, to clinicians in the UK on a 'named patient' basis in 1982 (Alpha), and in 1983 (Cutter), with licenses granted for importation in January 1984 (Cutter), and February 1984 (Alpha).

Dry Heat-Treatment: Baxter Healthcare

468. A dry heat treatment process was carried out in the last step of manufacture; when the product was being sealed in its final container, to avoid recontamination. Such was at a temperature of 60-68°C, for 72 to 96 hours to inactivate HIV. This failed to inactivate NANBH/NCV. Thus, this led to 'severe dry-heat' processing, of 80°C for 72 hours or 100°C for ½ hour. Factor IX processes were carried out at 60°C for 144 hours.

469. However, it was critical for the process to ensure an appropriate residual moisture content of the final product: if the product was too dry, the virus inactivation efficacy could be reduced. Under this method, parvovirus was more resistant. Baxter Healthcare applied for a FDA license for its Dry-Heated Factor VIII product in June 1982, which was then granted in March 1983.

470. Such was therefore potentially available, subject to availability, to clinicians in the UK on a **'named patient' basis from at least June 1982** onwards; and licensed for purchase and importation **from March 1983**.

Vapour / Steam Treatment: Immuno AG

471. This proved a less common treatment process, although it was subsequently utilised. A two-stage process was developed by Immuno AG for a steam inactivated concentrate product: (1) steam was generated from a wetted product for 10 hours at 60°C; then (2) for 1 hour at 80°C; all within a closed system. **An abstract for such was published in 1980,** before a clinical safety study was published in **June 1984**.

472. A four-year gap is noted, during which time the emergence of HTLV-III became apparent. It is queried why HTLV-III did not accelerate Immuno inactivation processes. However, it is noted Dr Eibl, an Immuno representative, attended the infamous 24th January 1983 Excelsior Hotel, Heathrow, meeting with Senior Haemophilia Clinicians.

473. At such meeting[337], Immuno discussed two hepatitis viral inactivation methods it was developing, and a pending concentrate product subject to patent issues, expected to be resolved and available by April 1983. It is apparent from the minutes, Senior Haemophilia clinicians were aware of: inactivation of NANBH by Immuno's viral inactivation processes; a pending patent to be completed by April 1983, for a virally inactivated concentrate; and the increasing/encroaching advent of HTLV-3. Any clinician who suspected HIV was a virus (and it is submitted they ought to have done so, given previous knowledge of HBV), was then at least aware of the potential availability of an Immuno inactivated product on the immediate horizon.

Solvent Detergent inactivation: Dr. Edward Shanbrom

474. Dr Shanbrom's 'Solvent Detergent' method was patented in October 1980, before release in February 1982.[338] Such later claimed to also inactivate both HTLV-III/HIV and NANBH/HCV, as was subsequently shown to be the case when further research was eventually undertaken by others, who introduced different 'solvent' agents. As HBV was known to be lipid at around this period, it is considered there were even further reasons to pursue this method, early on.

475. The solvent detergent method achieved virus inactivation, whilst maintaining protein structure, to provide a safe and efficacious product. Subsequent studies suggested '*detergent or working at higher temperature, opens up the virus structure making it more accessible to organic solvent extraction*'. Although restricted to lipid enveloped viruses, HBV, NANBH and HTLV-III all proved to be such viruses[339].

476. Dr. Peter FOSTER commented on detergent inactivation in his witness statement[340]. He noted in June 1982, Dr Pepper (of the SNBTS HQ Laboratory) was keen to pursue research into detergent inactivation. However, at a meeting of the SNBTS '*Coagulation Factor Study Group*' in October 1982, chaired by Dr. Cash. This proposal was dismissed, as it was felt it should '*not be pursued at expense of heat treatment, which was considered a better option*'[341].

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[337] DHSC0001800 & PRSE0002647
[338] [BAYP0000018_021].
[339] [BAYP0000024_063 at page 6]
[340] [WITN6914001 at page 53/54]
[341] [PRSE0002206]

477. Dr Foster expanded on this slightly on the second day of giving evidence,[342] confirming awareness that Dr Shanbrom had patented a detergent method in 1982[343]. Concerns were raised at the meeting over what they did not know, leading to its rejection.The concern was that if it was effective, it might only be so against lipid envelope viruses.At that stage, it was not known if NABH or HIV was a lipid envelope virus or not. Detergent inactivation was thus '***considered not to be a top priority*** *at that point in time*'[344]. Dr Foster continued *"...there would be an issue of removing the detergent from the product because you couldn't inject it into the patients. That wasn't known how that could be achieved either, so there were a number of issues there that caused us to put* ***detergent at quite a low priority*** *at that time."*[345].

478. In the US, the New York Blood Center carried out further research leading to publication of an article in *TRANSFUSION* by Horowitz et al, on solvent detergent inactivation of viruses including HBV, NANBH and HTLV-III, received for publication in October 1984[346]. This affirmed and built on Dr Shanbrom's work; the resultant product approved for license by the FDA in 1985.

479. Dr Foster suggested[347] the reasons this had not occurred earlier was: solvent detergent only inactivated lipid envelope viruses; they did not know that AIDS was such a virus until 1984, or that NANBH was such a virus until 1989; the chemical reagents used were potentially toxic and had to be removed from the final product; and the manufacturing technology required to remove those reagents was not yet fully developed. This is at odds a little with the minutes of the October 1982 meeting, which deemed solvent detergent research was '*not a priority*'.

480. To recap, Dr. Pepper proposed further research into detergent inactivation, to ascertain if it was a viable option, in **1982**, following the grant of Dr Shanbrom's patent. Such was rejected on the premise of a lack of research to date and concerns about 'known unknowns', rendering it 'a low priority' not to be pursued at the expense of heat-treatment options. It is submitted that the appropriate response to such 'known unknowns' was to pursue further research to determine how effective detergent inactivation was or how it could be improved, building on existing research.

481. This was the type of research the Coagulation Factor Study Group should have been undertaking. Not only the state fractionators (BPL, PFL and PFC) should have made it a priority to obtain a method of viral inactivation, they should have been supported in this by the blood services. If we accept Dr Foster saying it was not known *how that could be achieved*, then it is submitted they should have been working to find it out,

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[342] Transcript – Dr Peter FOSTER, 25-3-2022, p.78/79
[343] (p. 78, Ln. 20-22)
[344] (p.78 ln 12-14)
[345] (p.78 ln 15-20)
[346] [BAYP0000024_063 at page 6]
[347] [WITN6914001_054 and WITN6914010]

rather than marking it a low priority. This was a missed opportunity. It is possible that under-resourcing meant that pursuing research into solvent detergents would be done at the expense of heat treatment. We comment further below on the research resources of state fractionators and blood services.

482. The inquiry has disclosed extracts from the book *Blood on their Hands*.[348] Aspects of Dr Shanbrom's account (deceased since 2012) are found therein, including:

(i) Dr Shanbrom being documented as saying the only reason his detergent inactivation was not taken up earlier was because *"industry had no interest"* (page 230);

(ii) When he was first named as a potential expert witness in the US litigation, he was, in his own words, *"threatened…The industry lawyers are suggesting to me that they will not approve any contracts to licence my new methods of sterilization because some plaintiff's lawyer in Hawaii submitted my name as an expert witness"* (page 116); and

(iii) He was apparently fired by Baxter, when he began cooperating with lawyers for the plaintiffs in the US litigation (page 141).

Clinicians' early use of inactivated products

483. To summarise, it appears the following techniques were *potentially* available on a 'named patient' basis and/or to be imported:

1) heating in a solution/pasteurisation from 1979 (research) and 1981.
2) dry heating of materials from June 1982 and March 1983.
3) vapour (or steam) / wet heating from (1980 – in abstract) possibly April 1983 thereafter, or June 1984 at the latest.
4) Solvent detergents from October 1980 and February 1982 – when patented.

Thus, there were evolving options, open to UK manufacturers, the DoH, and licensing/regulatory authorities to consider and/or to explore. Furthermore, any action should not have been predicated on FDA approval. Internal UK assessment could and should have been undertaken earlier. 'Named Patient' administration of known virally inactivated products was also an option.

484. In evidence[349], Dr Mark WINTER confirmed that once it began to emerge, UK doctors were very concerned about the transmission of HIV in blood products. They correctly suspected HIV was a virus. He was aware of evidence relating to American companies experimenting with heat-treated products, and that in mid-1983 the Germans had a

[348] For example CGRA0000763 – in relation to Dr Prince's evidence.
[349] Transcript – Dr Mark WINTER, 1-10-2020, p.138+

product (which he was unable to secure). They considered UK non-heat-treated products to still be a risk.

485. In February 1984, he and Dr. Savidge approached Alpha Inc, a US company with a factory in Norfolk, who had a license for American heat-treated products. Their aim was to seek supplies for four hospital centres: St. Thomas (Dr Savidge); Kent & Canterbury (Dr. Winter), Sheffield (Prof Preston), and Middlesex (Prof Machin).

486. For an additional 50% cost, Alpha agreed to provide their heat-treated concentrate supplies on a '*named patient*' basis, bypassing UK licensing restrictions. The hospitals started receiving products in May 1984, with all four moving completely onto such by June 1984, and (save for one HIV positive test in October 1984which, given incubation periods, was likely to have been infected prior to receiving Alpha products) there were no further HIV infections in those haemophilia centres.

487. Those Clinicians moved all their patients to heat-treated concentrates (other than DDAVP), and Dr Winter considered '*you were very, very unwise to continue to treat any patient with a concentrate that had not had a step to inactivate a virus*'.[350]

488. It is submitted that it was true from the outset of FVIII, that it was very unwise "*to treat any patient with a concentrate that had not had a step to inactivate a virus*". Dr Winter's move to heat treated products was some 15 months before the rest of the haemophilia centres, who were still using non-heat-treated products. These other centres eventually followed suit in September 1985. However, the four centres at the vanguard still approached Alpha a year after the first HIV case in the UK, and several years after the potential for first utilising inactivated products.

489. The Inquiry has heard no explanation for this delay, which stands in stark contrast to the clinicians' initial enthusiasm for *untreated* American concentrates. Internal documents from pharmaceutical companies go some way to providing an explanation: these companies perceived lack of seroconversion primarily as a marketing device, they were in competition primarily with one another over the claims and counterclaims of viral inactivation, and warily watched the results of each other's clinical trials over time.

Other factors

490. Options to reduce viral risks, pending provision of virally inactivated products, were not implemented: Minimising use of products (in the first instance) to when such was specifically required in terms of severity of illness/bleed; refusing to use any product that had not been through a virally inactivated process; utilising Cryoprecipitate from smaller pool donations; was

[350] Transcript – Dr Mark WINTER, 1-10-2020, p.140

491. Further delays to inactivation of viruses, and early clinical use of such, also arose due to:

(i) A lack of co-operation and/or sharing of information/processes between BPL and PFC, when heat-treated products (BPL's 8Y) were proving successful in inactivating viruses (HIV and HCV), at a time when Scotland was struggling with its version (PFC's Z8). Not only should there have been greater communication and co-operation between these fractionation centres, but in evidence Dr. Perry[351] lamented the lack of leadership from the UKHCDO (who had patients' details), to promulgate a policy to facilitate such, and identify the patients previously untreated as a priority to receive successfully inactivated products, regardless of where they resided in the UK – he considered this 'could have been fairly simple to put in place'.

(ii) Pharmaceutical companies put profits before lives, utilising patents and intellectual property rights to exploit treatments for financial gain. Morally this was repugnant, and on a humanitarian level it was indefensible.

Matters were exacerbated when Government bodies failed to appreciate opportunities for joint venture partnerships, to modernise the processes and products available, having rejected such earlier following pharmaceutical approaches from Travenol and others.[352]

[return to index]

[351] Transcript – Dr. Perry, 1/4/2022 – INQY 1000184
[352] DHSC00002179_082 (6-10-1975); DHSC0000027 (12-12-1978); DHSC0002313_057 (26-3-1979).

Chapter 10 - The decision-making of the Committee on the Safety of Medicines and its Biologicals Sub-Committee

492. In this short summary, the Collins CPs intend to address the role of the Committee on Safety of Medicines in the provision of advice to the Secretary of State and others in the conduct and settlement of the HIV Litigation.

493. At paragraph 2.4 of his statement given to this Inquiry, Dr Duncan Thomas states that:

> *The Licencing Authority was ultimately responsible for granting, varying or refusing licences for medicines which included drugs and biologicals'.*

At paragraph 2.5 he goes on to say:

> *'The Licencing Authority would be advised by a committee of experts called the Committee on Safety of Medicines (CSM)'.*

Following this at paragraph 2.6 he confirmed:

> *'There were other sub-committees of the CSM, but the sub-committee with which I was involved was the Committee on the Safety of Medicines sub-committee on biologicals (CSM (B)).*

494. At paragraphs 87-89 of the Master Statement of Claim in the HIV Litigation the then plaintiffs (in expanding on this area of responsibility) pleaded as follows:

> *87. At all material times, the CSM owed the following duties:*
> *(a) To give to the Licensing Authority and/or the First Central Defendants advice with respect to safety, quality and efficacy, in relation to human use, of any medicinal product to which any provision of the Medicines Act 1968 is applicable;*
> *(b) To promote the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given;*
> *(c) To keep themselves informed of matters likely to affect the patients to be treated with the product under their consideration;*
> *(d) To weigh the risks to those patients of continuing to be treated with the product in question;*
> *(e) In formulating their advice in respect of the product under consideration, to guard patients against exposure to the risk of serious and/or fatal side effects from the product;*

(f) In collecting and investigating information relating to adverse reactions and in formulating their advice, to have regard not only to events and experience in England and Wales, but to have regard to events and experience World-wide by means of research and personal enquiry and contact;
(g) To provide the Licensing Authority with appropriate and sufficient information and advice to allow the Licensing Authority to• ensure that information supplied and/or published by manufacturers of products and their servants and agents, notably in Data Sheets, effectively communicated any risks inherent in the use of such products and means by which such risks might be reduced or avoided.

88. By reason of their forming part of the Licensing Authority, at all material times advice, information and material obtained by the CSM and proffered to the Licensing Authority was also available to the Secretary of State for Health and his predecessors in office to assist and guide them in the discharge of their duties in that capacity.

89. In the premises, at all material times, The CSM, their servants or agents owed the following duties to the Plaintiffs:
(a) To discharge their responsibilities pleaded in paragraph 8 hereof and their duties pleaded in paragraph 87 hereof with due diligence and reasonable care;
(aa) To conduct themselves with reasonable care so as not to injure persons iable to be affected by their conduct;
(b) In discharging their said responsibilities and duties, to have special regard inter alia for the vulnerable position of haemophiliacs and their intimates;
(c) These said duties are and were owed to all the said categories of Plaintiff and each of them.

495. We submit that this represents an accurate account of the obligations and duties of the CSM

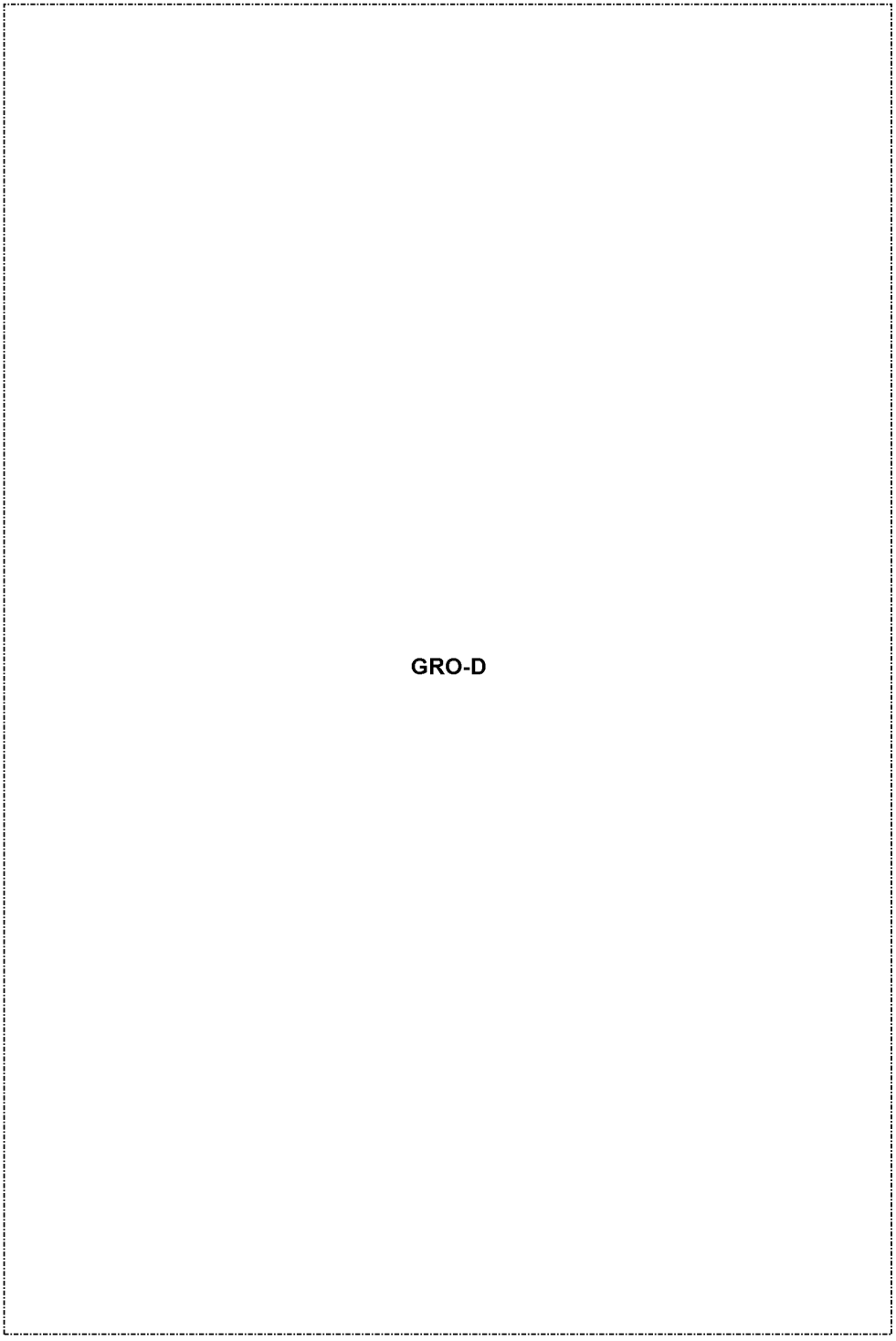
496. In the same Master Statement of Claim the plaintiffs then went on to plead breach as appropriate under the following headings:

- HEPATITIS RISK AND/OR RISK OF OTHER VIRAL INFECTIONS
- HEAT TREATMENT
- AIDS RISK

497. In his statement given to the Inquiry on 25th May 2022, Justin Fenwick KC expressed some concern and/or reservation at the inclusion of the CSM and Licensing Authority in the HIV Litigation. (Justin Fenwick's Statement – WITN70670010058)

' My only regret, which is not intended as a criticism of the plaintiff legal team who were no doubt putting their clients' case forward to the best of their ability, was that the claims included claims against the CSM and LA. The legal arguments for such claims were in my view always weak, they added little to the case against the DH and required a strong policy defence to discourage the attempt to use such claims to obtain compensation for unexpected side effects of medicines. The inclusion of such claims in this case engaged the same issues as in Opren and in the Benzodiazepine litigation which eventually collapsed at huge cost to the legal aid fund and the public purse when it became clear to the Plaintiffs that such claims faced insuperable difficulties. If such claims had not been made in this case, some of the obstacles to resolution would have been removed. I recognise that the Plaintiffs considered it necessary to bring claims in respect of policy decisions in order to give early victims a chance of establishing a case, which would have still involved important issues of principle but a settlement might have been easier if the claims had been limited by the exclusion of such policy issues. This is again a personal view with the benefit of hindsight and not something that I recollect being discussed at the time except to the extent reflected in my earlier answers'.

498. **GRO-D**



499. Whilst the details of the analysis may require further scrutiny, the principles remain intact and these principles were examined further when Sir Michael David Rawlings gave evidence to the Inquiry on 7th June 2022. The immediately relevant parts of the transcript are Page 96 – paragraph 13 through to page 117 line 13 as follows:

MS RICHARDS: Sir Michael, just still on the topic of blood products and licensing of blood products and hepatitis, a general question if I may. Would you expect that when the CSM or the Licensing Authority were considering whether to grant a product licence in the UK, that they would look to see how that product had performed in the US and any safety issues arising from its use in the United States?

A. I would hope so, yes.

Q. Secondly, could the Licensing Authority or the CSM have made it a condition that concentrates should not be supplied if they were used -- sorry, made from plsma taken from prisoners?

A. Well, I suppose I'm disappointed, but of course, as you know, I wasn't round at that time.

Q. No, quite. But in principle, if it was known that plasma was being collected by the pharmaceutical companies in the States from prisoners or other high-risk groups, could the CSM, in theory at least, have imposed a condition excluding such sources of plasma?

A. Well, it could have done, yes.

Q. Then more generally -- and again, conscious that you weren't around in the '70s, but drawing on your knowledge of the CSM more generally, are you able to offer any insight into how it was that these products made from large plasma pools were licensed notwithstanding the fact that it was known that they transmitted hepatitis which could have serious, indeed fatal consequences?

A. Well, did people know that?

Q. I can't really answer that for you, I'm afraid, Sir Michael.

A. Sorry, I don't know when --

SIR BRIAN LANGSTAFF: I think the evidence that we've had, professor, is that it was declared on the licensing application by the pharmaceutical companies themselves. So I think the conclusion has to be that the Committee must have known something of that, or at least sufficient to investigate further had they wished to do so. That's the evidence that we've had.

MS RICHARDS: Are you able to -- do you have any reflections on that as -- drawing on your knowledge of the Committee's decision making?

A. No, I don't, no. No.

Q. Can I then turn to a meeting of the Committee on Safety of Medicines in July 1983. This was looking at the risk of AIDS and factor concentrates. So I'm just going to take you to a couple of documents, Sir Michael, just so that we can see what material existed. If we start with ARCH0001710. You'll see, Sir Michael, this was a decision of the Biologicals Subcommittee on 13 July 1983. And if we go over to the second page, you'll see near the top the heading "Acquired Immune Deficiency Syndrome". It says: "The Sub-Committee's consideration of the question of AIDS and licensed blood products was augmented by the following expert advisers ..." Then five individuals are identified: Professor Bloom, Dr Craske, Dr Galbraith, Dr Gunson and Dr

Mortimer. And then a series of conclusions are set out. Now I'm not going to take you through those conclusions, Sir Michael, I just want you to see the document. That's the Biologicals Subcommittee meeting on 13 July. And the Biologicals Subcommittee was deciding what, if any, action should be taken in relation to the continued importation and use of factor concentrates given the risk of AIDS. Now that came before you and your colleagues later in July of 1983. And we can see that at DHSC0006259_007. So if we just go to the top of the page, please: "Committee on Safety of Medicines, Minutes of the meeting held on 21 July 1983 and 22 July 1983." And you were one of those present, Sir Michael. If we go over the page, and look at the bottom, the bit that's been highlighted in yellow on the screen: "Tabled paper 4 summary of main points from a consideration of AIDS and license blood products by Biologicals Sub Committee 13 July 1983." That's the set of minutes I showed you a moment ago. "5.1. Dr Smith spoke to this paper and reported to the Committee on the above discussion. "5.2. The Committee endorsed the recommendations of the Biologicals sub-committee." Now first of all, Sir Michael, do you have any recollection of this meeting or of the CSM's consideration of this issue?

A. No, I don't, not at that time, no. No.

Q. It would appear from what's set out here and from other documents that I don't need to trouble you with that the only material before the CSM itself was Dr Smith's paper and that the CSM didn't have any of the underlying materials that the Biologicals Subcommittee may have seen. Does that surprise you or
was that normal?

A. No, that would have been reasonably normal, I think. I mean, the experts on this subject were in the Biologicals Subcommittee. There were very few members of the CSM itself who had any expertise in this area.

Q. So we obviously can't really, from the minutes and what you see on the screen, really glean anything about the Committee's decision-making process, the fact that it's said that it endorsed the recommendations of the Biologicals Subcommittee, might this be an example of the CSM essentially simply rubber stamping what the Biologicals Subcommittee had resolved?

A. It could well be interpreted in that way, yes.

Q. Then if we just go to the paper that Dr Smith produced. It's on the next page, please, of this document, please, Paul. We can see there, if we look at the top of the page, this is Dr Smith's tabled paper 4, "Summary of main points from a consideration of AIDS and licensed blood products by CSM(B) 13 July 1983". You'll see the first paragraph explains that the subcommittee had been helped by the various expert advisers whose names I showed you a minute ago. Neither the Biologicals Subcommittee -- sorry, neither the minutes of the meeting of the Biologicals Subcommittee nor this paper from Dr Smith sets out what the advice of those experts was, what their contributions to the meeting or to the discussion were. Does that surprise you, that we can't tell from these documents what the experts were advising?

A. No, I don't think so. I think it was sort of summarising the views of the subcommittee.

Q. Then if we just look a little further down the page, please, so first of all to the paragraph numbered (2), so this is the reasoning of the Biologicals Subcommittee which you and your colleagues on the Committee were endorsing. Paragraph 2 says this: "Patients who repeatedly receive blood clotting-factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small. The risk appears to be greatest in the case of products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence (eg, New York and California), and in those who repeatedly receive concentrates in high dosage. Balanced against the risks of AIDS (and of other infections transmitted by blood products) are the benefits of their use; in the case of haemophilia they are life-saving." I wanted to ask you about two statements in that paragraph, Sir Michael. First of all, the suggestion in the first sentence that the "evidence so far available suggests that this risk is small". I appreciate you can't remember this meeting and you don't know what evidence was considered, but would you have expected the Biologicals Subcommittee to have gathered as much evidence as it could, as was available by July 1983, about the extent of the risk?

A. Yes. Yes, I mean, I don't know what -- because this is really a sort of summary.

Q. Yes.

A. And it appears to be greatest in the case of products derived from the blood of homosexuals and IV drug users. And I just wondered if they'd got any numbers associated with that, but I don't know.

Q. The Biologicals Subcommittee appears to have been of the view -- this is the end of that second paragraph -- that blood clotting-factor concentrates were life-saving for haemophiliacs, and you yourself in your statement, Sir Michael, used that term on more than one occasion: that they were life-saving. Do you know what the basis was for believing that factor concentrates were life-saving for haemophiliacs? Would you simply have taken that as read, do you think, on the CSM?

A. Well, I think we understood that haemophilia -- or was until these products became available -- was indeed life-threatening. People with haemophilia had catastrophic haemorrhages and all that could be -- before these concentrates became available, all that could be done was to give them blood and fresh plasma in the hope that it would take effect. So I don't think that -- so I mean, it was -- and of course also in haemophilia, quite apart from the catastrophic haemorrhages that haemophiliacs got, or used to get, they also had chronic bleeds into joints and – you know, giving them chronic arthritis and so on. Q. That wouldn't be life-saving, however, would it?

A. No, but catastrophic haemorrhage would be.

Q. Yes. Would you have expected the Biologicals Subcommittee to rigorously examine and interrogate the evidence about the advantages of factor concentrates when reaching its recommendations?

A. Yes, I do. I do. And we haven't mentioned it yet, but one of the medical staff of the Medicines Control Agency or the Medicines Division was a woman called Frances Rotblat who, before she joined the Medicines Division, had done a lot of research on haemophilia and concentrates. She was a great woman and she died not long ago, about six months ago.

Q. Yes.

A. And she had an obituary in the Times.

Q. Indeed, there's no evidence, I should say, Sir Michael, that Dr Rotblat contributed anything in writing or orally to the materials before the Biologicals Subcommittee.

A. No? Well, we took great notice of what she had to say about biologicals.

Q. If we just go over the page, this is paragraph numbered 4, so the paragraph at the top of the page and I just want to ask you about the -- well, actually, I'll read the whole paragraph and then ask you: "The possibility was considered of withdrawing US preparations from the UK. It was concluded that this was not at present feasible on the grounds of supplier. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates. This should reduce markedly, although not eliminate, the risks to the recipients of these products, and the Subcommittee strongly supports this aim." Pausing there, you'll see that it's being said there that the perceived level of risk did not "at present" justify serious consideration of withdrawing US preparations and that that wasn't "at present" feasible on grounds of supply. So it appears to be contemplating a situation that might change or, indeed, the balance of risk might change. Would you have expected the Biologicals Subcommittee, and indeed the CSM, to keep this issue under review and to actively look at it again after July 1983?

A. Would hope so, yes.

Q. There is, I think, at present, no evidence to suggest that the Biologicals Subcommittee or the CSM did so. Does that surprise you?

A. Yes, I'd have thought at least the Biologicals Subcommittee would have done.

Q. Then the last sentence of this paragraph reads: "The Subcommittee was also informed that the UK Haemophilia Centre Directors have adopted a policy for use of US Factor VIII in order to minimise risks as far as possible." Now, there's no evidence that the actual policy adopted by the Haemophilia Centre Directors was before the Subcommittee. But would you have expected the Biologicals Subcommittee again to rigorously examine what the policy was and whether it struck the balance in the right way?

A. Well, I'm not sure. I mean, the Centre Directors knew what they were, sort of, talking about, so I suppose that's -- so the Subcommittee assumed that they did.

Q. Could we look at one further document, CBLA0000043_040. Now, Sir Michael, there's no suggestion that this is a document that you saw or that your colleagues saw at the time in July 1983. You'll see it's a letter from Dr Galbraith of the Communicable Disease Surveillance Centre to a Dr Field at the Department of Health and Social Security. It's dated 9 May, so it's couple of months before the Biologicals Subcommittee meeting and then the Committee on Safety of Medicines meeting. If we look at the text of the letter, the first paragraph refers to reported cases of AIDS in haemophiliacs. Then the second paragraph says: "I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified. Appended is a paper in which I set out my reasons for making this proposal." If we go over the page, this is the paper referred to in the letter, and it sets out six points. Point 1 is that: "The AIDS epidemic in [the States] is probably due to a transmissible agent. "2. The agent is probably transmitted by blood and blood products", and details of reported cases are given. Point 3, if we could just zoom in on paragraph 3, Paul. It says: "Although this number of cases of AIDS associated with the administration of Factor VIII concentrate is very small in relation to the number of individuals receiving the product, this may NOT indicate that the risk is small", and he goes on to explain why. The next page, please, Paul. We can zoom in on paragraphs 4, 5 and 6. Paragraph 4 says that: "Factor VIII concentrates ... would appear to have a high risk of being contaminated with AIDS because homosexuals and drug abusers are known to be frequent blood donors ..." Paragraph 5 makes the point that there's: "... no known means of ensuring that blood or blood products are free of [AIDS]." Paragraph 6 refers to the extremely high mortality rate of AIDS. Now given that this was a document which the Department of Health itself had, do you consider this is the kind of material that the Biologicals Subcommittee and indeed the Committee itself should have been provided with?

A. Yes, I think at the very least the Biologicals Subcommittee should have been provided with it.

Q. Looking at it now, do you think, doing the best you can, if you and your colleagues had had this document, known then what we now know about AIDS, urgent action would have been taken and it is possible that those products would have been immediately withdrawn ..." What kind of information did you have in mind, Sir Michael, when you say, "if we had known then what we now know about AIDS"?

A. Well, I think if we'd known then what we know about AIDS, that it's caused by a virus -- because at that point it was suspected it was an infectious agent. If we'd known it was caused by a virus, and if we'd known how

frequently pool donors in the US had -- had the virus, then I think we would have done something different. At least I hope we would have done.

Q. I'm going to move now to ask you just a handful of questions about heat-treated factor concentrates.

A. Yes.

Q. So I think we only need to look at one document to start with. It's DHSC0003947_015. If we just look at the top of the page, please, Paul to see the date. So this is a CSM meeting on 22 November 1984. Again, you were present. If we go to the last page, please, Paul. Paragraph 17, "Any Other Business - AIDS": "Dr J Smith informed the Committee that heat treatment of Factor VIII, which is used in the treatment of haemophiliacs, abolished detectable infectivity of AIDS virus added to the preparation. Therefore, companies should be encouraged to apply for variations of licences to permit widespread use of heat-treated Factor VIII, so that the incidence of AIDS in haemophiliacs might be reduced. "Professor Rawlins reminded the Committee that heat-treated Factor VIII is more expensive than the standard preparation. Widespread substitution of the heat-treated product may cause haemophilia centres to exceed their budgets. "The Committee requested that the Licensing Authority propose to the Companies concerned that they make early applications for variations to use a dry heat treating process in the manufacture of their factor VIII products." Sir Michael, first of all, what was the relevance of your observation about the expense of heat-treated Factor VIII?

A. Well, I don't know. And I'm sort of surprised I said that, really, because a little -- you know, not long afterwards I was recommending that all patients with haemophilia were given heat treated, and that we should, as it were, ignore the expense or accept the expense. So I'm not quite sure why what I said – why I said that then.

Q. Then if I can just draw your attention to a paragraph of your statement and ask you about that. Paul, can we have on screen WITN6406001, and it's page 79 of your statement, Sir Michael, paragraph 17.6. So in paragraph 17.6 you were commenting on the passage we've just looked at. You say this: "It is difficult to recall the CSM's exact intentions now but I think that the reason the CSM recommended encouraging companies to apply for variations rather than making heat treatment a mandatory requirement was because there would have been a concern about such a mandate leading to a shortage of Factor VIII products. As the Inquiry knows, these products were life-saving and life-changing and the implicat ons of their becoming suddenly unavailable would have been very serious. While, when judged with the benefit of hindsight, this may seem to have been the wrong approach, in late 1984, the full implications of the AIDS virus were still not widely understood." *First of all, Sir Michael, would it have been possible for the CSM to recommend making heat treatment a mandatory requirement? Your statement –*

A. It would have been, yes. It would have been, yes.

Q. Was any consideration given, do you know, to the issuance of a "Dear Doctor" letter to try to ensure that clinicians only use the heated product by this time?

A. I doubt it because there were concerns that the heat-treated product was more expensive, and I -- somewhere else in my statement I've talked about the conversations I had in Newcastle.

Q. Yes, and we'll look at the Newcastle situation in a few minutes. Then you say, in the last part of paragraph 17.6 of your statement that: "... in late 1984, the full implications of the AIDS virus were still not widely understood." It was widely understood by late 1984, wasn't it, that this was a virus with a high mortality rate and transmissible by factor concentrates, so what more information might the CSM have needed at that point in time?

A. I'm not sure. "... the full implications of the wise virus are still not widely understood." I don't know what I was saying there, I'm sorry.

Q. If we just then move forward from -- this is late 1984. If we move forward to March 1986, MHRA0036364_002. So we can see at the top of the page this is a meeting of the CSM, 26 March 1986, at which you were in attendance. If we go to page 4, please, bottom of the page. You will see it says -- "The Safety of Heat Treated Factor VIII", is the heading. The context of the questions here, Sir Michael, is that Dr Peter Jones, who obviously you knew, had raised concerns, as had others, about the Armour heat-treated product transmitting AIDS. That's why the Committee was looking at the safety of heat-treated Factor VIII. It says: "The Committee considered this paper and endorsed the recommendations of the Subcommittee on Biological Products as follows: "12.1. The Committee were glad to receive this data on the follow-up of alleged transmission of HTLV-III by heat treated Factor VIII. The Committee agreed that there was insufficient evidence for action to be taken on any specific product." I'll come back to that in a moment. If we look at the top of the next page: "12.2. Close surveillance should be maintained on the two possible cases of HTLV-III transmission in recipients of Armour material. "12.3. The Committee advised that, if any of the data provided by manufacturers on viral inactivation suggested a danger, urgent consultation should be sought with appropriate members." The first question, Sir Michael is this: the committees recommended close surveillance on the two possible cases of HTLV-III transmission. What kind of surveillance would the Committee have had in mind? What would that have entailed?

A. Well, it would have asked the physicians, the doctors looking after the patients, to find out -- to follow them up. You know, there were two possible cases of transmission. Did they materialise or not? I think they'd want further details from the doctors looking after the patients.

Q. So if we then just go back to the bottom of the previous page, if I can just remind you of the Committee's wording there. So it refers to a paper and then it says: "The Committee agreed that there was insufficient evidence for

action to be taken on any specific product." I just want to show you the paper in question, and then ask you about that conclusion of insufficient evidence. The paper is at BPLL0001351_018. You'll see, Sir Michael it's headed "The Safety of Heat Treated Factor VIII".

A. Yes.

Q. It refers in the introductory paragraph to Dr Peter Jones making statements that he felt that heat-treated Factor VIII wasn't safe, citing in particular the Armour product. I'm not going to take you through the detail of the paper now, I think we just need only go to the last page. Under the heading "Summary", you'll see this was by Dr Rotblat, who you mentioned a few minutes ago, 4 March 1986.

A. Yes.

Q. And she says this: "There are three known cases of seroconversion for HTLV-III antibody after heat treated Factor VIII. "One - the American case - appears to have other risk factors. This case is associated with the Hyland product. "Two cases seroconverted after treatment with Armour material from a batch known to contain an AIDS donor." So you'll see from this paper, Sir Michael, there were two cases treated with Armour, they've seroconverted, there were no other risk factors, and a batch was known to contain an AIDS donor. Why wasn't that sufficient evidence for the CSM to take decisive action about the Armour product in March 1986?

A. I don't know. I just don't know, I'm afraid. I can't help you, sorry.

500. On any basis, the input of the CSM and or its sub-committee was sadly ineffective and whilst the difficulties presented by policy as opposed to operational breaches are well recognised it is submitted that here there was a clear operational breach by the CSM. The existence of this breach may have come to the plaintiffs' legal team too late in the day, but nevertheless recognised by them, the breach at which the Secretary of State would not have been exposed to a potential finding of liability.

501. Interestingly and perhaps of only anecdotal interest is a letter before the Inquiry from Dr Galbraith dated 14th April 2008 in which he says:

> *'I found my original letter to the Department of Health concerning the withdrawal of American clotted Factor VIII and enclosed is a copy for your records. I would like to give Joe Smith another little shock by sending it to him. Can you please remind me of the committee he chaired which toned down or ignored my warning'.*[353]

[return to index]

[353] WITN1055133_0001

Chapter 11 - The decisions and actions of pharmaceutical companies manufacturing/supplying factor concentrate

Introduction

502. The main impression that the CPs will take from the evidence relating to Pharma companies during this Inquiry is their failure to participate despite the fact that:

(a) they knew about the transmission of hepatitis through blood products in the decades before the 1970's
(b) they knew about the virtually universal contamination of products with non A non B hepatitis in the mid 1970's and 1980's;
(c) they were aware of the developing position with AIDS and the fact that it may be transmitted by blood and blood products
(d) they failed to put adequate warnings on their product labels

and yet those companies have watched but not actively participated in any meaningful way in this Inquiry. We invite the Chair to reach his own conclusions as to why they have taken this cowardly stance.

503. The only oral evidence the Inquiry heard was from Sarah Middleton (Speywood) and Christopher Bishop (Armour) the latter whose oral evidence was unsatisfactory with his stock answer to any probing question being that he could not remember or that it was the responsibility of others.

504. The Inquiry has been provided with a number of additional witness statements (from those not giving evidence) setting out the various companies' corporate histories which is interesting insofar as demonstrating that "Pharma Industry" companies had/have a tendency to periodically sell (under the guise of a buy-out) the assets of a company leaving a worthless shell with any contingent liabilities so as to make it more difficult to pursue the actual culprits.

505. It should also be remembered that, without exception, the various US incarnations, fought the various US litigation tooth and nail, undoubtedly with the assistance of UK affiliates. Of course, they are businesses, but this is not an ethical way of doing business when that business is health, and when lives depend on it. It is noted that many of those infected, or their bereaved families, in the US received individual settlements running into millions of dollars.

506. One of the other notable features of the evidence that has been presented is the uncanny ability of the witnesses to shift the question of knowledge/blame/responsibility to another individual/Department and /or Company which is particularly evident in the evidence of Mr Bishop.

507. Counsel to the Inquiry has produced several Chronologies and Presentations which we accept and do not repeat. In this Chapter we draw the Chair's attention to general themes and highlight the (largely) industry-wide attitudes to the production and sale of their products.

508. The Chair is fully aware of the history of the Hepatitis viruses and AIDS generally and the response by the main pharmaceutical companies. In addition, the Chair has had the benefit of a series of detailed oral and written presentations from CTI and again these are not repeated here.

509. In 1970, there is evidence that scientists working at Cutter knew that the plasma used to manufacture Factor concentrates carried a risk of transmitting hepatitis (some employees working with plasma received injections of gammaglobulin every few months to ameliorate the risk).The firm knew that cases of hepatitis were occurring in patients using Cutter's products and that some patients were dying as a result of those Hepatitis infections .

510. It is submitted that the fact of employees merely working around plasma used to manufacture FVIII taking injections of gammaglobulin, in the early 1970s, in efforts to protect themselves from hepatitis, demonstrates a level of knowledge around FVIII source plasma posing a clear and significant risk to health.

511. In short it is our submission that the commercialisation of the collection of blood and production of blood products in the USA in the 1950's/ 1960's led to an industrialisation of the process with blood collection, supply and demand left to the marketplace rather than ethical regulation[354]. Big Pharma companies and influential blood "bankers", (all making substantial profits) were keen to increase their own market share at the expense of the end users of their products: many of whom paid with their lives.

512. Somehow along the way a sort of collective amnesia seems to have blinded all those concerned with the manufacture of blood products and the treatment of Haemophilia to the very real and known dangers of the *"potentially rapidly fatal*" hepatitis viruses.

513. We submit to the Chair that for many, many years the selection of paid blood donors, some of whom were bled by plasmapheresis, was simply wrong, was always known to be dangerous[355] and the products should not have been licenced until a suitable method of virus inactivation was available

Licensing of Factor Products in the UK in the 1970 and 1980s

514. Our submission is that there has been deliberate dishonesty by the pharma companies in pursuit of profit. That dishonesty was never challenged properly by the Government, its agencies, the NHS or Clinicians.

515. Our further submission is that the abject failure by the Government or its agencies to properly challenge the pharma companies led directly to injury and death.

516. We would also submit that the treating clinicians failure to be aware and/or if aware adequately warn their patients also contributed to the injury and death of thousands

General Background

517. As the Chair is aware, manufacturers of drugs and biological products (including blood products) were required to have a product licence to be allowed to sell their products in the UK and those licences were granted by the relevant Minister on advice from the Licensing Authority ("LA") which was ultimately responsible for granting, varying or refusing licences for medicines which included drugs and biologicals.

518. Dr Thomas usefully sets out in his witness statement to the Inquiry[356] what information and evidence manufacturers would be required to provide which for blood products would have included how the product was created, information about donors (including donor selection criteria, testing for hepatitis B and exclusion policies i.e. who should not give blood), and the manufacturing policy.

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[356] Written Statement of Duncan Thomas - WITN6405001

Brief summary of the grant of product licences to non-UK manufacturers

519. Immuno A.G (Kryobulin manufactured in Austria) and Hyland (Hemofil manufactured in the US) were each granted a product licence in early 1973 (Kryobulin subject to certain conditions). Both had previously been supplying small amounts of Factor VIII product to named haemophilia patients.

520. The CSM(B) was well aware of the higher risk of hepatitis in the imported blood products.

521. By way of example, when reporting to the CSM(B) on Hemofil, Dr Thomas concluded:

> "*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. Hyland screen all their donors for hepatitis associated antigen, which reduces but does not eliminate this risk. However, no attempt is made to disguise the risk of hepatitis and it may be considered that the decision to use this material could be left to the individual clinician who can balance the potential hazard against the anticipated therapeutic benefit to patients."*[357]

522. Subsequently, product licence applications were also made for the Factor IX products Porthromplex (Immuno) and Proplex (Hyland)

523. In 1974 Abbott applied for a product licence for Profilate which was granted in 1975 despite the hepatitis risk[358] and which was then varied to allow a change in production method and add a number of further centres for plasma collection, eight of which were not owned by Abbott[359]

524. Armour followed suit in 1975 with its application for a licence for Factorate which was granted in March 1976.

525. There was much competition between the different Pharma companies to secure contracts with the various Haemophilia Centres and one of the key tools at their disposal was price.

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[357] DHSC0105593002; DHSC0105593003; MHRA0033322_060 (Kryobulin); DHSC0105593_006 (Hemofil)
[358] MHRA0000091_005 and MHRA0000091_012, pp.15-16
[359] MHRA0000091_012, pp.1-2

Immuno

526. With the price in mind, in 1976 Immuno made an application to vary the product licence (0215/0003) to add to the sources of the plasma to include licensed plasmapheresis centres in the United States to enable them to market and sell either European plasma based Kyobulin or the cheaper American plasma based Kryobulin.

527. The reason for the change was said to be that

> "*It is possible to sell Factor VIII Concentrates produced from plasma of US origin at lower prices than European-based material. Because of the preference in the UK market for this lower priced material, we also wish to make it available. Packs of Kryobulin from alternative source material will be of a clearly distinguishable colour eg blue as compared with present red. We will continue to make available European as well as the proposed new concentrate derived from American Plasma*"[360]

528. This was explored with the Chair during CTI's presentation on the licensing of the product[361] where a memorandum dated 26 November 1976 was displayed which refers to an internal meeting during which the application to change the licence is discussed and which states that there would be Kryobulin 1 which is the European plasma based Kryobulin (with a lower risk – citing a publication) and Kryobulin 2 made from US Licensed Source Plasma (proven to have a significantly higher hepatitis risk – publication also cited)[362].

529. There appears to have been a delay of around a year in processing the application and it is unclear as to whether the US sourced Kryobulin was ever supplied on a "named patient" basis, On 27 January 1977 further information was requested from Mr Fletcher, the Senior Medical Officer tasked with assessing the application[363]. The response appears to have been supplied and then mislaid as can be seen from Diana Walford's internal memo chasing the further information[364] which appears to have been supplied on 1st February 1977[365]

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[360] MHRA0033321_085
[361] Inquiry Transcript 23 September 2021 page 81
[362] SHPL0000071_083 and SHPL0001094. Interestingly om 8 August 1979 Professor Ingram wrote to Dr Rizza asking him to expand the record of the Minutes of the Eighth Meeting of the Haemophilia Reference Directors when referring to a conversation with Mr Berry of Immuno and replace the latt er part of the sentence with " …. who had said that the American ('blue') material was offered for those who wished to take advantage of the lower American price, whereas the European ('red) material was still available for those who felt that it carried a lower risk of hepatitis, although the company regarded both products as equally safe'LOTH0000012_136
[363] SHPL0000271_077
[364] MHRA0033321_009
[365] MHRA0033321_066

530. One of the queries raised by the SMO was whether the

> *"proposed variation refers to "Licenced Plasmaphoresis (sic) Station in U.S.A." Is this intentionally in the singular? If so which specific station is proposed? If it is meant to be plasma phoresis (sic) stations in general this should be stated as should any limitations or lack of them i.e. continental U.S.A. only or does this include Hawaii etc.? Does it include all States?"*[366]

531. The response to that was that the

> *"Source Plasma (Human) is obtainable from licensed plasmapheresis stations located in all states of America including Hawaii. Source Plasma production, sale, inter-state shipment and export is regulated by the U.S. Federal Law. We are at present obtaining material from plasmapheresis stations in New York, Baltimore, Birmingham (Alabama), Philadelphia and Knoxville"*[367]

532. The use of language was also the subject of a discussion between the Chair and CTI regarding the use of the word "*obtainable*" and the geographical locations of the named stations[368].

533. It appears that Diana Walford may have had some concerns regarding some of the additional information as "!?" appears as an annotation initialled DW. However, notwithstanding those concerns, the application to vary the licence was approved on Dr Walford's advice (reference to Committee having been struck through on the form) on 7 March 1978[369] and the variation was authorised on 28 March 1978.

534. This allowed Immuno to market and sell the cheaper but less safe American Product to Haemophilia Centres. During the hearing the Chair and CTI discussed the question of efficacy and safety and how that was approached by the CSM when considering an application[370]:

535. The conclusion drawn by the Chair was that the CSM were effectively

> "*licensing Immuno to produce a less safe product, assuming that it is as efficacious, on that assumption?* CTI agreed that *" ... according to the internal Immuno AG documents, it was a product that they considered to have a significantly higher hepatitis risk"* – despite what they may tell their customers

[366] MHRA0033321_066
[367] MHRA0033321_066
[368] Inquiry Transcript 23 September 2021 pages 84 and 85
[369] MHRA0033321_063_001
[370] Inquiry Transcript 23 September 2021 pages 86 and 87

536. There was a further exchange between the Chair and CTI, regarding discussion of Kryobulin at the eighth meeting of the Regional Haemophilia Directors on 6th April 1979 where the two versions were discussed by the Directors.

537. The minutes of that meeting record that

> "*Concerning factor VIII concentrates (Kryobulin) supplied by Immuno Ltd. "It was pointed out that the company was now selling Kryobulin factor VIII at two prices, the cheaper preparation being made from American plasma. The implication is that the cheaper product carries the higher risk of plasma viral hepatitis. This has worried some of the Directors. Professor Ingram has been in contact with Mr Berry of Immuno who had said that their action was aimed at making available to clinicians material which may carry less risk of transmitting hepatitis."*

538. The Chair then observed

> "*That expression of the reason for providing two priced products as that -- it was to make available the safer product, though more expensive, as opposed to the inference from the German document translated, which was that it was exactly the other way around. It was Immuno seeking to give or put on the market something which was cheaper because, well, it was riskier, from American plasma, but their main object was not safety, it was cheapness.". He* went on to say *"If that's right, and if Mr Berry had been properly informed* [which we assert he would have been] *and if it's properly reported what he said to Professor Ingram, it's almost deceptive. I don't know about the "almost".*

539. Subsequently on 8th August 1979, Professor Ingram wrote to Dr Rizza and asked him to expand the record of his conversation with Mr Berry and to replace the latter part with '*'... who had said that the American ('blue') material was offered for those who wished to take advantage of the lower American price, whereas the European ('red') material was still available for those who felt that it carried a lower risk of conveying hepatitis, although the Company regarded both products as equally safe.''*[371] in the minutes of the meeting.

[371] LOTH0000012_136_0001

540. It is clear therefore that some haemophilia centre directors were aware, at least by 1979[372], that some Kryobulin was made from European plasma and some from USA plasma and that the USA plasma derived product was cheaper[373].

541. Whilst there may have been a lack of understanding as to the difference in risk in using the blue or the red product and the difference in the origin of the product[374]. There is no evidence that clinicians ever sought to clarify or inform themselves of the higher risk of the blue product which they should have investigated

542. There is no evidence whatsoever that the difference in risk was ever communicated to the patients despite there also being concerns that African plasma was being used to make Kryobulin, and the product remained in use[375] and there is no evidence to suggest that efforts were made to investigate suspicions held by Directors that African plasma was being used. An investigation should have taken place.

543. Over time, Immuno regularly reduced the price of the Kryobulin Blue pack:

- In October 1980, the price was reduced to 7.5p per unit:
- In April 1981, the price was reduced to 6.8p per unit:
- In October 1981, the price was reduced to 6.5p per unit:
- In April 1982 the price was reduced to 6p per unit.
- By the end of December 1982, the situation was described at a BPL meeting as a "price battle".

544. Immuno also manufactured the Factor IX product Prothromplex. As at 1981 they "*only had permission to use European plasm for Prothromplex*"[376]. There is some suggestion in or around June 1983 that Prothromplex made from both European and American sources were being used[377] and the Inquiry was going to look into this further

545. It is our submission that the government was aware or should have been aware of the increased risk in licensing the Factor product and as a result intentionally exposed the end users to it.

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[372] Given what was known by 1979 about the various sources of plasma used to make Kyrobulin , it is with disbelief that some HCD's appear to have held Kryobulin as comparable to NHS FVIII as can be seen from the references below.
This paper from 1981 groups FVIII as being either "US Commercial" or "NHS or Immuno" - https://www.dropbox.com/s/thrx28lsxh4tf8x/DHF0011711.PDF?dl=0
The same as above can be seen on p8 of HCDO0000135_023
This incorrect grouping probably led some HCD's to use Immuno products where they would have used NHS had the red/blue difference been properly attributed and understood nationally.
[373] TYWE0000106
[374] PRSE0000539
[375] PRSE0000539
[376] SHPL0000271_040
[377] DHSC0002229_055

546. Whilst pharmaceutical companies are businesses whose aims are to make profits. It was the healthcare provider – the Government NHS/Department of Health – whose roles are to protect its patients/citizens, which was demanding blood products at ever reducing prices and the businesses supplied what was demanded.

Should a licence be subject to further review – The Hyland/Travenol tale

547. The reasonably contemporaneous background information is to be located in the annotated Draft Statement of Dr Kingdon prepared in 1990 by Clifford Chance the legal team representing BPL in the UK HIV Litigation.

548. Hyland/Travenol manufactured Hemofil (Factor VIII) and Proplex (Factor IX)

549. Both products appear to have been made from large pools of 15,000 donations per pool and up until the mid 1970s when the "*FDA mandated source plasma as a licensed product*[378]" it is clear that "*a certain amount of plasma was imported for the production of concentrates*". It should be noted that this is an annotated correction of the original draft prepared by Clifford Chance the uncorrected version of which read *"…. A number of manufacturers in the United States imported plasma from countries such as Haiti and certain countries in Africa*."

550. Hemofil was originally imported into the UK on "named patient basis" It made an application for a product licence in July 1972, when the company was warned about the relevant statutory provisions and it was included in the first central contract for Factor VIII concentrates, which commenced on 1 November 1973.

551. The summary report prepared for the CSM(B) noted the hepatitis hazard associated with the products that were being manufactured as a result of the donors (who "*do not inspire confidence*") and the *"very large plasma pools*" where it was also noted that "*the firm make no attempt to disguise this potential hazard*".

552. It may be that the DHSS inspector was persuaded by the modern, well-equipped fractionation plant rather than the ingredients. It should have raised alarm bells

553. In December 1975, a World in Action, documentary which showed so called "skid row" donors being bled by plasmapheresis on multiple occasions, was aired on UK television. It discussed the very real and serious risk of viral hepatitis.

554. On 9 December 1975, following the World in Action documentary, a Note of a Meeting of the Divisional Management Group (DHSS) noted that "*A similar product manufactured by Armour had recently been cleared by the Committee on Safety of Medicines; Supply Division were anxious that it should be licensed as it would be*

[378] Ref Kingdon's statement

available at a lower price than the Travenol product. There was some doubt as to whether the collection of blood products for either product was satisfactory".

555. It appears on the evidence that no action was taken by the CSM(B), Licensing Authority, PHLS, NIBSC or the Medicines Division following the documentary. Indeed, they went on to approve licences for two further manufacturers and allowed the Immuno licence variation to import "Riskier product"

556. We would submit that the above demonstrates again the failure by the Government and its agencies through its actions (to grant a licence), inactions (not investigate obvious safety issues) to ensure the safety if its citizens

Should a licence be revoked when there are known safety issues – The Armour Story

557. Armour's application for a licence was, following the revelations in the World in Action documentary, supposed to be subject to a more enhanced application process with further information requested as a condition of granting the licence. This is a short point and the licence should not have been granted at all in the circumstances.

558. As a condition to the grant of the licence Armour was asked to:

(a) Provide information on the number of donations from which plasma is pooled for the manufacture of each batch; and
(b) The rejection rate of donors or donations on a centre by centre basis.

559. It is clear from Counsels presentation to the Chair that the information provided in relation to those two conditions was inadequate to say the least and CTI suggested that one of the matters that the Chair may wish to consider in due course is the extent to which the "*enhanced consideration of Armour's application in fact resulted in any greater reassurance as to the safety of the product*".[379]

560. We submit that plainly it did not.

561. We also submit that the DHSS failed to hold Armour to the conditions it had set and exposed the end users to a fatally dangerous product.

562. When Armour entered the UK market other brands were already established and Armour's main selling point again was price.

[379] Inquiry transcript 28 September 2021page147

563. For example, in November 1977 Mr Bishop wrote to Dr Winfield[380], inter alia, setting out the prices for the supply of Factorate In that letter he states that they are

> "*very conscious of the fact that all Centres are working to very tight budgets. We are also fully aware of the implications of the new contract prices in respect of maintaining or increasing current levels of treatment and home therapy programmes within the limits of these budgets. An analysis of the new terms will reveal the true economic advantage of placing some, if not all, of your commercial concentrate business with Armour. By purchasing FACTORATE against a given [pound] sterling budget, your Centre will be able to obtain between 50% and 97.5% more Factor VIII concentrate than other commercial products approved for sale on the DHSS contract. By purchasing Factorate there will be no need to reduce your programme involving the use of commercial concentrate in order to keep expenditure within the confines of your budget for 1978. Coupled with this considerable price differential are the added benefits of our presentation.".*[381]

564. CTI explored this letter in evidence with Mr Bishop and queried whether the fact that the Armour product was being offered far more cheaply that other commercial concentrates "*played a significant role in Armours dominance in the UK*"[382].

565. In 1978 price is again at the forefront of the Armour sales pitch asserting that their "*prices are the lowest on the existing contract for Factor VIII concentrate by 23-42%."*[383]

566. With Armour we move from price to a different issue – whether and if so when should a product licence be withdrawn.

567. Again, the Chair has the benefit of the excellent Chronology and presentations prepared by CTI and the oral evidence of Mr Bishop we simply draw his attention to the themes and attitude of those employed by Armour, officials within the DHSS, the CMO and the treating clinicians.

568. Based on the available evidence referred to in the paragraph above, in relation to Armour's heat treated product, it is submitted that:

(a) Armour continued to sell heat treated Factorate when it knew (or should have known) that it may be infected with HIV as the heat treatment process employed was not effective enough.

(b) Dr Peter Jones tried to make the information public but he was "reprimanded" by the Government and effectively driven into silence over the issue.

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[380] UHDB0000012
[381] Same letter is sent to Dr Biggs OXUH0003868_011.
[382] Transcript 4 November 2021 p 46
[383] BPLL0002161

(c) Factorate was eventually allowed to be "withdrawn" thus avoiding the licence being revoked one year after the company knew (or at least should have known) that its product was dangerous and nine months after the government was made aware of the problem.

(d) A number of People were infected with HIV and Hep C from this product during these periods.

(e) Armour had told clinicians, such as Dr Peter Jones, that individual donors for this product had been tested for HIV, when that was not the case. https://www.irishtimes.com/news/specialist-says-company-s-assurances-about-safety-of-blood-product-were-a-lie-1.317559

(f) This episode only further illustrates the care-free, profits over patients attitude that Revlon Healthcare subsidiary, Armour, held.

(g) During the period, the department of health repeated past mistakes by playing down risk, looking the other way and even suppressing the facts. This is another example of cover-up.

Cutter/Bayer/Speywood – Donor selection and the recycling of infected plasma

569. In October 1975 Bayer UK Limited made an application for a product licence in respect of Koate which was later granted to Speywood but for present purposes we are interested in donor selection and other risky practices.

570. It is clear from the evidence that Cutter obtained plasma from questionable sources in the early 1970's including Haiti[384] and Mexico[385] but was likely to have ceased these imports when the F.D.A required plasma for fractionation be sourced only in the US because of the risk of hepatitis in 1975. However, this practice continued certainly to October 1975 with plasma being imported from Nicaragua[386].

571. The assessor's report noted that

> "*The raw material is supplied by no less than 54 different firms, which are classified in the submission according to whether the firm is owned and operated by others or Cutter owned, whether the plasma is collected by plasmapheresis or obtained from whole blood or whether the apparatus used is owned by Cutter or the firm concerned. The list includes a number of American State Prisons."*[387]

[384] BAYP0003700_001
[385] BAYP0003700_005
[386] BAYP0003777_0001
[387] Insert ref and Transcript 30 Sept 2021 page 17

572. It is also noted to *"suffer from being prepared from multi-centre donations which cannot be properly controlled by inspection. Nevertheless each individual donation is said to be tested by radioimmunoassay"*[388]

573. The warning section of the label in use in 1975 stated that "*Konyne concentrate is a purified fraction of pooled plasma obtained from many donors. Since the presence or absence of hepatitis cannot be proven with absolute certainty, the presence of hepatitis should be assumed and the hazard of administering Konyne concentrate should be weighed against withholding it".*

574. The Application also states that "*Since there is a definite risk of hepatitis, we suggest that the physician gives consideration to explaining to the patient (or the patients family) the relative risks of giving or withholding this product. Then, should the patient develop hepatitis, as a result of the injection, it will not come as a surprise, and there is not nearly the likelihood of resentment, which would almost certainly follow an unexplained and unexpected infection"*[389].

575. Despite the known and clear risk and the Minister (David Owen) *personally vetting all submissions"*[390] the licence was granted. As ever the price was important and probably affected the success of the application.

576. The fact that Koate ever licenced is truly shocking.

577. Cutter continued to obtain plasma from high risk areas and there is clear evidence that Cutter had used plasma from targeted homosexual donors in the production of factor concentrates before some unspecified date in 1982[391].

578. Following a request by the FDA in August 1982 to voluntarily exclude plasma obtained from donors – typically gay men – who had been recruited because they were likely to have high levels of antibodies to hepatitis B in their plasma, in or around early September 1982, Cutter informed the FDA that it would suspend the use of such plasma in the production of factor concentrates[392].

579. The suspension may also be linked to the fact that on 12 August 1982 the FDA Bureau of Biologics had requested that Cutter quarantine four units of plasma from a donor hospitalised for AIDS. It was noted by Dr Hershberger that "*We were extremely fortunate that we were able to quarantine [these units] before they were pooled. Had they been pooled the BoB [Bureau of Biologics] might have found it politically*

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[388] Transcript 30 Sept 2021 page 20
[389] BAYP0000001_098_0011
[390] PRSE0003913 and Transcript 30 Sept 2021 page 10
[391] T/script 30 Sep 2021, pp.124-125, and pp.136-137 and CGRA0000282 (which concerns plasma collected before 11 August 1982.
[392] CGRA0000330 – written presentation para. 36(a), also mentioned in th e oral presentation

expedient to make hard line decisions regarding the products made from the pool. This kind of risk will continue for some time until there is solid data to prove that AIDS is not transmitted by blood products. Meanwhile we should try and help to BoB develop a rational policy for dealing with AIDS that will withstand political panic"[393]

580. We submit that this comment demonstrates the prevailing attitude of the fractionators that the FDA (and CDC) needed to be "managed" through the crisis rather than actually accepting the likely risk that AIDS was transmitted through blood products.

ABPI Code of Practice and sales marketing

581. In addition to the use of "competitive" pricing tactics to capture sales within this market place the various companies employed other methods which in the face of it went against the voluntary guidance in place at the time one assumes to protect the purchasers and ultimate end users from high pressure sales and marketing within the pharmaceutical industry

582. The 1974 Edition of the Association of the British Pharmaceutical Industry Code of Practice [394]was in force when the four Pharma companies' products were first sold in the UK. It set out various principles which those in the industry had agreed to comply with. Of particular interest here is that the guiding principle of the Code which

> *".... emphasises the importance in the public interest of providing the medical and allied professions with accurate, fair and objective information on medical products so that rational prescribing decisions can be made."*

583. Mr Bishop was asked by CTI whether he was familiar with the Code and he responded that he was and that they (he and his sales team)

> *"... performed strictly to it under the strict guidance and -- well, the strict guidance and examination of our own Medical and Regulatory Department".*

584. The Code also sets out that

> "*Information about medical products should accurately reflect current knowledge or responsible opinion."*[395] And that *"Information about medical products must be accurate, balanced and must not mislead either directly or by implication.*[396]and finally *"Information must be capable of substantiation, such*

[393] CGRA0000652
[394] ABPI0000015
[395] Para 3.2
[396] Para 3.3

substantiation being provided without delay at the request of members of the medical profession"

585. Paragraph 11 set out that the Medical Representatives (i.e. sales people)

> *" .... must be thoroughly trained and possess sufficient medical and technical knowledge to present information on the company's products in an efficient manner."*[397]

586. Finally, paragraph 13 sets out that

> "*no gifts or financial inducements shall be offered or given to the members of the medical profession for purposes of sales promotion*". And that "*Gifts in the form of articles designed as promotional aids, whether related to a particular product or of general utility, may be distributed to members of the medical and allied professions provided the gift is inexpensive and relevant to the practice of medicine or pharmacy."*

587. The Chair heard evidence from many witnesses that the pharmaceutical companies

588. Our submission is that throughout the relevant time Armour did not comply with this code as is evidenced by Mr Bishop's oral testimony for the reasons set out above. In fact, on the evidence before the Inquiry, none of the pharmaceutical companies supplying Factor VIII or Factor IX complied with the Code.

Use of discarded Hepatitis B infected plasma

589. The Chair has seen evidence that pharmaceutical companies collected plasma, specifically and intentionally, from those thought or known to have been previously infected with Hepatitis (predominantly the gay community) and that some of this plasma was subsequently used in the manufacture of FVIII.[398] The Inquiry has seen examples of advertisements places in gay community magazines encouraging plasma donations.[399]

590. Targeted Hepatitis plasma should never have been used in the manufacture of FVIII and in particular, FVIII which had not been subject to any form of viral inactivation.

591. It is nothing short of shocking that the evidence presented by IBI Counsel on 28th Sep 2021 shows that, at least some manufacturers, were engaged in utilising targeted plasma

[397] Para 11
[398] IBI Transcript, 28th Sep 2021, s76
[399] CGRA0000375.

well into the 1980s. This was despite the ever-increasing knowledge about Hepatitis viruses being prevalent in certain high risk groups throughout the 1970s

592. The practice of using targeted plasma meant patient exposure to high risk donors was guaranteed by way of products utilising this type of skimmed plasma.

What should have been done differently?

593. The products should not have been licensed for use in the UK until effective viral inactivation was available

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Chapter 12 - Transfusion practice and what could or should have been done differently or earlier

594. It is noted that other RLRs are solely representing transfused patients. We are likely to adopt their submissions, insofar as they are compatible with the submissions made herein.

595. Reference is made to other chapters of our submissions concerning viral inactivation; blood collection, supply, manufacturing processes, and distribution, and specifically: blood donor screening, surrogate testing, delays in implementing HIV and HCV testing, which are not repeated herein.

596. We see similarities between the over-prescription of factor concentrates (for those with bleeding disorders) and the over-use of blood transfusions in surgical and other cases. We invite the Chair to find as follows:

597. Clinicians approached the administration of blood and blood products without assessing the genuine 'need' for such. Consideration ought to have been given to avoiding transfusion of mild haemophiliacs and PUPs whenever possible. In respect of whole blood transfusions:

> *"Did all the patients require whole blood? The answer is no, for many recipients could have received red cell concentrates (Chaplin 1969; Rush and Stewart 1969; Williams 1969; Gollub et al. 1971)."*[400]

598. We contend elsewhere that senior Haemophilia clinicians should have reviewed and revisited policies of home treatment and prophylactic treatments, particularly for mild haemophiliacs and PUPS. Consideration ought to have been given to limiting the supply of concentrates in favour of lower-pool products, cryoprecipitate, DDAVP, or alternative treatments/non-treatments, when assessing the risks against benefits of any treatment. The guiding policy should have been not to treat if such would result in harm / greater harm than if treating.

599. Similarly, we contend that clinicians ought to have considered alternatives to whole blood transfusion. This may have entailed:
    i. Iron supplements.
    ii. crystalloid volume replacement.
    iii. oxygenation.
    iv. intraoperative red cell salvage procedures during surgery.

[400] (per John D. Cash, Principles of Effective and Safe Transfusion. PROC. R.S.E. (B), 71, (Supplement), 5, 1971/72. via Penrose Inquiry: PRSE0002637

v. Natural foodstuffs, e.g. spinach, prunes, etc.

> *"3.1.2 The most clearcut indication for red cell transfusion is in the patient who has dangerous bleeding ("haemorrhage") after trauma, surgery or childbirth, when prompt replacement of red cells can be life-saving ..."*[401]

600. Clinicians should have ensured that all relevant factors were considered when assessing the need for treatments or transfusion, before determining to administer a transfusion.

601. There should have been set out guidelines (earlier, or at all in some instances) seeking to limit the use of blood transfusions, with specific criteria for the administration of such, including:

i. evaluation of how much blood has been lost, before deciding to administer any unit/s of blood, and never to administer more blood than was lost
ii. Haemoglobin thresholds; (see also §16 and §29, NHBT0006696_002[402])
ii. Blood pressure levels;
iii. Pulse rates;
iv. Mental state;
vi. Urinary flow;
vii. tolerable anaemia levels – especially during pregnancy - when assessing anaemia levels;
viii. the amount of blood lost;
ix. the consequences of not treating,

With greater attention paid towards identifying variable thresholds for a transfusion per se, and discouragement of unnecessary transfusions or transfusion volumes.

602. Clinicians should have avoided the habitual practice of providing two post-natal units of blood, '*to be on the safe side*', to women after labour, without any appraisal of need or desirability. Where required, at all administration should have been restricted to one unit.

603. 'Maximum Blood Schedules' for specific surgeries and procedures should have been adopted and distributed nationally, at an earlier stage. The Royal Colleges (Haematology, Obstetrics & Gynaecology; Surgeons; Anaesthetists; Dentistry) could have sought ownership of such guidance at an early stage, particularly as knowledge on long-term adverse sequalae was increasing in and from the 1970s.

604. In hospitals and Haemophilia centres, regular (monthly/bi-monthly) Internal Audits and reviews should have occurred, in respect of transfusions of blood and blood products,

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[401] (Dr Derek R. Norfolk: The use of blood and blood components in clinical medicine. February 2011. via Penrose Inquiry: PRSE0000786

[402] NHBT0006696_002

to review administrations, the appropriate reporting of adverse incidents and near misses, and provide advice and guidelines to staff where necessary. Such could have been supported by an annual external audit to identify any inappropriate trends, which have not been picked up or rectified. In hospitals, such should have encompassed multi-disciplinary team meetings involving: haematologists; obstetricians; Gynaecologists; Surgeons; anaesthetists; and dentists; working to one common set of guidelines, applicable across all disciplines within any hospital or other clinic.

605. There was inadequate communication undertaken by clinicians with their patients, in non-emergency situations, regarding the risks of transfusion and/or therapeutic treatments. Recipients were often not given any information or advice at all; and were not warned by medical professionals of the risks of infection involved in receipt of a transfusion.

606. Further to this, recipients were not warned or informed of such matters following their transfusions, and/or after an emergency had abated. Following receipt of a transfusion there ought to have been a form after the event, with (i) a mandatory provision for a patient to sign, to state they were aware of the fact of transfusion; (ii) the risks associated with such transfusion were set out next to such signature; with (iii) a mandatory requirement for an out-patients follow-up, to check for symptoms of jaundice, fatigue, brain fog, etc. No after care or follow-up was provided in most cases.

607. There should have been separate formal arrangements for obtaining informed consent for transfusion, separate and distinct from the normal procedure of obtaining overall general consent for treatment. The need for specific consent should have evolved sooner, particularly in the 1960s and 70s, and it should not have taken the advent of HIV in the 1980s to sharpen clinical focus.[403]

608. Clinicians did not seek informed consent, not even in the way that they were required to for prison inmates as set out under the Medical Defence Union publication of 1952. The specificity of consent to transfusion procedures should have developed more rapidly over time, particularly considering the minimum standards required for procedures, examination and treatment of prisoners being incarcerated in the United Kingdom. These principles were enshrined in a publication of 12 June 1953, by the MDU which was prepared for the Prison Commission, and required:

(i) Consent must be genuine informed consent, not just acquiescence
(ii) There must be a real expressed willingness to undergo the treatment
(iii) The nature, risks and objective must be explained in plain terms
(iv) Risks should not be minimised in the explanation

[403] Dr Derek R. Norfolk: *The use of blood and blood components in clinical medicine* February 2011, Conclusion, p.23. Penrose Inquiry: PRSE0000786

We invite the Chair to consider that it is astounding that the above principles were in place for UK prisoners from as early as 1953, yet for patients requiring transfusion, they do not appear to have been a major issue for clinicians in the decades that followed.[404] [405]

609. Inadequate hospital documentation was recorded and retained, concerning the fact of transfusion, with patients frequently passed around hospital departments, and sporadic or inadequate note keeping. This frequently led to failures to identify the fact of a transfusion on any discharge summary, and/or failure to inform a patient's GP.

610. The advantages of a computer-assisted "audit trail" for blood transfusion records was considered in August 1983. Computerised storage systems would have enabled a particular donation to be traced retrospectively to a specific transfusion event, and also enabled a specific blood donation to be tracked forwards through the various stages and modes of distribution, to identify a particular recipient. However, this was not a legal requirement.[406]

611. There should have been regular education of clinicians and patients about the importance of minimising use of blood, transfusion and blood products, due to transfusion transmitted infections, and the need to limit or minimise risks.

612. Clinicians should have engaged with the BTS, BPL and attended hospitals / clinics, or vice versa, for annual seminars or conferences - as happened at the North London Regional Transfusion Centre, on topics such as:
    i. the use of blood and alternatives.
    ii. higher plasma levels in pregnant women with corresponding reduced red blood cell count: (a) their higher tolerance level of blood loss; and (b), they requirement for less units of blood to restore their previous levels when being transfused,
    iii. maximum blood schedules for various surgical and other procedures,
    iv. recent topics of interest, e.g. new products (now - synthetic blood research), viral safety steps, screening, testing, common hazards, etcetera

613. The ACVSB failed to lead on blood safety. Although of a significantly high level, in that the Committee gave direct advice to ministers, they were largely reactive and failed to proactively lead on safety measures. They monitored the rest of the world to see how far the UK could reasonably lag behind, whilst purporting to consider all reasonable

[404] MOJU0000001_008 (National Archives file: PCOM 9/1394, Medical Defence Union Limited: Consent for Examination and Treatment, 12 June 1953).
[405] MOJU0000001_013 MDU letter of 17th April 1953
[406] (see Diana Walford, Principle Medical Officer, letter to W. Wagstaff, Director, Regional Transfusion Centre, 8 August 1983, from National Archives file: JA 398/41- Retention and Transfer of Blood Donor Records Jul - Aug 1983) Not apparently on Relativity.- could not find this

measures, and adopt safety precautions at the last possible moment, and sometimes not at all. The minutes are littered with such references, such as:

> *"The recommendations were that routine screening should be introduced only after a confirmatory test becomes available, after the FDA have approved the test..."* ([407])

614. Furthermore, they culpably decided not the perform an HCV lookback exercise, as recorded in the summing up of the ACVSB recommendations of their 7th meeting, where it was decided that any blood found to be positive in the pilot study would not be used. They then made a conscious decision not the perform any lookback for previous donations from an HCV-positive donor, to determine whether recipients had been infected.[408]

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[407] PRSE0003019 Fourth Meeting of the ACVSB. 6 November1989. *Non-A Non-B Hepatitis*, para 23
[408] PRSE0000976 Seventh Meeting of the ACVSB, 2 July 1990, Chairman's Summing Up, para 22

Chapter 13 - Whether the organisation of domestic blood collection, plasma supply, product manufacture, and product supply contributed to the extent to which infections were suffered

615. Reference is made to the earlier chapters herein on 'Self-Sufficiency', and 'Viral Inactivation' the contents of which are not repeated, though clearly relevant to the current chapter. In summary, it is apparent that:

(a) There was from the outset, an absence of central planning, control, and organization in the: collection of blood; the supply of plasma; and the manufacture and supply of products;

(b) There was not one UK wide 'National Blood Transfusion Service' overseeing the system of collecting blood; supplying plasma; manufacturing and supplying products, provided with a single direct budget for the same. Accordingly, there was never centralised co-ordination and/or control, to serve all patients in need, regardless of where they happened to live in the UK, as opposed to regional interests.

(c) Collection of blood was erroneously left under the control and budgets of 14 separate Regional Transfusion Centres, each with their own local supply interests and distinct budgets to serve;

(d) Situating two manufacturing plants in two separate countries, which then fell under two different regimes was unfortunate, particularly when Dr Lane replaced Dr Maycock at BPL in the mid 1970s, whereupon the attitude and degree of support, co-operation, and unanimity of common interests between the two nations was allowed to diminish.

(e) PFC at Edinburgh had a greater manufacturing capacity than was utilised, which led to a missed opportunity for it to manufacture and provide increased products for the whole of the UK, through receiving plasma from the North of England, as well as Scotland and Northern Ireland. PFC could have assisted BPL and the whole of the UK.

(f) There was insufficient investment in BPL, which led to diminished production capabilities, and research and development into manufacture of products. It later failed an inspection, necessitating significant investment somewhat late in the day.

(g) Concentrate products were allowed to be manufactured and provided for patient use, without ever undergoing viral inactivation processes. This should not have occurred.

(h) There was a gross under-assessment of needs and demands, allowing demand/use to outstrip production capabilities in the UK. Partly this was due to an unchecked expansion of clinical use, with prophylactic and home-treatment programmes, leading to importation of foreign concentrates and undermining purported objectives of attaining self-sufficiency in UK blood and blood products.

616. Against such backdrop, it is apparent there are several issues which could have been adopted, either earlier or at all, on a UK wide basis which would have minimised, reduced or possibly obviated the scale of infections suffered.

Surrogate testing for NANBH

617. As identified in earlier chapters, from the 1940s knowledge of the severity of serum hepatitis was steadily increased. **Serum hepatitis** (HBV) or 'Australian Antigen' was identified in 1964, and known to be transmissible by serum or plasma. Tests to screen HBV infected blood were pioneered in 1971, introduced across the UK in December 1972. **Infectious Hepatitis** (HAV) was identified in 1973, with tests introduced shortly thereafter in 1974.

618. In 1975, it was known that an agent/s other than HAV or HBV also caused post-transfusion hepatitis, identified by Dr.Alter, in the US, and termed '**NANBH'.** As previously stated it was known that exposure to these agents could result in severe illness and death.

619. In *A & Others v NBA & Velindre NHS Trust* [409], Burton J found [§99+]: that following the introduction of screening for HBV, NANBH was responsible for most, if not all, infections of blood by hepatitis; and that in the 1970s and 1980s, infection by NANBH was '*the major complication*' in blood transfusion.

620. A significant feature of *A & Others v NBA* was that although NANBH was not initially isolated in 1975, and could not therefore be directly tested for, there remained the prospect of 'surrogate tests' being undertaken, to try and identify the presence of such. These took the guise of testing for:

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[409] **A & Others (x6) v NBA & Velindre NHS Trust [2001] 3 ALL ER 289** Burton J
A claim under the CPA 1987, which came into effect on the 1 -3-1988. All claims pertaining to PTH infections after 1 -4-1991 were settled (90:10), as it was conceded anti-HCV tests should have been introduced by then. Thus, the claim concerned infections only between 1 -3-1988 and 1-4-1991.

(i) the presence of liver function abnormality – ALT; and
(ii) checking for past exposure to HBV – anti-HBc – as being suggestive of NANBH exposure too.

621. ALT tests were used by hepatologists, to measure the level of enzymes in the blood (Alanine Aminotransferase) to diagnose liver disease. Raised ALT levels suggested an abnormality of liver function, which could indicate the presence of hepatitis *or other liver conditions*: such as alcohol abuse, drug misuse, obesity. Thus, ALT tests were a possible indicator of NANBH but this was not conclusive. However, Burton J had concluded that *'the most frequent if not only symptom or indicator of NANBH was raised ALT in the blood'* [§99(ii)].

622. Prior to the discovery of a NANBH / HCV screening tests, ALT tests were introduced and utilised in: Germany (1965); Italy (1970); and the US (1986); but never in the UK.

623. Anti-HBc tests – A virus or antigen, may have an envelope containing a core, hence references to 'surface antigens' or 'core antigens'. A healthy person will develop antibodies to such, to resist those antigens. The screening test for HBV involved identifying Hep B surface antigens (HBsAg). From the HBsAg screening test, a further test was developed (though not used for screening) which identified the presence of antibodies to the Hep B core antigen (anti-HBc).

624. The anti-HBc screen test allowed identification of whether someone had previously had HBV in the past, which was perceived as a 'lifestyle marker'. Past exposure to HBV suggested it was more likely a person had also been exposed to the NANBH agent.

625. 'Aach & others', in The New England Journal of Medicine (1981) 23rd April[410], undertook a 'Transfusion Transmitted Viruses Study' of transfusion donors and 1,513 recipients or products between 1974-1979. The study identified a NANBH attack rate of 10%. Clotting factor concentrates prepared from multiple donors were NOT given. They conducted ALT tests on the cohort; and ascertained that increasingly higher levels of donor ALT were indicative of an increasing presence of NANBH (45%); concluding that blood screening for ALT levels would reduce the incidence of NANBH post-transfusion hepatitis. (*Recipients receiving two units of elevated donor ALT levels had a 91% hepatitis contraction rate*).

626. These findings were by no means new. There had been studies into transfused hepatitis and raised donor AST levels by 'Bang et al', in 1959; and raised donor ALT and AST level by 'Brandt et al in 1965', albeit such had smaller cohorts, as referred to in 'Aach et al's article.

[410] [PRSE0001650]

627. Taking account of previous studies (from 1959-1972) into sources of donor blood, 'Aach et al' observed that '*the risk is almost certainly due to the inverse relationship between socio-economic status and rate of infection with hepatitis viruses*', [411] which indicated a need to test donors.

628. Their study found that about '*40% of the cases of NANBH post-transfusion hepatitis among recipients in the study could have been prevented by discarding units with an ALT level in the upper 3% of the distribution (ie ALT> 46 IU)*' and '*a larger number of cases could have been prevented by lowering the "cut-off" to <30 IU*" which would have required discarding 9% of the blood collected.

629. The authors concluded '*screening donor blood to eliminate units with elevated ALT levels would result in a substantial reduction in NANB post transfusion hepatitis …… the high correlation between an elevated ALT level and infectivity of transfused blood provides a compelling argument that such screening should be instituted*'.

630. Surrogate screening was an alternative to a specific screening test for NANBH/HCV being discovered. It was already available, and a viable alternative pending discovery of a specific screening test. It is submitted that doing nothing to screen for hepatitis was not an option that should have been deployed. Such was not precautionary, and was an implicit acceptance of a known risk (viral hepatitis infection).

631. The date of 'Aach et al' 's report – 1981 - (and those preceding it) is significant. It is submitted that if surrogate donor screening tests for hepatitis were introduced in the UK in 1981 (or earlier, in line with Germany and Italy), the incidence of NANBH/HCV would have significantly fallen, and the incidence of HIV may have been incidentally, but significantly, minimised or reduced.

632. Furthermore, by then US researchers (*to their surprise*) [412], had concluded that blood identified as having elevated ALT levels, and blood identified by anti-HBc tests as containing HBV antibodies, did NOT materially overlap, so that any blood positive on both tests was even more likely to have been infected with HCV. This was why in part the US persisted with both these surrogate tests for 4 years after ELISA screening for HCV was introduced.

633. Burton J, concluded '*the scales have come down in favour of the introduction of these surrogate tests, and indeed both kinds of surrogate test ..*' as '*..once ALT testing is to be introduced, the addition of anti-HBc adds little by way of extra disadvantage, cost, blood loss or inconvenience, and may be of substantial advantage.*'[413] It is submitted is the

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[411] [PRSE0001650]
[412] See Burton J, in *A & Others v NBA & Velindre NHS Trust* [2001] 3 ALL ER 289, at §108(iii)
[413] At §141

correct analysis, there was sufficient objective evidence for the UK to have reasonably introduced surrogate tests by 1981, if not earlier, as Germany and Italy did.

634. It is submitted that fears of a significant drop in blood donations were no more than base assertions, unsupported empirical or other evidence, indeed 'Aach et al's research suggested otherwise (see above) and had shown the level of blood discarded in consequence of such tests was insignificant.

635. Given the increasing knowledge of the severity of NANBH sequalae (particularly in the 1970s), the availability and identifiable benefits of surrogate testing, it is submitted that would have outweighed the known probable deterioration in health arising from not doing so. Furthermore, Burton J, noted that any decrease in donations received would be from '*donors who were in any event unwanted*' but might lead to advantages for such donors of '*counselling and diagnosis*'.

HIV Donor Screening

636. Surrogate testing of donations was never formally pursued in the UK, from the 1970s or subsequently. Although AIDS leaflets were later published to deter potentially infectious donors (see below), it is submitted that the transfusion services were remiss in delaying screening of donors by direct confidential questioning of their private lives. Such was a simple, effective precaution, that could have been easily implemented earl;y on, without causing offence if delivered appropriately.

637. Reference is made to the European Council Committee of Ministers Recommendations of June 1983[414] on AIDS, which recommended:

(i) Recognising the necessity to provide pertinent information to blood donors, attending physicians and selected recipient groups in order to avoid, as far as possible, donations by persons in risk groups, without inappropriate discrimination and emotive over-reaction amongst recipients;

(ii) to take all necessary steps and measures with respect to the Acquired Syndrome and in particular: …. to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended); and

(iii) in its Appendix at §2 included "Hepatitis – persons with a past history of viral hepatitis are excluded permanently. Intimate contact with someone suffering from viral hepatitis requires deferral for 6 months".

[414] [MACK 0000307_0004 & NHBT0010651_004]

638. The first NBTS AIDS leaflet was published in September 1983[415]. The evidence indicates there was no uniform approach to: its distribution, and whether it should be sent by post to all registered donors, handed out to all attendees on arrival at the blood donation centres, left on seats and/or on the counter in waiting areas, or a combination / all of the above. It is submitted the gravity of potential HIV infection warranted all such steps be taken, but matters were left to the discretion of each centre, when central instruction or control was required.

639. Furthermore, as is apparent from the said leaflet[416], its terms are diluted and misleading, falling short in identification of '*groups of people who appear particularly susceptible*' including "*1. Homosexual men who have many different partners*" with "*Donors are asked not to give blood if they think they may either have the disease, or be at risk from it*", and in omitting to prohibit donations from those who have suffered hepatitis in the past. (a) Stronger language was required; (b) identification of susceptible groups should have included (MSM) "*Men who have (unprotected) sex with other men*" as well as '*Bisexuals*'; regardless of the number of partners; with (c) a prohibition on donating with such groups instructed they "*MUST not give blood*".

640. A meeting was held on the 9th February 1984, by the National Institute for Biological Standards and Control (NIBSC), to consider the source and use of factor concentrates in the UK. Its minuted[417] attendees considered the 'Infectious Hazards of Blood Products' (Dr. Craske report). Dr Thomas is noted as asserting that 100% of haemophiliacs could expect to be infected with NANBH (a prescient view); with Dr Tedder stating that HIV/AIDS was caused by an infectious agent (likewise, prescient). The meeting discussed potential implementation of FDA proposals for donor screening and testing processes in the UK, and how high-risk donors might be identified and excluded. Regrettably, despite discussions, no revision was made to the first AIDS leaflet at this time.

641. On the 23rd April 1984, Dr. Gallo announced[418] the isolation of the HIV/HTLV-III virus in the US, and stated his team were seeking to develop a screening test for such. In 1983, Dr. Motangnier in France, announced he had isolated the HTLV-III / LAV virus.

642. At the North London RTC in June/July 1984, Professor Contreras[419] went on a fact-finding mission to the New York Blood Centre with a colleague, Dr. John Barbara. They were trying to ascertain what they could do to try and avoid the transmission of HIV through blood donated at their RTC. In evidence[420], she volunteered that she had no knowledge of 'whether or not' she had ever seen the European Council Committee

[415] BPLL0007247
[416] BPLL0007247
[417] CGRA0000610 and PRSE0003071.
[418] DHSC0000455
[419] WITN5711001, at §261& §270
[420] Transcript – Dr. Contreras, 2-12-2021, p.90, ln 6-9.

of Ministers recommendations from the previous year, in June 1983. This is somewhat surprising, and considered indicative of the approach of the RTCs at that time.

643. During their trip to the US, they encountered implementation of a donor 'self-exclusion' questionnaire; and spoke to donors supportive of such steps and questioning. Several were seen to exclude themselves. The "Self-exclusion' questions concerned intimate lifestyle issues being asked in a confidential manner. On the flight back, Professor Contreras and Dr Barbara devised their own, similar, donor self-exclusion questionnaire, which they implemented at North London Regional Transfusion Centre. They adopted the same approach of confidential questioning as the New York centre.

644. It is submitted their early questionnaire and approach to questioning donors (which included a facility for potentially infected blood to be given for research purposes to save face at the RTC), could and should have been adopted, and utilised in all 14 Regional Transfusion Centres from mid-1984. This was a missed opportunity to share information, procedures and steps to attain 'best practise' throughout the UK.

645. Furthermore (similar to Surrogate testing), it is submitted that asserted fears that screening questionnaires would be morally repugnant or would be significantly put people off donating blood were ill-founded. There was no evidence this was the case in the North London Regional Transfusion Centre after introduction of its self-exclusion questionnaire, or that any drop in donors could not have been made up by the response to a national appeal. Dr Tedder[421] in evidence confirmed that exclusion of male donors who have sex with other men would have been a policy decision to exclude a risky population, and that it would not necessarily have resulted in a significant drop-off in donations.

646. At that time, in July 1984, there were also ongoing issues over confirmation of central funding for Dr. Tedder's research into a HIV test at Middlesex[422], with proposed trials at three Regional Transfusion Centres being anticipated to occur in October 1984.

647. It is submitted that, as it was known a HIV test was not available, screening potentially infected donors was critical, and more resources should have been made available for the resources that were available to them to minimise or reduce risk. The urgent objectives of the DoH should have been co-ordinated: (a) to attain a collective and consistent UK-wide approach; (b) sharing of materials; and (c) central control and guidance; rather than leaving matters to individual RTCs to determine.

[421] Transcript, Dr Tedder, 14-10-2022, p. 76/77
[422] MRCO0000541_033 & DHSC0001680

648. Screening tests for HIV were subsequently developed in July/August 1984,[423] trialled and tested, before being published in the *Lancet* on 1-9-1984[424]. The first commercial HTLV-3 tests were licensed in the UK in 1985.

649. Screening of Donors was still necessarily required in addition to such tests becoming available. The second AIDS leaflet[425] in January 1985, belatedly sought to address some of the previous leaflet issues: widening the group of donors identified as being 'at-risk' to include "*1. Practising homosexual and bisexual men*" with "*Donors in the risk groups must **not** give blood.*"

650. This revised leaflet took too long to be published and distributed, coming 16 months later. Lord Fowler admitted such in evidence, stating

> "*... It's then January 1985 when the leaflet is, as it were, signed off, and 1 February 1985 -- and again you've exhibited, I think, the relevant press release to your statement -- when it's issued. That is, on any view, far too long, is it not? A. Yes, it's too lengthy. We should have been able to do better than that*"[426] and when probed "*…. No, I think it -- I mean, I can't remember now what was happening in 1984, and what the health issues were in 1984, but obviously they -- it could well have been that either political or health issues were taking precedence. But we should have been able to have done better than that...*".[427]

Lord Patten was slightly more circumspect; but made a similar admission:

> "*Then if we go over the page, we will see the submission on the revision of the AIDS leaflet. Before we look at a couple of paragraphs in that submission, Lord Patten, we are now in August 1984. So that is almost a year since the original leaflet was published. Would you agree that, on any view, that was an unacceptably long period of time?*
>
> *A. It was certainly a substantial period, yes. Exactly what judgemental word one uses I don't know, but it is longer than it should have been ....".*[428]

651. Such delay is considered likely to have contributed to potentially fatal donations occurring, and it is submitted that at 1985, the advice should have been even stronger – to include exclusion of those who had had hepatitis in the past, and sexual contact with such persons in the preceding 6 months.

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[423] WITN3436003 (§180) & WITN6868001 (§5.25)
[424] NHBT0000068_015
[425] NHBT0096480_022
[426] Transcript – Lord Norman Fowler, 21-9-2021, page 47, ln 11-17.
[427] Transcript – Lord Norman Fowler, 21-9-2021, page 47-48, ln 24-4.
[428] Transcript – Lord John Patten, 20-5-2022, page 112-113, ln 17-1.

652. The third AIDS leaflet was published in the same year, September 1985[429]. It finally took a stronger line on donor advice/instruction, stating '*Do **not** give blood*' if you were "*1. Practising homosexual and bisexual men*" then included in the '*High risk groups*', and that "*People in the High-risk groups **MUST NOT GIVE BLOOD**. They should not attend donor sessions. The test may not pick up early cases of infection.*" However, the issue of past hepatitis infections was still overlooked.

653. It is submitted this position could and should have been reached earlier, back in 1983, when the first leaflet was published, particularly in light of the European Council Committee of Ministers Recommendations on AIDS in June 1983.[430]

654. From 1985, commercial HIV tests were deployed, and screening questionnaires sensibly continued. Heat-treated products were subsequently introduced across the board, and attention turned to treating those with HIV. However, NANBH continued to pervade.

HCV screening tests

655. The Chiron Corporation first identified a specific NANBH virus [HCV] in the spring of 1988. Its press release on the 10th May 1988 also announced it was seeking to develop a screening test.

656. Ortho Diagnostics Inc, and later Abbott Laboratories Inc, developed their assay screening tests which detected antibodies to HCV (anti-HVC). Details of Ortho Diagnostic's anti-HCV ELISA test was first presented in a symposium in Rome (September 1989), and disclosed publicly in a publication in October 1989.

657. An export license was obtained for the ELISA test at the end of November 1989, and the FDA approved the ELISA test on 2nd May 1990, when routine screening was introduced in the USA, alongside ongoing surrogate NANBH tests (until 1995). It is noted it was permissible to export the ELISA test before FDA approval was given.

658. In *A & Others v NBA*, Burton J, commented[431]

> *'... it was not appropriate or necessary, or legitimately expectable, that the screening should wait until after FDA approval if, as I am satisfied should have occurred, sufficient evaluation had taken place to allow for the United Kingdom's own decision to be made, like that of Australia and France and the other countries which started prior to FDA approval ...*".

[429] CBLA0002255
[430] [MACK0000307_0004 & NHBT0010651_004]
[431] See **A & Others v NBA & Velindre NHS Trust [2001] 3 ALL ER 289,** at §170

Other countries also included Finland and Japan, who had evaluated and introduced screening tests before 1st March 1990.

659. In the UK, Dr. Gunson had attended the Rome conference (September 1989) and reported back to the AVCSB & AVTTD committees of the pending HCV screening test. Concerns were initially raised about the sensitivity (ie not catching all – false negatives), and specificity (catching all those it should) of the first generation of ELISA test. However, no trials were undertaken. It is submitted that this test should have been introduced – even if only as a trial, alongside surrogate testing which should have been in place, to test those stated sensitivity and specificity concerns, to provide empirical evidence.

660. The ACVSB eventually recommended introduction of the ELISA test at meetings in July 1990 and November 1990. Ministerial approval for such was only then forthcoming on 21 January 1991. Implementation in the RTCs was delayed until September 1991, when second-generation tests were then deployed [save for Newcastle RTC, which had independently introduced the first generation test earlier, and was (wrongly) criticised for such].

661. In her evidence, Baroness Hooper acknowledged communications from civil servants over the progress of HCV screening were inappropriate, although this was not her contemporaneous view at the time, as she 'did not have her eye on this particular ball'.

662. It is submitted these delays were unjustified and indefensible. Dr. Gunson was appraised of the test two years before its introduction in the UK. Numerous infections could have been avoided over those two years.

Conclusion

663. It is apparent the government failed to identify and address the issues, omitted to centrally plan, control and/or co-ordinate a safe system for the collection of blood; supply of plasma; and the manufacture and supply of products, so as to prioritise patient safety with the means at its disposal.

664. In giving evidence[432], Dianna Walford encapsulated this failure, stating

> *"What one knew was that potentially there was -- blood transfusion was inherently hazardous. You did everything possible in the Blood Transfusion Service to reduce the hazard, the risk, coming out of blood transfusion. So anything you could screen for, you should screen for, any donors that should be*

[432] Transcript – Dianna Walford, 19-7-2021, page 17-18, ln 21-10.

asked not to donate you dealt with but, inherently, you don't know what you don't know. You only know that it could happen, and, in fact, it did happen."

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Chapter 14 The testing or treatment of previously untreated patients ("PUPS") and other non-consensual testing, trials, studies and experiments

665. We do not propose to repeat in this chapter the egregious happenings at the Lord Mayor Treloars School, which were canvassed in a dedicated chapter above. Those matters clearly bear on this chapter, and issue of testing and/or treating 'previously untreated patients' (patients referred to contemporaneously by clinicians as 'PUPs' or 'virgin' haemophiliacs).

Terminology

666. **'PUPs', 'virgin' patients and related terms:** When assessing the evidence before the Inquiry, a certain ambiguity lies around the phrase 'PUP' or 'virgin haemophiliac'. It is not used consistently. The ambiguity is around *what* the patient was not treated with or not exposed to.

(a) 'Untreated' may mean a patient who has not received factor concentrates but has been receiving some other anti-haemophiliac treatment.

(b) Equally, it may refer to a patient who has never received any clotting product (including cryoprecipitate).

(c) It may also refer to a patient who has received untreated factor concentrates but who has not received *heat-treated* factor concentrates.

(d) The acronym 'PUP' alternatively may stand for 'previously *untransfused* patients'[433] i.e. those who have not been treated by transfusion.

(e) Some Treloars survivors understood the phrase 'virgin haemophiliac' to have a further connotation, namely it referred to a minor who had not been exposed to sexually-transmitted disease, nor engaged in intravenous drug use or consumed alcohol (thus eliminating certain causes for hepatitis, liver cirrhosis and/or HIV).[434] This is supported by documents that refer (for example) to "... no seroconversion on any other 'clean virgin' not otherwise at risk for AIDS…"[435]

667. Complicating the picture further, there are also references to 'minimally treated' or 'previously very low volume treated' and 'infrequently treated' patients; as well as 'naïve

[433] Statement of Dr John Cash to the Penrose Inquiry, PRSE0002836, para 12.141 (sic).
[434] Oral evidence of Stephen Nicholls, transcript of evidence 01/05/19 , page 50 INQY1000002
[435] Internal communication from Mr Bishop to Dr Harris, 25/04/86, ARMO0000526.

patients'. The ambiguity around the phrase 'virgin patient' was recognised contemporaneously by those designing clinical trials.[436]

668. **'Research', 'trials', 'studies', 'tests'**: It is necessary to clarify that these terms have a more formal and less formal meaning, in order not to caricature what CPs say occurred.

(a) In some cases, CPs were enrolled into formal research studies that had protocols, required ethics approval from local hospital ethics committees (which may not have been sought; if sought, may not have been abided by and/or should not have been given), and which had a predetermined methodology with identification of control groups, etc.

(b) In other cases, 'trial' means something more informal. This refers not to a rigorous study intended for publication and peer-review but rather (i) the routine gathering of data from haemophiliacs' medical records [with or without consent], (ii) combined with a scientific interest in evaluating what effect these treatment decisions have on the 'macro picture' of epidemiology, and what this indicates about the magnitude of known risks; (iii) for dissemination among in-groups such as the UKHCDO meetings. The line between formal and informal trials may be indistinct. CPs suggest that the scientific interest unduly influenced those self-same decisions as to treatment, rather than a precautionary approach to the safety of the individual patient.[437] The evidence shows clinicians had a sense of detachment, fatalism and culpable inadvertence to risks. Many simply adopted a sit-back-and-wait approach to emerging risk.

(c) CPs also use 'trial' to mean prescribing treatments speculatively, without disclosing the unproven nature of the treatment, and with a secondary purpose of gathering information. The use of Interferon in treating HCV is such an example.

669. **'Non-consensual'** as used herein covers both the situations where consent was absent entirely due to a lack of knowledge on the part of the patient/parent, as well as inadequate consent that could better be characterised as trust and acquiescence because the patient/parent was insufficiently informed.

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[436] See e.g. letter from Dr Boulton to Dr Cash dated 27th June 1986, PRSE0002000 at page 1.

[437] In an exchange between the Chairman, CTI and Dr Charles Hay during his evidence on 05-11-2020, INQY1000073 at page 30 , pages 117-119, Dr Hay said that the line between interventionist and observational studies depends in part on the intention of the researcher. He acknowledges the risk of introducing bias in observational studies but says they are easier to conduct than interventional ones. 'That is the advantage of a randomised comparison because then you have negated any biases from the operators. And randomised comparisons are always interventional by definition but can be difficult to conduct.'

Introduction

670. The first, and most obvious, point to make about all of this is that the mere existence of unsavoury terms like 'PUPs' or 'virgin haemophiliacs' within medical parlance of itself demonstrates awareness that there were two categories of patient. One category of patient had been exposed to a risk, while the other category had not. In and of itself, this demonstrates a knowledge of risk.[438] The terms themselves were widely understood in the medical profession, but patients did not find the terms familiar[439] (as they should, had they been fully informed as to treatment)[440] and some misunderstood them as terms of endearment.[441] Many infected/affected gave evidence of being shocked to see reference to trials in their/relatives' medical records.

671. However, the truth is even more sinister than that. Our clients contend, and we ask the Chairman to conclude, that some clinicians regarded untreated patients as a suitable 'control' group for surveys, and patients were used as 'guinea pigs' without their knowledge or consent. That is to say, patients were viewed as research subjects rather than, first and foremost, as individual persons who depended upon clinicians for therapeutic intervention in order to promote their health and wellbeing. Some clinicians overlooked the patient-doctor relationship and perceived their patients instead as expendable indicators of epidemiological patterns. (Note that this tendency to aggregate all haemophiliacs, rather

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[438] See, for example, the medical records of Luke O'Shea which record '1 October [1985] blood test request for virgin haemophiliac, post first exposure heat treated VIII' and it is stamped 'danger of infetion'. A note then records: 'As an infusion of DDAVP had not controlled the bleeding he then received 1,680 units of Alpha heat treated Factor VIII concentrate. This boy also was a virgin and had never received any blood products in his life. Both patients received Profilate list number 360210, lot number A60311. Both patients will attend for fortnightly follow-up blood examples for liver function tests, blood count and virology. I hope they will be suitable for the heat treated trial." (Transcript London Tuesday 4th June 2019, page 6) The following exchange took place during Mr O'Shea's oral evidence about this:

> *"MS RICHARDS: It is right to say that in response to your witness statement, Dr Machin has said has it was standard practice to stamp these forms with danger of infection but if we just go back to 1696003, this is the test result before that request for a test, before Luke was given the factor products, and you, Luke, have pointed out it doesn't bear the stamp "danger of infection".*
> *LUKE: Yes, agreed.*
> *SIR BRIAN LANGSTAFF: Did Machin say what the criteria were for putting the stamp on, to make it standard practice? In other words, standard practice in what circumstances?*
> *MS RICHARDS: Sir, it's in Dr Machin's statement. I think it's just described as being standard practice: "Routine practice at the Middlesex Hospital to label all blood test tubes and laboratory request forms from all haemophiliacs as danger of infection on yellow stick on forms."*
> *SIR BRIAN LANGSTAFF: When it plainly wasn't, if this is an example.*
> *MS RICHARDS: Sir, yes.*
> *SIR BRIAN LANGSTAFF: Thank you. This followed the giving of Factor VIII and then the testing to see if there was infection following?*
> *MS RICHARDS: Yes."*
> [Transcript London Tuesday 4th June 2019, pages 10-11]

[439] For example, Shelagh O'Shea said in her oral evidence: "I had never heard of a virgin haemophiliac until I saw [my son]'s notes, it had never ever been mentioned or I'd never heard the expression before."Transcript London Tuesday 4th June 2019, page 8, lines 1-3.

[440] Shelagh O'Shea confirmed that her son being entered into a trial had never been discussed with her, despite reference to this in his medical notes.Transcript London Tuesday 4th June 2019 , page 8, lines 9-19.

[441] Evidence of Myles Hutchison, Transcript – London – Thursday 31 October 2019 (Jryna Batters, Myles Hutchison, Paul Hutchison, Mrs AU, Mrs AV) page 50. See also evidence of Paul Hutchison, ibid, page 64.

than seeing them as individuals, also affects other aspects of the patient-clinician relationship. Another example of this is failure to distinguish mild, moderate, and severe haemophilia and/or the individual patient's frequency of bleeds when making decisions to prescribe factor concentrates.) The result of this is that significant numbers of patients were involved in non-consensual testing, trials, studies and experiments.

672. The second point to make relates to this failure to see patients as individuals having varying severity of haemophilia. The second point is this: at one time or another, every patient is a PUP. In the first instance, every patient is untreated – especially if that patient is newly-diagnosed and/or a child. The implication of this logical observation is that each patient represents potential research fodder to someone inclined to see things through that distorted lens. Thus we see in evidence that PUPs were perceived as valuable commodities:

(a) For example, Dr John Cash refers to 'Richard Lane's concern that [SNBTS] don't interfere with his existing programme on small pool product, in terms of using up these precious "virgin haemophiliacs!"'[442] Dr Cash's use of scare quotes may well mean he did not share the sentiment that virgin haemophiliacs should be viewed as a (scarce) resource, but he was nevertheless referring to a real sentiment that he attributed to Dr Lane.[443] However, other language used by Dr Cash suggests that he too saw things this way.

(b) Dr Cash refers to 'seeking access'[444] to patients. The inference to be drawn is that clinicians, rather than patients themselves, were seen as the gatekeepers. There is rarely any mention of patient consent.[445]

(c) Dr Cash does not want PUPs to be 'used up'[446] in trials of commercial concentrates because he wishes to trial SNBTS concentrates.

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[442] NHBT0008622_010.

[443] Consequently, there is a carving up of research territory proposed by Dr Cash: 'Perhaps the matter may be resolved on the basis that the small pool project is concentrated in Charlie Rizza's group.' [ibid., NHBT0008622_010] It seems that the personalities of clinicians and a fear of treading on toes eclipsed any concern for those patients who were 'virgin haemophiliacs'.

[444] Statement of Dr John Cash to the Penrose Inquiry, PRSE0002836, para 12.141 (sic).

[445] A limited, rare exception is the UKHCDO meeting of October 1979 (minutes are at JEVA0000171 pages 8-11). At that meeting, some haemophilia centres complained of difficulty in collecting the types of data that they had hitherto gathered, with Professor Bloom urging them to continue to do so because 'collection of data over the last ten years had been invaluable and had helped considerably with haemophilia management'. The types of data gathered included: name, diagnosis, treatment, factor VIII level, and inhibitor status. A review of systems for data gathering was to be undertaken. Exceptionally, consent to being on a register is mentioned. Dr Craske requests that data be continued to be gathered in the way it has always been. However, Dr Jones enters a limited objection in respect of carriers following a 'recommendation of the Clinical Genetics Society Working Party that carriers should only go into genetic registers if the patient concerned had given his or her approval (Ref.: Lancet I, 253 (1979)). It was therefore agreed that data on Carriers of Haemophilia A or B should no longer be collected on a National basis.'

[446] Statement of Dr John Cash to the Penrose Inquiry, PRSE0002836, para 12.141 (sic). See also a memo from Travenol: 'The UK trial at St Thomas' Hospital was discussed. Dr G Savidge is very keen to have product immediately as he has had to treat three of his five initial virgin haemophiliacs with non-treated product so *now has only two* patients left in the trial.' [SHPL0000983_002, emphasis added]

(d) It is submitted that this view was shared by clinicians as well as fractionators, as can be seen from the 'horse trading' of patients at UKHCDO meetings. For example, Dr Craske writes to Dr William Maycock about plans to enlist haemophilia centres to take part in a study of Lister Factor VIII, saying he will: "do most of the lobbying of Haemophilia Directors at the annual meeting…"[447] See further statements such as: "I have again spoken to Christopher Ludlam who continues to assert *his willingness* to participate in studies of new Factor VIII materials for patients, both virgin and multi-transfused."[448]

(e) In one sense, researchers can only reach patients through their physicians. However, in light of paragraphs (a)-(d) above, the impression given is that the assent of haemophilia centre directors is seen as crucial, whereas the assent of patients is not discussed – including on protocol forms.[449] Collection of haemophiliacs' data was routine.[450]

673. The language used by researchers tends to suggest they viewed the aim of the study as paramount and consequently objectify the (consenting or non-consenting) participants. Thus Dr Cash tells Professor Arthur Bloom that "We hope to have sufficient wet heat-treated Factor VIII for limited clinical studies by September '84. We are particularly keen to see part of this product is *put into 'virgin haemophiliacs'* and would much appreciate the assistance of the UK Haemophilia Centre Directors Working Party on Hepatitis."[451] In turn, Dr J Boulton tells Dr Cash: 'When I get a clear intimation of a date for such a product [a heat-treated product that improved upon 8Y], I would then be very happy to step up the campaign to *get it infused into people*.'[452] It would appear that in pursuit of scientific advancement and the greater good,[453] the wellbeing of the very group of patients who stood to benefit from any advances was forgotten.

674. **Beguiled or captive**: A striking aspect of the evidence that the Inquiry has heard relates to clinicians' unswerving faith in the benefits of concentrates, despite all evidence to the contrary. For example, Dr John Craske concludes a report of the UKHCDO Hepatitis Working Party in this way:

> "As a result of the first year's work of the Hepatitis Working Party, the problem of hepatitis from the point of view of the haemophiliac is more clearly defined,

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[447] Letter from Dr Craske, Consultant Virologist, PHLS, to Dr Maycock 17/12/76, CBLA0000524.
[448] Letter from Dr Boulton to Dr Cash dated 27th June 1986, PRSE0002000.
[449] See e.g. the forms attached to CBLA0000565.
[450] See footnote 13 above. It may also be that some entries from the 1970s found on the National Haemophilia Database, extracts of which are seen in many patients' records, relate to the prospective trials organised by Dr Craske. They relate to Kryobulin or Hemofil, which are the products studied in Craske's earlier work.
[451] Letter from Dr Cash to Professor Bloom, 17/02/84, OXUH0000680. Emphasis added.
[452] Letter from Dr Boulton to Dr Cash dated 27th June 1986, PRSE0002000. Emphasis added.
[453] In the same letter to Professor Bloom speaking of precious 'virgin haemophiliacs' NHBT0008622_010, Dr Cash says: 'I'm very anxious not to rock the boat, yet I would be delighted to *press* some of what I hope is *very much in the national interest*.'

but there remains much work to be done to devise methods to prevent the threat of chronic liver disease *clouding the undoubted benefits that large pool concentrates have brought*"[454] (emphasis added)

Despite acknowledging the threat of chronic liver disease, Dr Craske is in no doubt of the benefits of concentrates. Dr Craske does not appear to be thinking as a researcher in the sense of testing a hypothesis, but instead remains unshakeably wedded to a preconception of benefit even in the face of proof to the contrary. He is detached from his findings, calling hepatitis a problem from the patient's point of view. Perhaps researchers thought that they could learn something about disease epidemiology, and save future cohorts if concentrates lived up to their life-changing promise (but were without infectivity). In doing so, they may have lost sight of patients sacrificed to the gains of progress.

675. Indeed, concentrates were administered despite patients objecting and asking for cryoprecipitate.[455] During a meeting at Birmingham Children's Hospital which informed parents that some of their children had HIV, it was asserted that concentrates would nevertheless continue to be prescribed.[456] As one patient's mother said in her evidence: 'So, you know, we blindly carried on giving the treatment. But I do wonder, afterwards, why couldn't they just temporarily stop the Factor VIII treatment while they investigated exactly what was going on, and give us some more information? You know: why did we have to sort of blindly carry on?'[457]

676. The 'why' cannot now be known for certain. Some suggestions are ventured further below in this chapter. It is clear that there were close associations between prescribing physicians and pharmaceutical companies. These associations took many forms. They included hospitality, funded research (including free treatment to patients of the concentrate on trial), honorariums (whether paid directly to the researcher or to the hospital trust), and remunerated or non-remunerated roles as consultants or advisers to the companies. As Dr Geoffrey Savidge put it in his evidence to the Archer Inquiry, 'such incentives could be recommendations for this [product] or recommendations for that [product].'[458] More subtly, clinicians may have been beguiled into thinking that free treatment to patients in trials would benefit both patients and the greater good. Dr Savidge noted that some clinicians advised state bodies like BPL as well.

677. To anticipate the thrust of the submissions below, the following **summary** can be given: Victims of the scandal, in particular persons with haemophilia, were subjected to non-

[454] UKHCDO Hepatitis Working Party Report 20/08/78, HCDO0000135_029
[455] Evidence of David Cloke WITN1159001. The treating physician even referred to this 'intransigence' during the Heathrow meeting in 1983.
[456] Evidence of Brenda Haddock 06/10/22, INQY1000253 at page 15, page 59, lines 17-23.
[457] ibid. INQY1000253 at page 15 pages 58-59.
[458] ARCH0000011 at page 147.

consensual research involving known or suspected infected blood products. This non-consensual research happened at various times, depending on the virus in question.

(a) Patients who had not previously been treated were given concentrates, at a time when it was known or suspected that HIV was viral and potentially transmitted through concentrates, so as to monitor whether that theory was borne out. If this initially sounds implausibly heinous, recall that concentrates were being administered throughout the previous decade despite growing knowledge of the risks of viral hepatitis of all kinds. Despite symptoms such as cirrhosis appearing in children, jaundice was normalised by the medical profession as an inevitable side effect of haemophilia treatment.

(b) For example, Professor Bloom rejected Dr Chisholm's suggestion of reverting to cryoprecipitate in response to HIV at the Haemophilia Centre Directors meeting on 17 October 1983.[459] This is said to be on grounds that there is 'no proof' of the link. Professor Bloom had attended a meeting of the MRC Working Party the previous week, which discussed the idea "that blood product associated cases could enable some of these alternative hypotheses to be tested."[460] Thus, the possibility of a link between blood products and AIDS was raised at the MRC meeting, but no precautionary action was suggested there, nor at the subsequent HCD meeting. Those receiving blood products were explicitly described as test cases for different hypotheses on the cause of AIDS. This is also notwithstanding Professor Bloom's own patient in Cardiff being diagnosed with AIDS earlier that same year. It is staggeringly reckless to refuse to take precautionary measures despite first-hand experience of AIDS in a patient in one's clinical practice and second-hand discussion in meetings and the medical literature. This type of recklessness begs for an explanation, and explanation is ventured further below.

(c) Later, those who had not previously been treated were given heat-treated concentrates, when they were just being developed, in order to be the control group to see whether heat treatment worked or whether they too would develop HIV. There is written evidence of this – some of it quoted in this chapter.

(d) PUPs were given concentrates (which were known to have significant risks of NANB[461]) and then complacently followed up to study consequences and transmission by various means when the results of the studies should have rung alarm bells. Dr John Craske's experiments over more than a decade are a particular case in point and discussed in depth immediately below.

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[459] CBLA0001755, item 9.
[460] PRSE0000389.
[461] Not only was there discussion in the medical literature about transfusion hepatitis since the 1960s, 'serum hepatitis' was made a notifiable disease in 1968 (DHSC0000947) and jaundice was discussed by the UKHCDO from 1971 (HCDO0001014).

Case study: Dr Craske and HCV studies

678. Dr John Craske (PHLS) was Chairman of the UKHCDO Hepatitis Working Party. Dr Craske undertook research regarding the incidence and seriousness of hepatitis in haemophiliacs being treated with factor concentrates throughout the 1970s and 1980s.

679. Even before beginning his studies, Dr Craske knew that hepatitis was transmitted through blood products owing to the previous work of Dr Rosemary Biggs, which was referenced at meetings he attended. Particularly chilling from Dr Biggs' findings is the statement that 'mildly affected [haemophiliac] patients to whom very little treatment is given… do seem to have a high incidence of hepatitis if large pool fractions are used'.[462] However, Dr Craske's course of action was not to caution against the use of factor concentrates, but instead, to encourage studies, on a national level, into the effects of factor concentrates. From the mid-1970s, Dr Craske urged Haemophilia Centre Directors to take part in his various trials to study the incidence and severity of hepatitis in haemophilia patients receiving FVIII.

680. The evidence shows that Dr Craske followed a consistent pattern of collecting and receiving data which showed more and more haemophiliacs were being infected. Even though there was ample data to prompt changes of clinical practice, Dr Craske suggested further trials to collect more data, as opposed to taking any preventative action or raising concerns.

681. The periods of time that Dr Craske proposed for his trials were unnecessarily long and doubtless played a role in why dangerous FVIII remained in use for more than a decade. Early studies by Dr Craske lasted for one year; others went on for two years (with two-year extensions) and there is at least one example of a study extension over five years. It may well be that Dr Craske was curious about incubation periods for hepatitis, but there was extant evidence in chimpanzees and in published work (e.g. Prince et al 1974[463]) to urge caution and draw preliminary conclusions. The studies carried out by Dr Craske investigated extremely narrow questions that did not materially advance the sum of human knowledge and whose answers could be predicted in advance, for example, investigating transmission by different brands of commercial factor concentrates.

682. Not only were the trials unethical given the state of knowledge at the time, they lasted far too long. This meant that, by the time the trials ended, many haemophiliac patients would be infected. As a matter of probability, the more time that passes, the greater the chance that any particular patient would be given an implicated batch of FVIII. Whilst some

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[462] Draft of *Factor VIII Concentrates and the treatment of Haemophilia* by Rosemary Biggs: Includes Tables, Charts, and Figures supporting studies (approx. 1973) [OXUH0003615] at page OXUH0003615 at page 10. This study includes an acknowledgement that thanks Dr Rainsford for pr oviding data about boys at Treloars: OXUH0003615 at page 18.

[463] Referenced by Dr Craske in HCDO0000135_029

of the research carried out by Dr Craske was observational and retrospective in nature (i.e. examining data that had already been collected as a matter of routine), other studies were interventional and prospective (i.e. involved administering factor concentrates). The retrospective studies were hampered by past practices of data collection, which did not always permit of direct comparison.[464]

683. There is no evidence to suggest that any of the patients being recruited into Dr Craske's trials were aware of their participation. Even if it could be shown that one, or a small number of, patients were aware of their involvement, the evidence the Inquiry has heard from those infected and affected that the vast majority of patients were not aware.[465] Even if a particular patient had been aware of their enrolment, it is difficult to envisage a patient voluntarily taking on the risks as they were known. Indeed, many CPs have said that they would not have consented had they been fully informed.

684. The lack of transparency around Dr Craske's work, and some hints that its unethical nature was well understood by others, can be found in the documentary evidence. For example, in a letter of February 1978, Dr Maycock says he is in "general agreement with the proposal to study the incidence of hepatitis" but cautions against some aspects of the study saying: "Too close investigation of these patients might suggest to any who were found to have chronic hepatic sequelae that they had been negligently treated originally and that a claim for compensation might be in order" and "it may be undesirable to be seen to giving emphasis to this complication".[466] Dr Maycock says patients should only receive one batch where possible. Dr Maycock's response was defensive; he did not propose the study should not go ahead.

685. Civil Service briefings blandly recorded statements like 'all haemophiliacs using blood products were infected with hepatitis C before heat treatment was introduced in the mid-1980s'[467] without recognising or acknowledging that DHSS-funded studies may well have contributed to patients receiving these products.[468]

Chronology

1-Nov-1974	Dr Biggs' 1973 jaundice study data, quoted above, are presented to a meeting of the UKHCDO. Dr Rainsford of Treloars, who contributed data to Dr Biggs' study, asks if any concentrate preparations have been tested for hepatitis. Dr Craske undertakes to *"draw up a plan to study the incidence of various types of hepatitis at different centres and the relationship of infection*

[464] HCDO0000135_029 (p1-2)
[465] See, for example, the evidence of Elisabeth Buggins 06/10/22 [transcript INQY1000253_page 5 at page 18, lines 1-19] who says that blood was routinely taken for tests but she did not question what it was used for, assuming it was for the patient's benefit.
[466] BPLL0002271_002.
[467] WITN6658003 (briefing for Hazel Blears on HCV in advance of an oral PQ from Brian Iddon), page 9 (internal page 8).
[468] HCDO0000135_029

	to the various types of material used". Dr Biggs stated that '*it was not yet proved that the commercial factor VIII was much more dangerous from the point of view of causing hepatitis than other preparations and that she hoped that this material would not get an unnecessarily bad name. It was in fact clinically invaluable while the NHS supply was so limited. Dr Craske agreed with this but said that he felt that a wholly NHS concentrate was likely to be safer…*'[469] At the outset, therefore, there appears to be a preconception that commercial factor VIII is 'invaluable' and resistance to believing otherwise. Secondly, Dr Craske predicts that NHS concentrate is safer than any commercial concentrates. Nevertheless, he continues to do comparative studies of commercial concentrates throughout the following years.
2-Aug-1975	The Lancet publishes a study by Dr Craske reporting an outbreak of hepatitis in those receiving FVIII.[470] The introduction begins by stating the 'considerable advantages' of freeze-dried concentrates. The second paragraph says *"Treatment with Factor-VIII concentrates exposes the patient to a higher risk of contracting transfusion hepatitis. Cryoprecipitate, in which each bag is made from one or two donations, carries a relatively low risk of hepatitis"*. Commercial concentrates carry the highest risk. *"A more general study is now in progress."* **(1975 Study)**
Sep-1975	Dr Craske sets up a year-long study, to begin in Jan 1976 **(HBsFVIII Study)**, *"To assess the value of regular testing of serial specimens of serum obtained from Haemophiliacs on regular replacement therapy for HBsAB"* .[471] *"This project is not intended to be an addition to the prospective study already being organised at certain large Haemophilia Centres by Dr Kirk and Dr Craske. It is hoped to interest Centres not taking part in the above project to participate in this study"*
3-Aug-1976	Dr Craske writes to various doctors telling them two patients developed NANB after receiving Kryobulin.[472] He asks doctors to let him know if any patients are similarly affected and receives affirmative responses.
19-Oct-1976	Dr Craske writes to Dr Maycock: *"there is a fairly constant incidence of hepatitis which occurs after transfusion of both English FVIII and other commercial preparations".*[473] Craske asks for collaboration to do more hepatitis FVIII studies. On 29-Oct-1976, Dr Maycock agrees to the request.[474]
17-Dec-1976	Dr Craske writes to Dr Maycock about the hepatitis survey and enlisting centres to take part. Dr Craske says he will *"do most of the lobbying of Haemophilia Directors at the annual meeting on Jan 13th"*[475]

[469] HCDO0001017 [p6]
[470] CBLA0000297
[471] BPLL0001436
[472] OXUH0000761_004 and JEVA0000149_0002
[473] CBLA0000472
[474] CBLA0000477
[475] CBLA0000524

13-Jan-1977	Dr Craske presents hepatitis data to HCDs regarding the **HemofilV1 Study**. He says *"he would like to continue with his study over the next two years"... "This continued study would include a follow up of patients who had had Hemofil associated hepatitis to study the incidence of chronic sequelae, and a comparison of jaundice associated with NHS Factor VIII and commercial products". "Dr Craske asked that data about treated patients should be sent to him in connection with the study on hepatitis"*.[476]
28-Jan-1977	Dr Craske reports HCDs approved "a further study of the incidence of hepatitis" (**Lister Study**) following FVIII.[477] A number of centres have already signed up to take part. The Lister Study replaces the HemofilV1 study.
9-Mar-1977	Dr Craske sends Dr Maycock a protocol for his Lister study and updated C3 form.[478]
7-Apr-1977	Dr Craske says he hopes to start the Lister study in April or Sep 1977.[479]
30-May-1977	Craske reports on the **HemofilV1 study**: *"The study had involved 26 Haemophilia Centres and the finding showed that of 371 haemophiliacs 66 had one or more attacks of Hepatitis. The incidence of infection by Hemofil was very high in susceptible patients - 6 out of the first 7 batches of Hemofil showed signs of HBV - and Dr Craske thought that approx the same incidence would arise from the use of all commercial products. He asked Directors if they would co-operate in extending his survey to Scotland for a period of two years"...*[480]
16-Sep-1977	It appears Dr Craske has not yet started the **Lister study**. Dr Maycock asks for update saying: "We have not yet distributed the ear-marked batches."[481] This is a clear indication that not all the studies were purely observational. Some were interventional.
22-Sep-1977	Dr Craske reports *4/6 batches* of Hemofil and *5/17 batches* of Kryobulin were associated with NANB. Many batches also contained HBV. He proposes to continue to collect more data about rates and severity of hepatitis infections and different products.[482]
22-Nov-1977	Dr Craske confirms the **Lister study** has still not begun as he is waiting on information as to participants' monthly requirements for Lister FVIII, which he will try to 'screw out of them'. He describes the recent formation of the HCD's Hepatitis Working Party as a "problem" for the study and proposes the BTS is represented therein.[483]

[476] PRSE0001665 and HCDO0000392_057.
[477] CBLA0000565
[478] CBLA0000581
[479] CBLA0000592
[480] PRSE0002273
[481] CBLA0000655
[482] PRSE0000891
[483] CBLA0000690

13-Jan-1978	Dr Craske provides Dr Maycock with information needed for the **Lister study** to begin and, presumably, it begins shortly thereafter.[484]
30-Jan-1978	It appears the **Lister study** has begun. Dr Craske tells Dr Maycock of two new studies he wants to do: (1) *"to study the incidence of hepatitis associated with all brands of Factor VIII, over the next three years, in much the same manner as we have done with Hemofil"* (**1978 Study**); and (2) "to look up the incidence of chronic sequelae in patients who received the heavily contaminated batches of Hemofil in 1974/75, and other associated problems" (**OxV2 Study**).[485]
8-Feb-1978	Dr Craske publishes a project outline for the **OxV2 Study**.[486]
20-Feb-1978	Dr Craske is told by Dr Maycock that Dr Maycock is in *"general agreement with the proposal to study the incidence of hepatitis"* but cautions against some tests and aspects saying: *"Too close investigation of these patients might suggest to any who were found to have chronic hepatic sequelae that they had been negligently treated originally and that a claim for compensation might be in order"* and *"it may be undesirable to be seen to giving emphasis to this complication"*.[487] Dr Maycock says patients should only receive one batch where possible.
20-Aug-1978	Dr Craske's Hepatitis Working Party report:[488] *"An application for a research grant was made to the DHSS in April of this year to provide financial support for the surveillance programme for hepatitis"..."and for a pilot project to investigate the incidence of chronic liver disease in patients treated with Hemofil in 1974-5"... "Approval has now been given to this project which will last for three years"*. An abundance of data about lots of patients being infected and the incidence of chronic liver disease. Dr Craske says he visited the USA and was aware that *"they have carried out almost 100 liver biopsies on patients with chronically elevated serum transaminases in collab survey, and nearly 50% of these have histological chances compatible with cirrhosis, chronic active or chronic persistent hepatitis"*. Despite screening, HBV continues to occur with every brand of FVIII including NHS concentrates; it is clear that the test not sensitive enough. *"There remains much work to be done to devise methods to prevent the threat of chronic liver disease* ***clouding*** *the* ***undoubted benefits*** *that large pool concentrates have brought".*
13-Nov-1978	A letter from Dr Gowans (PHLS) confirms:[489] *"neither of the two laboratories in PHLS that are concerned with the study of the frequency and epidemiology of NANB hepatitis is involved in trying to identify the antigen."* and *"Dr Craske works closely with the directors of the Haemophilia Centres with whom he has a grant for the investigation of the prevalence and*

[484] CBLA0000713
[485] CBLA0000724
[486] CBLA0000713
[487] BPLL0002271_002
[488] HCDO0000135_029
[489] JEVA0000169

	behaviour of hepatitis in patients treated with Factor VIII"
29-Jan-1979	Dr Craske chairs the Hepatitis Working Party meeting.[490] Various points are made about current hepatitis studies. Dr Craske says chimpanzees have been infected with NANB from FIX. An annexed study says use of FVIII *"could lead to chronic persistent, or chronic active, hepatitis with eventual progression to cirrhosis*". A study of patients is then suggested at Oxford and Edinburgh (20 at each centre). On page 10, there are criteria given for hepatitis and *"definite association with a Batch of FVIII of IX Concentrate"* which includes 3 associated cases and other criteria. An increase in cases of hepatitis is attributed to mild haemophiliacs (severe haemophiliacs having already been exposed to viruses), without any discussion of whether this treatment is appropriate for mild haemophiliacs [page 2]. Dr Craske notes: *"Our thanks are due to the Directors of the Haemophilia Centres in the U.K. for their contribution to the continuing survey of hepatitis in haemophiliacs. We hope that in the next two years some pertinent answers and possible solutions to this problem may become evident as the work continues."*[491] It is surprising that, after five years of study, pertinent answers and possible solutions are not expected for another two years. Further, there was already an abundance of evidence for an abundance of caution.
12-Feb-1979	The effects of coinfection are recognised. *"Dr Craske recalled evidence from haemophiliac studies that non-A non-B infection might severely damage a liver already compromised by previous viral hepatitis"*.[492] Dr Craske says NANB hepatitis *"certainly"* transmitted by NHS FVIII and hears Dr Zuckerman express a view that *"up to 40% of NANB infections progress to chronic liver disease"*
10-Jul-1979	An application is received at the MRC from Dr Craske for *"A study of acute hepatitis in a defined population in general practice in North West England"*. The assessor of the grant application asks whether the minutes accurately reflect evidence as to the spread of hepatitis in household contacts of haemophiliacs.[493]
15-Oct-1979	Dr Craske tells HCDs the *"Hepatitis Working Party would like data to be collected for 1979 in the same way as it had been collected for 1977 and 1978."* and *"Dr. Craske presented a draft Form C3 which he proposed to circulate to all Haemophilia Centre Directors asking for information on patients thought to have developed chronic hepatitis."*[494].
20-Nov-1979-21-Nov-1979	Meeting of the Haemophilia Centre Directors at which data gathering is discussed in detail.[495] The meeting discusses whether to continue collecting

[490] HCDO0000270_091
[491] ibid.,page 9.
[492] WITN4461093
[493] JEVA0000170
[494] PRSE0000539
[495] CBLA0001028

	data on types of material prescribed and incidence of hepatitis. Dr Craske tells HCDs he is interested in collecting more data on patients. Dr Craske thinks there are different types of NANB viruses in different products. *"Dr. Craske commented that most patients thought to have developed chronic liver disease had not previously had an overt attack of hepatitis."* The meeting agrees to continue to collect data. The following passage is telling as to attitudes regarding consent to data collection: '*It was agreed that the Haemophilia Centre Directors should have access to the names of only their own patients but Working Party Chairmen [this would include Dr Craske] could have access to relevant data from the full computer files. The recent request by the BMA to GPs that they should oppose the names of patients going into computer files, was raised and the Haemophilia Society representatives were asked how the Society would feel about patients' names being put on a computer file. Mr Polton said that he did not think that any of the Society's members would object to their name going onto a computer file. All haemophiliacs know their names are held in files at Haemophilia Centres and this was something they accepted as being necessary and did not worry about*.'
Sep-1980	Glasgow Symposium. Dr Craske's NANB presentation reports *"low contamination ratio for cryoprecipitate"* and "*commercial concentrates had a high attack rate (14.6%).*" (page 9) He writes: "*There is an increased risk from commercial Factor VIII compared to NHS VIII… but no firm conclusion can be drawn until prospective studies have been carried out*." (page 11). This appears to be unduly conservative, given that he expressed the same view in 1974. He reports 50% of biopsied patients have "*histological evidence of chronic persistent hepatitis. Other patients showed evidence of chronic liver disease or cirrhosis...*". Factor IX concentrates are therefore '*strongly contraindicated*' for non-haemophiliacs due to the hepatitis risk [no justification is made for continuing to give them to haemophiliacs]. He goes on to say: "*It seems likely that some patients will develop severe chronic liver disease over the next 10 years*." Summing up, Dr Craske writes: "*There is, therefore, **a high risk** from the use of FVIII or IX concentrate that the patient will contract NANB hepatitis, and a 20-30% chance of resultant chronic hepatitis*". In the 'discussion' section, Dr Craske says: "*the advantage accrued by volunteer donations is probably eliminated by having to use a large pool*."..."*The end result of this is that the risk of the large pool NHS concentrate and the commercial concentrate may be similar*" [496]
1-Mar-1981	Preliminary results from Dr Craske's Hepatitis studies.[497] He says the results justify continuing these studies for "*the next five years*". He confirms all FVIII is transmitting NANB. *"These preliminary results suggest that there is a 90% chance of contracting NANB hepatitis when first transfused with either NHS or commercial concentrate."*

[496] HSOC0003356

[497] PRSE0000158 and HCDO0000270_054

25-Jun-1981	Dr Craske presents hepatitis data to meeting: *"40-50 cases were reported per year"*. The DHSS advocates more prospective studies: *"to provide a collection of well documented sera and other specimens for the use in development of serological tests for NANB hepatitis"*.[498]
9-Oct-1981	Craske presents report circulated to HCDs of 3-year study. The report is clear that patients are being infected with NANB Hepatitis and some have chronic liver disease. Dr Craske makes recommendations suggesting further studies, asking for liver samples.[499]
13-Sep-1982	K Milne reports data from Craske showed: *"the risk of contracting hepatitis from large-pool NHS concentrate is unexpectedly high"*. It is difficult to see why this should be 'unexpected'.[500] The same report states *"assessment of liver damage should be made at autopsy whenever possible"*.
27-Sep-1982	The UK Working Party on Transfusion-Associated Hepatitis is established. The Terms of Reference (as suggested by Dr Craske) include: *"To promote the investigations of the epidemiology of transfusion-associated hepatitis"*[501]
20-Apr-1983	Dr Craske presents data on NANB infections and chronic liver disease [p7]. Those on cryoprecipitate *"showed no hepatitis"*.[502]
19-Sep-1983	Dr Craske provides updates on various projects. *"The 1974 Hemofil study was being reviewed and it was hoped to have report early next year on the findings of this work"*.[503]
10-Dec-1983	Dr Craske's NANB Study is published in the BMJ.[504]

686. Dr Craske's activities are described as a case study because he was quite evidently not the only researcher carrying out PUP trials into NANB. Studies continued into the 1980s with research into heat treatment. Professor Charles Hay, for example, mentioned a PUP trial of Alpha Profilate in 1984 involving patients at various haemophilia centres including Sheffield, the Royal Free and St Thomas Hospitals.[505]

687. The Chairman encapsulated the moral issue in an exchange with Professor Ludlam as follows:

> '*SIR BRIAN LANGSTAFF: ... Most clinical trials, I think, are like that, aren't they? That you have a product which is not put on the market, as it were, or distributed generally unless and until clinical trials have demonstrated efficacy and safety.*

[498] PRSE0004843 [4.2]
[499] CBLA0001464 (SNB0017354)
[500] DHSC0001313
[501] PRSE0000292 or PRSE0001047
[502] PRSE0004669
[503] DHSC0002237_081
[504] WITN3289046
[505] Transcript, London, 4 November 2020 – Professor Charles Hay, page 28, lines 11-24.

A. That's my understanding, yes.
SIR BRIAN LANGSTAFF: The process with VIIIY was, as I understand it, this: that it was all BPL product that was made -- F8, Factor VIII -- from September 1985 was VIIIY. It was in general distribution. No other product was distributed, as I understand it, after the start of October 1985. So all the product manufactured in Elstree was heat treated and it was VIIIY. So the clinical trials were rather different because they weren't prior to the introduction of a product; they were after it had come in to use, really to see if it was going to be effective against non-A, non-B hepatitis. Am I right?

A. I think that that is correct, yes.'[506]

688. This, in a nutshell, is why Core Participants assert that they were treated as guinea pigs.

Case study: HIV and heat treatment

689. The Fractionators' Expert Report to this Inquiry states: 'The ultimate proof of virus inactivation was the absence of disease in patients.'[507] If such a bald statement can be made today, in the context of this Inquiry, it does not take a significant leap of imagination to venture that clinicians were inclined to test the 'ultimate proof' contemporaneously with the development of heat treatment. Indeed, this is not contested in the evidence – documentary records exist of protocols for such studies.[508] In addition to the correspondence cited above,[509] Dr Cash discussed it in his evidence to the Penrose Inquiry.[510] In England, as with Scotland, "It was suggested that BPL manufacture a limited scale batch of heated dry product with a view to conducting a small clinical trial in virgin haemophiliacs (or at least those with no previous exposure to concentrates and who have normal L.F.T.'s) [sic]."[511] Dr Likiat Parapia also described heat-treated PUP trials in evidence to this Inquiry,[512] as did Professor Christopher Ludlam.[513]

690. Even before the advent of heat treatment, when the threat of AIDS is known but still relatively novel, the documentary evidence shows that patients were (in the language of the medical records) 'followed up' and that statistics about them are collated, aggregated and discussed at UKHCDO meetings and sometimes in medical literature.[514] The consistent evidence of the infected and affected is that they were unaware of any such testing, and

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[506] Transcript – London – 4 December 2020 – Professor Christopher Ludlam (continued), pages 38-39.
[507] EXPG0000044, page 84. The report makes reference to PUP studies generally at pages 71 and 93.
[508] MACK0001300_020. Note particularly the exclusion of 'patients who have previously been transfused with fractionated pooled plasma products, i.e. factor VIII or IX concentrate', at page MACK0001300_020 at page 3
[509] E.g. OXUH0000680.
[510] PRSE0002836 at page 5 to PRSE0002836 at page 8. Compare PRSE0002563, letter Dr Cash to Dr Archie McIntyre, 18/01/86.
[511] 14th Meeting of the UK Haemophilia Centre Directors, Oxford RHA 17 October 1983, p.2. [PRSE0000040].
[512] Transcript – London – 9 October 2020 – Professor Liakat Parapia, INQY1000070, pages 134 to 136.
[513] Transcript – London – 4 December 2020 – Professor Christopher Ludlam (cont), page 31.
[514] See e.g. 14th Meeting of the UK Haemophilia Centre Directors, Oxford RHA. 17 October 1983 [PRSE0000040].

indeed there are documents suppressing diagnoses of AIDS 'in order to avoid undue worry to your patients'.[515] Whether or not these were formal or informal studies, and whether or not they were observational, is a nicety that does matter to CPs. They were profoundly unethical.

691. Professor Ludlam was questioned on the distinction between research and treatment. The exchange is worth setting out in full, as he was one of the few Reference Centre Directors to give evidence. It is submitted that his responses to questions demonstrate that clinicians of the day did not maintain a distinct boundary between therapeutic and investigative treatments. They ought to have.

> *'MS RICHARDS: Your and Dr Steel's analysis of results and conclusions that you drew from them were published, I think, in The Lancet in 1983 and further in The Lancet in 1984. I wasn't proposing to go to the detail of your findings, but that's right, isn't it?*
> *A. That's correct, yes.*
> *Q. Do you still maintain, as you told the Penrose Inquiry, that this was not research but was part of the general monitoring of patients?*
> *A. Yes, I do. It was monitoring the patients because abnormalities had been shown in other patients with haemophilia that might be of significance, and I felt that it was my obligation to conduct similar investigations on our patients.*
> *Q. It's right, I think, that in relation to the work you've been describing, you didn't obtain -- seek or obtain ethical approval?*
> *A. Not for this particular -- these particular investigations because I consider them to be part of what we should be doing to monitor the health of our patients.*
> *Q. You did seek ethical approval, I think you've said, for work undertaken in 1984 as part of the same research which involved skin tests?*
> *A. Certainly, I -- the skin testing was part of the ongoing assessment of immunity, but it was less clear what the results might be or how they might be interpreted. But it involved a procedure, applying a small device to the forearm of patients, and we didn't inviteeverybody to do this because they had to come back two days later and have the skin test results read. So we only invited people who would find it easy and convenient to come back two days later. But I sought ethical approval for this because it was, ifyou like, an invasive -- although small -- procedure.*
> *Q. Why was the skin testing research, but the blood testing analysis and investigation not research, when the purpose of the two was identical?*
> *A. (Pause). I think it was because the results of the -- and one only does this in prospect, you must know the results are going to be. The skin testing was a rather more speculative investigation. The fact that it produced some very interesting and important results is perhaps a separate issue. There is a dividing line, I think, between -- I could have done the ... I could have done, I think, the skin testing perhaps without ethical approval but I had a very low threshold for applying for ethical approval and I thought, well, this is something that is new. It's a little bit uncomfortable and invasive, it's not hazardous, but that I should obtain ethical approval for it. I could have applied for ethical approval for doing the lymphocyte subset, but*

[515] Wessex Regional Transfusion Centre, letter to Head of Quality Control BPL. 4 October 1984 [DHSC0002247_090 + CBLA0000010_209]

I -- that seemed to me so much part of my responsibility to try to provide the best care, to be curious about my patient's immune system, it seemed very pertinent in the early 1980s, and if I could do that simply and that my results might be helpful for the patients, then that was the right thing to do.

Q. You know, professor, that patients have told this Inquiry that they were not aware of their participation in something called the AIDS Study. The Inquiry obviously has written evidence from Dr Carr about his involvement. Were you yourself directly involved in discussions with patients about the samples for the AIDS study and what they were required for, or was that left to Dr Carr?

A. Dr Carr certainly saw most of the patients because it was his responsibility to see people who -- you know, when they first came up with acute bleeds. I'm sure I will have seen some of the patients, possibly not only when they came up acutely with bleeds or other reasons, but at my review clinic, and I would have explained what we were doing.

Q. When you say you would have explained what you were doing, what can you remember actually explaining as a matter of fact about this work to patients?

A. I was asked about this at the Penrose Inquiry in some detail. I'm afraid my memory has faded rather, and I would ask you to view the Penrose Inquiry as the best I could do in -- 10 years ago.

Q. Can I ask you ... just a question arising out of one paragraph in your witness statement that I think is related to this. WITN3428001, ... page 81. You'll see the question that you were asked at the top of the page: "Did you continue to use blood products to treat patients, after becoming aware of the possible risks of infection of HIV? Why?" Then in paragraph 211 you say: "I continued to use blood products after it became apparent that AIDS in 1982 might be caused by a transmissible virus for the following reasons ..." You've set out a number, many of which we've covered. If you go over the page, if we look at (j), please. It says: "Part of continuing to use blood products was to establish from early 1983 onwards an active programme to monitor the immune status of those with haemophilia." One reading at least of that, professor, is that one of the reasons for continuing to use blood products after you became aware of the risk of AIDS was to see if yourpatients developed the signs of AIDS. Is that what you meant?

A. No. What I meant by this sentence in (j) is that it had become clear in 1982 that the immune status of some patients could decline very markedly and give rise to a clinical condition of AIDS in the United States. There was much uncertainty about the causeand that uncertainty persisted until, I would suggest -- and I have evidence -- at least until February 1984. It was therefore, I think, very important to monitor the immune status of patients, because one of the possibilities is that the immune decline was in some way related to the treatment they were receiving, separate from a putative AIDS virus. It's clear from the studies we did, that and others, that the clotting factor concentrates did, in fact, cause immune suppression, sufficient, I would suggest, to pre-dispose the children in Birmingham to tuberculosis, to a patient I reported -- or Dr Watson, now Professor Watson, when he was working with me, reported a patient who had features of AIDS and candida esophagitis in 1992, but was HIV negative but was clearly immunosuppressed by the concentrate. I don't know if we're going to come on to discuss it but when patients were exposed, unfortunately, to this implicated batch that was infected in Edinburgh in the spring of 1984, it was those with the most abnormal T cell ratios that were at greater risk of infection. So these, I think, are clinical evidence that use of clotting factor concentrates led to immune suppression. Having reviewed some of the literature recently, I think it's probably because of the immunoglobulin of the clotting factor -- the Factor VIII concentrates that was responsible,

and it may be that is why patients with haemophilia B, who are treated with a different product, who had normal T cell numbers, they didn't get – tended not to get infected. They were at far lower risk of HIV infection, and that has only occurred to me in the last couple of months, that maybe many more people got HIV with haemophilia A because they were pre-disposed as a result of the immunoglobulin in -- call it a contaminant, it wasn't meant to be there, whereas there was very little immunoglobulin in Factor IX concentrates. That's a bit speculative, but it occurred to me that that could be a possible explanation as to why people with haemophilia B, not so many became infected. There were other possible explanations, if you want me to go into them, I'm happy to do so, but I suspect you don't.

Q. Is one of the reasons why you were resolved to continue using factor concentrates your desire or ambition to have this active programme of monitoring immune status, which you could only undertake if patients were receiving factor concentrates?

A. We assess the immunity of people on cryoprecipitate, as well, and probably no treatment, as well. Sorry, is that your question? Was it only people who got concentrates who got immune tests?

Q. It wasn't quite my question, I am trying to understand you were saying -- it may be a partial answer, but I'm trying to understand what you say in paragraph 211(j), which appears to suggest that a reason for continuing to use factor concentrates was your wish to be able to monitor immune status. In other words, professor, did your, whether you call it research or investigative ambitions, drive the treatment policy?

A. No, no, no, no, no. Treatment decisions were driven by what seemed to be best for the patient, but if what seemed to be best for the patient was the use of clotting factor concentrates or other therapy, then that should be monitored, as we were doing for all the other monitoring investigations. I'm sorry, no. It was not the other way round.

[...]

SIR BRIAN LANGSTAFF: ... I'm just fascinated by this recent exchange because, if I've understood it correctly -- please tell me if I am wrong -- what you are describing is 1983, early 1983, you realised that factor concentrates not only gave rise to a potential risk of non-A, non-B infection and a real risk of HIV infection, but there was a third problem, which was neither hepatitis or HIV, but that was the problem that it might, in any event, separately, give rise to a deterioration in the immune system which, in general, would not be a good thing. Have I understood that correctly?

A. Absolutely correctly, yes.

SIR BRIAN LANGSTAFF: So there were now three reasons why factor concentrates were potentially undesirable if there were any proper alternative?

A. Yes.

SIR BRIAN LANGSTAFF: The -- so far as monitoring was concerned, what would you -- what was the purpose, had the monitoring shown a decline in the immune system? What treatment -- how would treatment differ in consequence?

A. Well, what we did was to repeat the immune tests we were doing, the subset tests, and one of the things we observed was that they didn't decline; they stayed steady. Which was, if you like, reassuring. What wasn't reassuring, and I've not described the results of the skin tests, but in a word, the skin tests show the more factor concentrate you received, the lower score you got on your skin test. So there was a direct dose relationship between the skin test results and -- and that was more concerning. We followed that up over the years, and in

people who are HIV negative, that stayed constant; it didn't decline further. Unfortunately, the people who developed HIV infection, their skin tests declined...'[516]

692. Furthermore, there is evidence which shows that it was clearly contemplated, without any ethical qualms on the face of the available documents, that human beings could be used in infectivity studies. A letter from Dr Bloom and Dr Charles Rizza to all haemophilia clinicians in 1982 stated:

> "*Infectivity of initial batches is tested by injecting the product into Chimpanzees. However, it is stated that it is unlikely that Manufacturers would be able to ensure this form of quality control in all future batches. 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 clearcut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates.*"[517]

693. The SNBTS Minutes of Factor VIII Study Group from 30 March 1982 appear to equate the disadvantage of using animal models and human beings, stating that the one (animal modelling) was expensive and the other (human beings) would lack a known-positive control in experimentation.

> *"The use of animal models for infectivity study purposes was discussed. Chimpanzees would cost £10,000 per animal test per 6 months. If humans were used it would not be possible to have a "known positive" control... ...It was agreed that infectivity was the crucial question and the* ***dilemma*** *over the use of chimps (an endangered species), owl monkeys (information to be supplied by Dr Sommerville when available) and humans formed the basis of a long discussion.'*[518]

This dilemma appears to be purely practical rather than ethical. The Minutes record that '*it was stressed that access to animal models was required immediately*.'

694. The meeting of the MRC Working Party on AIDS in October 1983, referred to above, failed to recognise the opportunity to avert the AIDS epidemic in the UK.[519] The meeting identified a 3-year time-lag between the state of the AIDS epidemic in the USA and UK, in that the UK was lagging 3 years behind the USA. This should have been seen as advantageous, but was squandered, with no-one suggesting trying to avert or lessen the incidence of infection among people with haemophilia. The emphasis instead was on making the most of a unique research opportunity involving people with haemophilia in the United Kingdom, where the equivalent opportunity for research in the USA was lost.

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[516] Transcript – London – 4 December 2020 – Professor Christopher Ludlam (continued), pages 78-86.
[517] Bloom, A. L., Rizza, C. R., Letter to all haemophilia centres. Oxford Haemophilia Centre, Churchill Hospital, 11 January 1982. [ARCH0001640]
[518] SNBTS Minutes of Factor VIII Study Group. 30 March.MACK0001245_010
[519] Medical Research Council Working Party on AIDS. Minutes, 10 October 1983. [PRSE0000389].

695. No-one at the meeting objected, and no-one gave a contrary view which might have gone some way to protecting people with haemophilia in the UK. It is particularly disappointing that nothing by way of a dissenting voice was recorded from the Department of Health observers present. The Minutes record:

> *"There followed discussion on the varying and considerable period of incubation (1 to 4 years) and the possible relationship between the size of inoculum of the proposed agent and the length of latency."*
>
> *"It was noted that blood product associated cases could enable some of these alternative hypotheses to be tested."*
>
> *"The underlying immunological and virological status of the high risk groups before they encountered the "AIDS agent" could thus be defined."*[520]

696. The foregoing gives the impression that clinicians were not proactive in averting risks to their patients. Some were unduly conservative, adopting a wait-and-see approach to emerging threats. Data gathering was routine, and non-consensual. Clinicians conflated treatment and research, and saw research opportunities where they should have foreseen human disasters.

Interferon

697. Core Participants will say that since interferon was originally licensed as a cancer therapy, it was not isolated specifically for the treatment of active viral hepatitis. Patients will say that this treatment with interferon was undertaken with no thought given to its potential impact and long-term side-effects. Victims were coerced into taking the treatment by being told that if they did not, they would be dead within 5 years. They will say they were 'treated' as recipients of 'New Trial' medication.

Conclusion

698. **Clinicians**: Such behaviour calls for explanation to the mind of reasonable people and finders of fact. How could physicians who – presumptively – are moved by principles of beneficence and non-maleficence come to prescribe and recommend (even against objections from patients) fatal treatments? Particularly where their use is not indicated or contraindicated (due to risk) and/or where less risky products can be obtained. In response to Brenda Haddock's question, we cannot at this distance completely know why. Clearly there is not one simple explanation for a widespread phenomenon among clinicians, and different clinicians will have had different mixtures of various motivations and beliefs. However, the evidence suggests a blend of the following features:

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[520] ibid., PRSE0000389.

(a) Clinicians had reservations about cryoprecipitate (which have been dealt with in the chapter on myths and lies). Concentrates were perceived as more convenient and clinically effective.

(b) Commercial concentrate was prescribed due to scarcity issues with NHS concentrate.

(c) Some clinicians were in the thrall of pharmaceutical companies.

(d) Many Haemophilia Centre Directors were both treating physicians and experts in their field. They conflated the roles of researcher and physician. They saw themselves as a specialist, intellectual elite with a vocation. They may have seen themselves not just as clinicians for individual patients but as acting for a whole cohort, perhaps even for the benefit of science and medicine as a whole. They held their peers in high regard, but did not see their patients as individuals. In particular, PUPs were viewed as valuable commodities.

(e) There was a sense of fatalism about the life expectancy and standard of living for severe haemophiliacs. There may have been a double-think. On the one hand, factor concentrates are enhancing your life because you may have suffered joint damage and the possibility of early death from haemophilia (without any treatment at all). On the other hand, seroconversion from past use of concentrates will lead to your early death in any event. Jaundice was normalised. That sort of double-think may have soothed the consciences of clinicians who – on the one hand – set out to dedicate their professional lives to improving the health of a population of people; but, at the same time, knowingly or recklessly prescribed those people with incredibly damaging, life-altering, or fatal medicines. Clinicians may have viewed haemophiliacs as being compromised in their life expectancy and therefore being entitled to lesser legitimate health expectations.

(f) Data gathering was routine, with clinicians rather than patients as the gatekeepers. By routine monitoring/follow-ups, clinicians may have thought that they could learn something about disease epidemiology, and save future cohorts if concentrates lived up to their life-changing promise – but were without infectivity.

(g) There may have been a distorted narrative of progress in the minds of some clinicians, with cryoprecipitate being viewed as a retrograde step and a concurrent blind faith in the 'undoubted benefits' of concentrates. The Expert Fractionators' Report notes the dramatic increases in life expectancy during the period that cryoprecipitate was the main treatment for haemophilia. Speaking roughly, over a couple of decades, life expectancy for haemophiliacs trebled. It

is quite possible that this pace of change outstripped clinicians' baseline expectations for their own patients' longevity. Furthermore, because this period overlapped somewhat with the manufacture of concentrates, it is quite possible that clinicians misattributed the success of cryoprecipitate to factor concentrates (perhaps aided in their delusions by pharmaceutical companies).

699. None of this is to excuse any clinician who acted for any of the above reasons. It is merely to proffer explanations for what, on any view, is mystifying and troubling behaviour on the part of the medical profession. The above paragraph is necessarily speculative, but it is hoped that the Inquiry may find it useful.

700. **Patients**: Core Participants will emphasise the following points.

(a) They did not consent. The little written information that is in evidence (such as letters from the Lord Mayor Treloars School to parents) does not provide enough detail for consent to be valid.[521]

(b) Non-consensual trials are contrary to customary international law, as well as a number of international conventions such as the Helsinki Declaration (as amended in 2000), the Geneva Convention, and the Nuremberg Code. It was unethical at the time and ought to have been recognised as such.

(c) Victims were exposed to multiple pathogens even after the risks of coinfection were recognised in research. Each exposure represented a further wave of harm, which compounded pre-existing physical and psychological harm. The medical profession and/or government missed myriad opportunities to adopt a precautionary approach to future treatment, especially with regard to the risk/benefit balance.

(d) Unnecessary treatments were given when treatment was not essential, despite the known risk of using factor concentrates. The view of patients as commodities rather than individuals may go some way to explaining why concentrates were used in children and mild/moderate haemophiliacs despite risks, counterindications and the availability of suitable alternative treatments. – as well as a seeming blindness to the risks compared to benefits and a seeming amnesia about alternative treatments.[522]

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[521] See e.g. WITN7547002_0002 and WITN7547002_0004

[522] *A Prospective Study of Hepatitis in Haemophiliacs First Treated With Factor VIII OR IX Concentrates* by Dr C.R. Rizza and Dr. J. Craske, November 1982, states: *"This is particularly relevant when assessing the risk of chronic sequelae after transfusion of factor VIII in patients with mild coagulation defects for whom this treatment is not usually essential,…*
…the only sure way of assessing the risk of transfusion hepatitis associated with new brands of concentrate where attempts have been made to inactivate hepatitis viruses by heat… …is by use of chimpanzee inoculation experiments, or trials of each product compared with an untreated product in a group of subjects where the

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susceptibility to hepatitis is known to be high. We have demonstrated such a group in the patients with mild coagulation defects already studied at Oxford…
…. So far 40 patients have enrolled in the study of whom 18 have contracted non -A, non-B hepatitis."
MACK0001615_0004

Chapter 15 - Consent, communication and information-sharing

701. The evidence heard by this Inquiry as to the communication of adverse diagnoses, as well as the withholding of information on diagnosis and risk, demonstrates every variety of bad practice. Rightly, it has led to a focus on duties of candour.

702. The Inquiry has heard that teenagers were told of terminal diagnoses while parents were kept out. It has heard that spouses were told of their partner's diagnosis (in breach of confidentiality) and left to break the news. This is not the only instance of sensitive personal information being shared without permission, and a lack of care around sharing data. The Inquiry has heard of parents finding out about their children's diagnoses through catching sight of their medical records or seeing their name pinned to a fridge. Diagnoses were communicated callously, communicated in hospital corridors by nursing staff, accidentally overheard, communicated months and years after being known (on the assumption that it was done before) and even held back. Parents' wishes were not respected when they asked that their children not be told that they were dying.

703. At times of crisis, the infected and affected were spoken to rudely and unsympathetically by doctors and nurses.

704. There has been a distinct absence of communication in other cases -- about risk, the withholding of diagnoses thought to be anxiety-provoking, about the purposes and requirement for tests, and so on. Every suppressed diagnosis led to the patient's family being exposed to the significant risk of contracting the same illness.

705. In other instances, the information given to patients was simply inadequate or incorrect.

706. We do not intend to further summarise the evidence of infected and affected, nor to discuss the evidence of clinicians or the medical ethics expert group. In relation to the conclusion that Core Participants wish the Chairman to draw, it is simply this: the infected and affected suffered every conceivable example of unethical practice around communication or its absence. This grounds our submissions on recommendations for education and training and on consent.

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Chapter 16 - Non-financial recommendations

707. Infected and affected Core Participants want three things from this Inquiry: **closure**, **reassurance** and **financial security**.

a) **Closure** through the findings of fact in the Inquiry's final report. Previous chapters have made submissions on the conclusions that the Chairman should draw.

b) **Reassurance** through regular health monitoring and care, and the rebuilding of damaged trust relationships with government and NHS actors (including apology, reparation and making amends according to the Inquiry's recommendations) so that this kind of scandal can never happen again. The present chapter addresses what is needed to give Core Participants the reassurance they ask for.

c) **Financial security**: Chapter 18 deals with compensation.

708. On 20 June 2022, we put forward our initial submissions on non-financial recommendations on behalf of the infected and affected represented by Collins Solicitors.[523] Since then, having heard the further evidence on recommendations and having read the initial submissions of other parties, we set out our revised views in this chapter.

709. We should state at the outset that there is little disagreement between those repres enting the infected and affected. Many of the apparent differences are superficial: they are just differences of emphasis or the particular method each party opts for to operationalise a good idea. The initial submissions entered by Leigh Day on behalf of Core Participants note that proposals around 'education, commissioning, provision of psychological support and provision of health services and domiciliary services are supported by other groups.' [524] Where relevant below, we have commented on the interim submissions made by other infected and affected parties.

710. By contrast, few NHS bodies made any submissions – the notable exceptions being NHSBT, SNBTS, and the Belfast Health and Social Care Trust. No government party made any submissions of substance. When they do so, we shall respond. Nevertheless, Core Participants note the commitments made by Matt Hancock, then Secretary of State for Health, in his evidence to this Inquiry. Mr Hancock was asked by CTI:

> '*MS RICHARDS: Do you consider ... that there is a moral responsibility on Government to address the impact of what's happened to those infected and affected?*

[523] SUBS0000015
[524] SUBS0000003, paragraph 3.

MR HANCOCK: Yes, I do.'[525]

At the conclusion of his evidence, Mr Hancock said:

'*MR HANCOCK: -- I want to -- there's something I want to say very directly to those who are infected and affected, because we've heard some incredibly moving stories so far, and there's many, many more still to come in terms of the pain and the hardship and also the appalling stigma at the time of some people who were infected and their loved ones. And so, as well as reiterating the apology, I really want to make sure that you know that we in the Government support the Inquiry to -- to go everywhere and find every detail and hear all of the voices and to find as many answers as possible, and I've instructed my Department to do that and also to improve the financial support and to create parity as much as we possibly can. And I hope that this Inquiry finally brings about the closure that many people are seeking as well as, no doubt, making recommendations on the practical changes that we can -- that we can bring about. I'm determined to make improvements even whilst the Inquiry's ongoing but then we'll also listen very carefully to the Inquiry's conclusions. This is a tragedy that never should have happened and we owe it to all of those who are infected and affected to make sure that it never happens again and we learn all the lessons fulsomely.*'[526]

The infected and affected expect the present government to honour Mr Hancock's promises.

711. The recommendations that we submit should be included in the Chairman's final report are detailed below. In outline, they are as follows:

(a) Government apology
(b) Memorials
(c) Ongoing network & support events
(d) Improved patient treatment and information
(e) Testing for those potentially infected
(f) Medical training
(g) Consent
(h) Record-keeping
(i) Haemovigilance, database of blood/products, and improved transfusion practices
(j) DWP and HMRC implications
(k) Civil Service
(l) Research
(m) Independence from the pharmaceutical industry
(n) Coroners
(o) Taskforce

[525] INQY1000121 at page 32Transcript of evidence 21/05/2021, page 126, lines 15-19.

[526] INQY1000121 at page 51 Transcript of evidence 21/05/2021, pages 201-202, lines 8-25 and 1-11.

(p) Freedom of information
(q) Public Inquiries
(r) CPS and GMC review of evidence
(s) Other

712. We try to avoid repeating the recommendations of the various Expert Groups which, in general, we endorse.

A. A recommendation that there should be a full and complete apology

713. Core Participants acknowledge the apologies made by many Inquiry witnesses during the course of oral and written evidence. Nevertheless, in light of the treatment of the infected and affected, the length of time over which they have had to fight for justice and the history of obfuscation and incomplete explanation, there should be an unconditional and unqualified full apology by the Government to all those infected or affected, recognising that they were wronged by the use of contaminated blood and blood products and further wronged by the time it has taken for the scandal to be properly investigated.

714. The apology should made openly in the House of Commons by the Prime Minister and published, along with:

(a) A long-term commitment to remedy and make reparation to all victims (infected and affected), to put them so far as possible in the position they would have been in, had they not suffered the illnesses and/or injuries inflicted on them;

(b) A Government undertaking not to seek the enforcement of any previous compromise agreements or settlements which required the waiver of the right to make further legal claims arising from contaminated blood or blood products;[527]

(c) A Government commitment to create and fund a body comprised of a representative cross-section of core participants/groups identified from this Inquiry, to consider annually and review: the processes of identification of infected and affected persons; their treatment; welfare; care; eligibility and payments systems made available to them, with scope to compare the provision of the same in other countries.

[527] See also the Haemophilia Society at paragraph 37 (which is more extensive in that it asks for a ban on waivers and non-disclosure agreements within government litigation). Thompsons at paragraph 18.3. Further, Thompsons Solicitors propose at paragraph 18.1 that legislation be passed in Scotland to lift the prescription/limitation bars on court actions. If the Inquiry is receptive to this, parity suggests it should be extended to all the UK jurisdictions. We note that the Independent Inquiry into Child Sexual Abuse (IICSA) made a similar recommendation in respect of child abuse to the one proposed by Thompsons in respect of the infected blood scandal.

(i) As proposed by Leigh Day, it should be in a format accessible to all the infected and affected. As proposed by Thompsons Solicitors, the apology should be specific, complete and sincere.[528]

(d) A complete apology will include, but not be limited to:

(i) Accepting the conclusions of the Inquiry and emphasising the reasons behind payment of compensation;

(ii) Acknowledging moral and legal responsibility for the infections and their aftermath;

(iii) Acknowledging the work done by campaigners to reach this point;

(iv) Expressing admiration for the dignity and restraint for those who have lived with the impact of this scandal throughout their lives, and who have undergone the difficult experience of hearing and giving evidence in this Inquiry;

(v) Paying respects to the dead;

(vi) Expressing gratitude and paying tribute to the extraordinary love, humanity, and self-sacrifice of those who cared for their relatives through devastating illness;

(vii) Retracting false statements, including that patients were given the best available treatment and would have died otherwise;

(viii) Retracting insulting insinuations, including that patients' lifestyles were to blame for their illnesses;

(ix) Expressing remorse for evading responsibility and for repeated failures to respond appropriately;

(x) Stating what steps are being taken, and will be taken, to implement the recommendations of the Inquiry;

(xi) Committing to no repetition of such a tragedy in future.

(e) We have no objection to the suggestions of other Core Participants that other UK ministers (including the health secretaries of the various nations), NHS

[528] Sincerity can be demonstrated in several ways, including by acting promptly on recommendations and by ministers attending memorial events.

leaders and the UKHCDO participate in this apology. Nor do we object to any apology being delivered also in writing or sent to individual CPs.

B. A recommendation that there should be memorials

715. A permanent, substantial, national memorial, funded by central government but organised by an independent group made up of representatives of the infected and affected should be established to honour the deceased and living victims of the infected blood disaster in each of London, Cardiff, Edinburgh and Belfast. There should be a further memorial dedicated specifically to the children infected at Treloars School.

716. Furthermore, there should be a review by hospitals, transfusion centres, and other healthcare bodies, after consultation with that independent group, of the appropriateness of all existing installations / memorials / statues honouring any medical staff involved in the administration of contaminated blood and blood products to such victims.

717. In light of the slight differences between CPs as to the location and nature of the memorial, this should be determined by the consultation above.

718. We have no objection to other CPs' suggestion that the memorial be part-funded by the residual monies of the former Macfarlane Trust currently held by the Terence Higgins Trust, nor to the Scottish memorial being part-funded by the voluntary donations already raised.

C. Recommendations for ongoing network and support events

719. Recommendations in respect of counselling and treatment are made separately below, but funding should be made available for a biannual networking/support event for those impacted (affected and infected), for a period of at least three events after the conclusion of the Infected Blood Inquiry.[529] Many people impacted live in isolation and the time they have been able to spend with others similarly impacted, under the auspices of the Inquiry, has been greatly beneficial to their wellbeing and mental health. Such an event could usefully be combined with a public presentation / update as to the ongoing process of providing compensation and implementing the other recommendations the Inquiry will in due course make.

D. Recommendations relating to improved patient treatment and information

[529] This recommendation is supported by Leigh Day, SUBS0000003, recommendation 12.

720. Along with numerous other parties,[530] we suggest that there should be a recommendation to replicate the non-financial aspects of the Republic of Ireland's arrangements as outlined in the evidence of Brian O'Mahony.[531] There is one qualification that we suggest below, however. This is to include:

(a) A Health Passport (called the 'Health Amendment Act 1996 card' in the original Irish scheme). The card should be available digitally as well as in hardcopy, and should be valid for life. This would both prove the patient's right to access their entitlements as well as setting out their medical history so as to avoid the need for them to repeat it to various healthcare professionals and any DWP officials.[532] The card should bear a QR code linking to a public webpage that explains the scheme itself to anyone unfamiliar with it.[533] The services to which this card entitles the holder free of charge should include all those outlined in Mr Mahony's statement at paragraph 77.

(b) Fast-track NHS prioritisation of treatment for the infected and affected should be introduced, comparable to the 'two week rule' in Ireland, in recognition of the fact that their condition was inflicted on them by the state (noting that in damages for negligence the cost of private medical treatment would be awarded by a court to ensure the swiftest possible and most efficient recourse to treatment).

(c) For the avoidance of doubt, notwithstanding the differences in the welfare schemes of the United Kingdom as compared with the Republic of Ireland, the UK scheme should entitle the bearer of the card to private treatment if priority treatment cannot be provided on the NHS. This is especially important for residents of Northern Ireland.

(d) We endorse the observation of the Haemophilia Society that: 'Such a recommendation need[s] to encompass appropriate swift mechanisms to challenge any refusal of such identified needs to ensure that any difficulties are quickly addressed, and resolved, without the need for litigation. For example, a Case Manager could assist individuals from a financial perspective and support them in making claims for benefits and support generally.'[534] In our interim submissions, we recommended that there be a 'one-stop' advocacy service akin to a case manager. We remain of the belief that this is necessary regardless of whether a

[530] Milners, paragraph 4; Watkins & Gunn, paragraph 3; Thompsons, paragraphs 4 and 5; Leigh Day, paragraph 86; Saunders, paragraphs 11-18, 29 to 31; Haemophilia Society, paragraph 34.
[531] WITN7418011.
[532] For this reason, we favour the existence of a 'health passport' regardless of how provision of these services is achieved in practice. Leigh Day propose some other potential solutions, such as excluding someone's income from assessment under the Care Act2014 and the Statutory Care and Support Guidance or by the provision of services via the support schemes/any compensation framework (Leigh Day, recommendation 23).
[533] This is a point pertinently emphasised by Thompsons at paragraphs 5.2 to 5.4.
[534] Haemophilia Society, paragraph 36.

Patient Safety/Safeguarding Advocate[535] and/or Commissioner for Persons Infected and Affected by Blood and Blood Products[536] is also recommended, as other parties propose elsewhere.[537]

(e) The government to procure bespoke:
    (i) life insurance (to include cover for funeral expenses),
    (ii) mortgage protection insurance, and
    (iii)travel insurance for the infected.

(f) Our one qualification on the Irish scheme is that no change need be made to the National Liver Offering Scheme.

721. The psychosocial support and physiotherapy services accessible through the 'health passport' should be specialist in the treatment of those with bleeding disorders and/or infected and affected by the infected blood scandal.[538]

722. The evidence of the specialist psychological support panel on 11 November 2022 left no doubt that, notwithstanding the benefits of improved access to psychotherapy for English patients generally, the community of infected and affected cannot be adequately served except by specialist support. Therefore, improved psychological/counselling and physiotherapy support should be made readily available at a comparable level across all nations, regions and NHS trusts to all the infected and affected, such counselling and support to be delivered by those trained in and familiar with the specific background of the contaminated blood scandal. It goes without saying that there should be no limit on the number of support sessions available.

(a) *Timing*: Core Participants urge that this bespoke support is in place prior to the release of the Chairman's final report, because this event will be experienced as momentous and many within the community will need access to support.

(b) We disagree with the view expressed by Saunders that consideration be given to specialist support being provided through Haemophilia Centres.[539] Instead,

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[535] See, for example, Milners Solicitors, paragraph 12 (available to all NHS patients with a life-altering or chronic condition); Leigh Day, recommendation 18 (available to victims of major tragedies) and 19.
[536] See, for example, Watkins & Gunn, paragraph 42. SUBS0000012
[537] We note that there is already a Patient Safety Commissioner for England and a similar Bill proposed in Scotland – these were introduced after the June 2022 initial submissions. There is (or will be) a scheme for NHS Guardians of Safe Working and is (or will be) a Health Services Safety Investigations Body (HSSIB) and a Maternity and Newborn Safety Investigations Special Health Authority (MNSI).
[538] We have no objection to Leigh Day's SUBS0000003 proposal that family therapy should be one of the therapies available – Leigh Day, paragraph 5 – and the evidence that we heard on 11/11/22 tends to confirm that a variety of therapies should be offered by the specialist support psychologists.
We endorse Thompson's suggestion that funding for specialist provision that is already in place in the devolved nations should be ringfenced (paragraph 6) and have no objection to a single national physiotherapy service for Scotland (paragraph 7). We note that Thompsons are supported in these proposals by the Scottish Health Boards, Recommendations 2 and 3.
[539] Saunders, paragraphs [8]-[10].

for the reasons articulated by Watkins & Gunn,[540] the provision should be entirely separate from any NHS body that has historically been implication in the seroconversion of haemophiliacs. Furthermore, the infected & affected community is broader than haemophiliacs.

(c) It is equally obvious that Haemophilia Centres themselves require investment and improvement in all the ways set out by Saunders[541] and other infected and affected parties.[542] We endorse those suggestions. To the extent that crucial services accessed by hemophiliacs are available only through GUM clinics, expertise should be transferred.[543]

723. A "one stop" advocacy service should be introduced on a national basis, by which trained staff who are familiar with the history of the contaminated blood scandal and the issues for the infected and affected, can swiftly and effectively assist with access to social care, benefits, medical support, etc.

(a) This is akin to the services of a case manager in care regimes for serious personal injury and should save the infected and affected having to make the same case and explain the same issues many times over to different agencies. It should enable and assist those who may be less adept at form-filling and arguing their own case, and alert them to the full range of entitlements, benefits and services which are available for their conditions.

(b) This type of assistance, offered one-on-one to individuals, must be additional to any recommendation for a Safety Commissioner or similar champion at a national level.

(c) We agree with Leigh Day that the advocacy service should include assistance with obtaining comprehensive welfare benefits (including housing, income support, and social care) but should not be limited to public sector benefits. It also should facilitate access to financial support from the private sector, including banks, and assist with other administration – such as that around death certification and arranging funerals.

D1. Long-term follow-up of patients infected through blood/products:

[540] Watkins & Gunn, paragraph 2.
[541] Saunders, paragraph 21.
[542] Haemophilia Society, paragraph 33; Milners, paragraphs 3, 10; Watkins & Gunn, paragraphs 1 and 6; Scottish Health Boards, recommendations 4, 5, 6 and 7.
[543] Watkins & Gunn rightly draw attention to this, paragraph 6.

724. A central fund should be provided for GPs and Haemophilia Centres to be able to implement long-term follow-ups, and to raise awareness of these recommendations and train staff appropriately.

(a) A proactive annual "MOT" health assessment should be introduced for all infected and affected individuals to check on their physical and psychological welfare and to provide peace of mind. It goes without saying that it should be made available also to those said to have 'cleared' any infection (or reduced it to non-detectable levels).

(b) Long-term follow-up should also include regular liver investigations (to include ultrasound and fibroscans taking place at least bi-annually, and more frequently upon request). This should be available on a consistent basis (not to vary by nation, region or NHS trust) for all those who received contaminated blood and blood products, with the introduction of a 'best practice' protocol involving scans being done in the morning, a consultation with a Consultant Hepatologist the same afternoon and prompt and effective communication about all findings, positive tests and available psychological support. We note that this receives the support of Thompsons Solicitors and Watkins & Gunn Solicitors.[544]

D2. Future diagnoses of infections:

725. Routine health questionnaires, such as those upon registration with a GP practice, should ask whether the applicant has received a transfusion or blood products or anti-D injection.[545]

726. Any diagnosis of HIV or hepatitis for any person should trigger a bespoke individual look-back consideration of whether it may have been caused by infected blood or blood products.

727. Any diagnosis of HIV or hepatitis attributable to infected blood or blood products should trigger a pathway of further investigation and advice including physical and psychological treatment and support, follow-up screening and testing, and testing and screening of family and partners.

728. The evidence that this Inquiry has heard about the unsympathetic communication of diagnoses and even the suppression of test results leads us to recommend what should not need to be said: any adverse diagnosis should be given face-to-face (not in writing or by telephone), not rushed and there should be time for reflection, questions and answers, including a follow-up consultation to allow the patient time to consider the diagnosis.

[544] W&G, paragraph 8; Thompsons, paragraph 11.2.
[545] See Watkins & Gunn, paragraph 17.

Counselling should be made immediately available following an adverse diagnosis, to be taken up at any time.

729. Those diagnosed should be provided with simple but comprehensive materials (printed and accessible online) in respect of their condition, its possible progression, next steps in their treatment, medication and its side-effects, risks of transmission, steps to be taken in family and social situations, recommended lifestyle changes, available counselling and support, available grants funds and benefits, support groups and the availability of access to their own medical records. It is a prerequisite to this that GPs and primary care staff are apprised of support measures available.[546] The panel on eliminating HCV and tracing undiagnosed patients also highlighted the effectiveness *in certain nations* of decentralising tracing such patients away from GP champions and toward the third sector, pharmacists, and nurses.

730. We strongly endorse Leigh Day's Recommendation 1 that clear information on risk management, treatment and prognosis is essential and needs to be buttressed by signposting to support services such as the Hepatitis C Trust and psychological support. Posters, leaflets and websites should be available. The risk of transmission related to blood transfusions should be included on the first page — known as the "landing" page — of the Hepatitis C website, and not solely on the page specifically related to risk factors.

731. We strongly endorse the multidisciplinary model of hepatitis care urged by infected and affected Core Participants.[547]

732. We encourage the reinvigoration of efforts around national HCV elimination schemes, as do others.[548] We commend the suggestions of the panel convened on 17 November 2022 (who discussed the current status of efforts to trace undiagnosed HCV sufferers) regarding the elimination of obstacles thereto.

733. Improved palliative care and hospice access, consistent across nations and regions, should be provided for those who received infected blood or blood products. This is a critical issue for infected and affected Core Participants, and we endorse the views of the Expert Group as well as the submissions of others on this.[549]

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[546] Leigh Day, recommendation 1.

[547] Leigh Day, recommendations 1 and 6; Watkins & Gunn paragraph 1;; Milners, paragraph 20; Saunders, paragraph 22.

[548] Watkins & Gunn, paragraphs 14 and 15; Thompsons, paragraph 10; Leigh Day, recommendation 2. Compare NHSBT who note that there is a CQUIN PSS1 in place, paragraph 67.

[549] Leigh Day, recommendations 2 and 17; Milners, paragraph 22; Thompsons, paragraph 12; paragraph 22.2.

E. Recommendations for medical screening and testing for those potentially infected by contaminated blood or blood products

734. It is common ground across the infected & affected parties that provision and access to testing should be broadened and improved. The views of the National Screening Committee may be sought as to how best to achieve this. Our own suggestions follow.

735. There should be provision of 'one stop' priority testing units, within existing hospitals and/or Haemophilia Centres, to make freely accessible testing and scans for those who received blood products and blood transfusions and their carers. Test for HBV, HCV, HIV, liver cancer, renal cell carcinoma and other cancers, blood or hepatic conditions.[550] Consideration should be given to whether initial blood testing could be offered through pharmacies and/or at-home test kits, to broaden ease of access to it, with confirmatory hospital testing to follow if positive.

736. Testing staff should also be aware of and alert for signs of the other physical and psychological conditions which the Inquiry has heard may be linked to contaminated blood and blood products. We endorse the proposal that clinicians should be alert to the potential for HIV/hepatitis to cause autoimmune diseases like fibromyalgia or ME,[551] and would add to this Crohn's Disease and others.

737. In order for clinicians to be alert to such matters, a good deal needs to be done around medical education, post-qualification training and continuing professional development. This is addressed immediately below.

F. Recommendations as to medical training

738. While the parties are united[552] around the need for better training of medical and nursing students and professionals, the evidence on recommendations has brought to light the slight practical complications to realising change. It is clear that responsibility for developing undergraduate curricula lie with individual education providers, and responsibility for regulation and oversight is itself divided. Thus recommendations must be addressed to all the entities listed in the paragraph below, requiring them to cooperate with one another to achieve the recommendations. (It is tempting to propose a review of the regulation and provision of medical education itself, but that is not our preferred approach.) A further

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[550] See also Watkins & Gunn, paragraph 16; Leigh Day, recommendation 1; Milners, paragraph 19; Saunders, paragraph 22. We have no objection to Thompsons' suggestions at paragraph 13.1 that testing should be wider than this even.

[551] Leigh Day, recommendation 3.

[552] See: Leigh Day, recommendations 7 and 10 (listening and communication skills), recommendation 8 (CPD re HCV), unconscious bias training, training for commissioning bodies (paragraph 99). See also, Milners, paragraphs 17 and 18; Watkins & Gunn, paragraph B; Saunders, paragraphs 5 to 7; Haemophilia Society, paragraphs 40 to 41.

practical difficulty is the lack of powers of compulsion over provision and choice of CPD topic – albeit we believe these difficulties can be over-stated.

739. Much can be achieved by goodwill, promoting good practice and influence, i.e. any number of activities short of mandating particular courses of action. Dr Colin Melville on behalf of the GMC began his evidence by stating: 'May I just start by expressing our sincere acknowledgments of the things that have happened to folk, and our part, as the GMC, in *wishing to learn and how we take that forward*.'[553] We exhort all the bodies mentioned below to promote the learnings of this Inquiry to their constituents.

(a) The General Medical Council and Nursing and Midwifery Council in their role as setting out professional and ethical values and competences (particularly around the duty of candour), as well as their role as having channels of dissemination to common-interest parties such as NICE and CQC, referenced by Dr Colin Melville[554]

(b) the Academy of Medical Royal Colleges, the Royal Colleges themselves, and their devolved equivalents such as the Royal College of Physicians of Edinburgh, in their role as providing and accrediting CPD (particularly around communication skills);

(c) the Medical Schools Council and the Conference of Postgraduate Medical Deans Committee;

(d) Health Education England and equivalent bodies in the other nations;

(e) the Quality Assurance Agency for Higher Education and the Office for Students;

(f) Responsible Officers registered with the GMC in their role as overseers of appraisals and revalidation.

740. The above-mentioned bodies should turn their minds as to how best to achieve education in the following areas:

(a) The contaminated blood scandal should be a required part of the syllabus for undergraduate medical and nursing training, to ensure lessons are learned and not lost.

(b) There should be specific aspects of medical and nursing training so that the context in which patients were infected is understood and does have to be

[553] Transcript 15 November 2022, page 72, lines 12 to 15.
[554] Transcript 15 November 2022, page 134, lines 19 to 24.

repeated, questioned or doubted at consultations. Assumptions that, for example, HCV affects only certain lifestyles should be combatted.

(c) Specific medical training (updated and reinforced through CPD) should be introduced in empathy and how to communicate adverse diagnoses. The need for this is not made redundant by existing training such as the 'human factors' approach discussed by Dr Melville nor the compassionate workplace training discussed by Dr Mulholland.

(d) A system of auditing or peer review of GP records should be introduced to avoid the situation which occurred for many HCV-infected patients from whom the Inquiry has heard, of them returning with consistent complaints of symptoms only to be sidelined or misdiagnosed. This might usefully take place at appraisals.

741. We believe the lessons of this inquiry (in terms of clinical learning) are most salient for general practitioners, haematologists, virologists, hepatologists, obstetricians & gynaecologists, epidemiologists & public health experts, and nurses. However, there is no part of the healthcare profession – whether in clinical or even administrative practice – for whom the lessons around ethics cannot be instructive.

G. Recommendations as to consent

742. It is common ground among the infected and affected that there should be: Improved systems for patient understanding of, and consent to, proposed treatment.

(a) Improved systems to ensure clinicians are trained in, understand the need for, and implement, the obtaining of full and informed consent from patients.

(b) An obligation to warn patients prior to surgery of the potential for transfusion, and to get their advance directive, and fully to inform patients afterwards if emergency treatment was required and provided when they could not consent.

743. The Supreme Court decision in *Montgomery* was not a panacea, and the interim submissions of the NHSBT are candid about recent audit findings around consent to transfusion.[555] Further, the evidence of Dr Steer and Judith Richardson (among many

[555] NHSBT, paragraphs 30 and 33. We note that they prefer self-improvement, paragraph 33.

others) confirms that much must still be done to promote shared decision-making.[556] This is a cultural change that cannot be achieved by law alone.[557]

744. We therefore endorse the submissions of the Haemophilia Society that the findings of the Cumberledge Review are revisited when the Chairman writes his final report,[558] and the submissions of Thompsons Solicitors on the 2017 report of the Scottish Public Services Ombudsman which prompted a 2018 report on shared decision-making from the Scottish Government.[559]

745. We further endorse the idea of providing a consent prompt sheet, identified by Leigh Day (recommendation 9), Leigh Day's further recommendation 16 around obstetric & gynaecological surgery and around emergency surgery (recommendation 24).

746. We note that NHSBT has indicated a similar recommendation A3, but favours self-improvement over external enforcement.

H. Recommendations as to record keeping

747. Improved and proper NHS record-keeping such that the immense disadvantages faced by the infected and affected of which the Inquiry has heard should never occur again.

748. There are a range of legal regulations (in case law and statute), various guidance for different healthcare professions and diverse codes of practice across different NHS bodies and across the four nations in respect of record-keeping. Some of these still have discretionary rather than stipulated periods for their retention. These should be standardised and simplified.

749. The Inquiry should recommend consistent policies across NHS trusts and the four nations as to duration of keeping records, nature of the records to be kept, where and by what means they are to be kept. There should be audits to ensure so far as possible that records are being kept that way.

750. Such policies should be easily accessible so as to inform patients, carers (suitably authorised by the patient) and next-of-kin as to how to access those records. With the implementation of shared decision-making, the paradigm of a repository of records should

[556] Statement of Judith Richardson, WITN7421001, paragraph 46.
[557] We have no objection to the proposal that the test in *Montgomery* be set out in legislation (Leigh Day, recommendation 7) and/or improved (Milners paragraphs 14 and 15) but feel little optimism that these measures will make sufficient change in isolation. We note the evidence of Dr Colin Melville that the law followed the GMC Guidance in *Montgomery*, rather than the other way around (Transcript 15 November 2022, page 140, lines 18-19).
[558] Haemophilia Society, paragraphs 24 to 26.
[559] Thompsons, paragraph 27.

gradually fade – with patients accessing and providing input into their own records regularly.

751. We endorse the submissions of Leigh Day regarding the flagging of patient records where there has been a transfusion, with monitoring by the Care Quality Commission.[560] Likewise, we endorse the various submissions made by Thompsons on this matter.[561]

752. Likewise we endorse recommendation 25 of Leigh Day's submissions, which proposes a clear system of identifying who destroyed documents together with the date and reason for this. The Inquiry should consider the viability of giving notice to patients whose records are shortly to be destroyed (or their next of kin), as Elisabeth Buggins suggested and Leigh Day echo. Further, Leigh Day emphasise improving practices around recording blood transfusion in a patient's records, including in discharge letters. Dr Mulholland's evidence confirmed the importance of this.

I. Recommendations for haemovigilance, database of blood/products, and improved transfusion practices

753. We note that it is common ground between the NHSBT and the infected & affected practice around transfusion be improved.

754. We agree with the NHSBT's recommendations A1-A8.

755. We further agree with the Scottish Health Boards that the reporting of adverse events should be encouraged or mandated.[562] Saunders favour the early warning system of adverse events recommended by the Mid-Staffordshire Report, implemented in the 1990s.[563]

756. We endorse the recommendations made by Leigh Day and Watkins & Gunn.[564]

757. We were impressed with Professor Ian Roberts' evidence on tranexamic acid, and commend his proposals to:

(a) amend the NICE Guideline so that it identifies anybody at risk of blood transfusion and anybody having in-patient surgery as a potential recipient of tranexamic acid;

[560] Leigh Day, recommendation 1 and 3.
[561] Thompsons, paragraph 23 et seq. Other CPs, including Milners, agree – paragraph 8. Watkins & Gunn, paragraph 22, seem to be using law as a rather blunter instrument for the same purposes.
[562] Scottish Health Boards, paragraph 10.
[563] Saunders, paragraph 19-20.
[564] Leigh Day, recommendation 14; Watkins & Gunn, paragraphs 10 -12.

(b) NHS England and equivalent bodies to create a CQUIN for compliance with the NICE Guideline;

(c) in the absence of any application by a pharmaceutical company, the MHRA to amend the licence conditions for tranexamic acid to reflect its current indications in surgery and childbirth;

(d) NHS England to promote awareness of tranexamic acid, of the CQUIN and to encourage hospitals to include consideration of tranexamic acid on their 'safe surgery checklist' as recommended by the WHO.

(e) the NHSBT to establish an audit and information loop on which patients are/not receiving tranexamic acid.

758. A number of parties have commented on the feasibility and desirability of a comprehensive lookback database on the use of blood and blood products.[565] Regardless of the feasibility of such an exercise retrospectively, such a database should be established prospectively and a legal obligation to maintain it be brought into force.

759. There should be a licensed blood register identifying the origin of all blood and plasma products produced within, and imported into, the UK, to include all commercial and non-commercial providers.

760. Regular reviews of haemovigilance and blood safety screening systems should be undertaken by an independent review panel, who should have regard to the history of the contaminated blood scandal and lessons learned from it.

(a) The panel should have representation on it not only from doctors but also from patients, lay members and independent (non-medical) professionals to provide the broadest possible holistic overview.

(b) In conjunction with those reviews, steps should be taken to ensure that all SHOT reports are considered as part of the review process, along with consideration of the adequacy of systems of screening of blood donors in order to detect and respond to early warnings on the quality and efficacy of blood supply.[566]

(c) We endorse Thompsons' proposal that there be early adoption of new screening tests, regardless of false positives.[567]

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[565] NHSBT, paragraphs [25]-[29]; Watkins & Gunn, paragraph 21;

[566] We have no objection to Watkins & Gunn's proposals at paragraphs 35 -38.

[567] Thompsons, paragraph 16.1. We have no objection to their suggestions of improving donor engagement by giving them more information, including when they save lives (paragraph 15.1) and a ban on using prisoners as donors (paragraph 14.1).

761. Some NHS bodies have requested the Chair to state what approach to risk toleration they adopt. If the Chair is minded to make such a recommendation, we submit that the precautionary principle is the appropriate approach,[568] and we note Dr Susan Hopkins' evidence that the UKHSA 'constantly think[s]' about this.[569] Clearly the corollary of any approach to risk toleration on the part of NHS bodies is that patients must be fully informed as to what risks they are presented with. We therefore endorse the Chairman's suggestion to Dr Hopkins that patient autonomy should be identified as a relevant factor when considering whether to carry out a public patient notification exercise. The role that reputational harm plays in a decision to carry out a PNE should be clarified. As Dr Hopkins herself identified, a review of the effectiveness of the CAS system should be carried out.

762. We submit that there should be a patients' charter / NHS protocol to ensure that blood and blood products supplied by or on behalf of the NHS are of the highest standard and the safest nature reasonably possible. Recipient safety should outweigh any perceived donor right to give blood. Decisions around who can donate, and when, should be taken on a purely scientific basis seeking to minimise or keep risks to recipients as low as possible, recognising that it will always be necessary to discriminate in respect of blood donation, in order to maximise safety and minimise risk.

J. DWP and HMRC implications

763. There should be a full review of the implications of recommendations for the benefits/ tax systems applicable, and the financial implications of receipt of support and compensation by those infected and/or affected.

764. In particular, there should be greater communication and exchange of information between HMRC, the NHS and the DWP departments, to:

(a) facilitate expeditious processing of applications; and

(b) avoid the infected and affected being placed under suspicion by the DWP as being benefit cheats because of receipt of awards under the schemes; and

(c) avoid duplication of provision of information to differing government departments and entities; while

(d) avoiding breach of medical confidence, and affirming a right of non-disclosure.

[568] See similarly Watkins & Gunn, paragraph 38.
[569] Transcript 15 November 2022, evidence of Dr Susan Hopkins, page 47, line 13.

765. It is to be hoped that the 'health passport' can achieve these aims, but it will not do so without design.

766. In addition, there should be an exemption for infected and affected persons from having to: (1) fill in DWP forms; and (2) attend 'Back to Work' interviews; upon proof of eligibility for compensation/support under formal compensation schemes.

(a) To the extent that this is not already achieved, there should be provision of a DWP 'general exemption card' to ensure that compensation/support payments are wholly disregarded from means-tested benefits.

767. We note that there is broad agreement across the represented infected & affected parties as to this.[570]

K. Recommendations relating to the Civil Service

768. We endorse the recommendations of the Public Health Administration Expert Group.[571]

769. There should be a duty of candour for the civil service.

770. There should be improved separation of responsibility within the civil service so that internal reviews of potential failings (such as the production of the now-discredited chronology on self-sufficiency) or responses to external demands (such as the analysis of documents for disclosure in the HIV and HCV litigation) are not undertaken by those who might potentially be open to criticism for the underlying matters ("marking your own homework").

771. Civil Service training to ensure the lessons of this disaster are not repeated.

L. Recommendations for research

772. In this section, we draw together the suggestions for research raised by Core Participants. Core Participants recommend that funded research is commissioned into:

(a) the likely future prognosis and treatment needs of co-infected patients;

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[570] Leigh Day, recommendation 22; MIlners, paragraph 2; Watkins & Gunn, paragraphs 1 and 18; Thompsons, paragraph 5.1.

[571] We have no objection to Leigh Day's recommendation 7 and 18, nor Milner's paragraph 23 and suggestion that new ministers are provided witha briefing paper dealing with the full range of policies being implemented by the department. We note the relevance of the latter to paragraph 8a of the Chairman's Statement of Approach.

(b) the likely effects of the ongoing sequelae of HIV/HCV in later life, to allow planning for and provision of better-targeted health and social care in older age for the infected;

(c) the long-term effects of treatment for AIDS and Hepatitis C and the needs of infected women as they age particularly in relation to bone density;[572]

(d) any links between HCV and brain disease;[573]

(e) whether there is discrimination or bias against women/minorities within haematology leading to delayed diagnoses of women who bleed heavily as anything more than carriers;[574] and

(f) a number of other pertinent topics outlined in Thompsons' interim submissions at paragraph 13.3.[575]

773. In addition, there should be funding to accelerate the commercial production of:

(a) synthetic whole blood and improved recombinant products; and

(b) a test for vCJD, as canvassed in Professor Ironside's evidence.[576]

M. Independence of the NHS, the DoH, medical charities and treating doctors from the pharmaceutical industry

774. There should be a full, thorough and public register of commercial interests and influences. Steps should be taken to ensure that all contacts with commercial pharmaceutical companies by clinicians, health bodies and medical charities are recorded and are publicly accessible. 'Contacts' here includes sponsorship, funding, research funding, publishing, gifts, hospitality and all other perks. The obligation to report to the register should be placed on both parties to the relationship, and should be bolstered in ethical guidelines.

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[572] Haemophilia Society, paragraph 38.
[573] Watkins & Gunn, paragraph 5.
[574] Milners, paragraph 5; see further on other minorities, Leigh Day, recommendation 15.
[575] For brevity, we have not set them out here. We should say that we have no objection to their suggestion of a research subjects' rights framework, produced in consultation with patient advocacy groups. (Thompsons, paragraph 24.1).

[576] Milners, paragraph 19.

775. We note that Milners and Watkins & Gunn make similar observations. We endorse Milners' suggestion that these interests be disclosed to patients.[577] We have no objection to such a register being attached to the GMC register (as Watkins & Gunn propose) but that does not go far enough. This is because it omits health bodies and charities – which they anyway separately believe should be on a register. Further, we do not think it ought to be limited to 'conflicts of interest including transfers for value', as they suggest.

N. Recommendations as to Coroners

776. For the reasons set out in the following chapter on coroners, a recommendation that:

(a) inquests into deaths arising from contaminated blood/products are determined either by
  (i) a narrative conclusion, or
  (ii) a new short form conclusion – that is, "i*llness / disease acquired from contaminated blood or contaminated blood products*."

(b) This short form conclusion be added to Form 2 of the Schedule to the Coroners and Inquests Regulations 2013.

(c) the Chief Coroner be invited by the Inquiry to assess the desirability of providing guidance on the above.

777. Further, a recommendation that legal aid be made available for all Coroners' Inquests into the deaths of recipients of contaminated blood products or infected blood transfusions.

O. A recommendation on monitoring implementation of these recommendations

778. Since making our interim submissions, we have become persuaded of the necessity of recommending a taskforce to monitor the implementation of this Inquiry's recommendations themselves. This is because there has been a distinct lack of progress on implementing Sir Robert Francis' compensation scheme. While Core Participants had hoped that the present government might respond to this Inquiry more vigorously than it engaged with the Archer Inquiry, statements made during Parliamentary debates and in written evidence before this Inquiry[578] do not inspire confidence. Other Core Participants had submitted that there be a taskforce similar to those recommended by the Cumberledge Review and the Mid-Staffordshire Review.[579] The alternative, as the Haemophilia Society point out, is to convene this Inquiry indefinitely.[580]

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[577] Milners, paragraph 16; Watkins & Gunn, paragraphs 23 to 27.

[578] (such as that of Jeremy Quin WITN7526001).

[579] Thompsons, paragraph 1.1 and 1.2; Haemophilia Society, paragraph 27; Leigh Day, recommendation 28.

[580] Haemophilia Society, paragraph 27.

779. Regardless of the response of government, a taskforce would usefully be employed in supervising the implementation of recommendations in Northern Ireland so that the infected and affected in Northern Ireland are not disadvantaged by comparison with the other nations.

780. Members of the taskforce might, we submit, include current members of the APPG.

781. Further, we strongly endorse the suggestion (supported by Lord Jonathan Evans, Chair of the Committee for Standards in Public Life)[581] that there be a legal duty mandating a positive and prompt response on the part of government to reports of Public Inquiries

P. A recommendation as to freedom of information

782. In light of the difficulty CPs have experienced in battling to obtain information, there should be a review of public authority compliance with Freedom of Information Act 2000 requests, to consider:

(a) Categories of exemptions under the Act, and whether such should only apply when 'necessity' is established for the same;

(b) Compliance with requests made for medical information, and blood product supply information, and provision of all notes for those treated within their regions/remit;

(c) Whether greater incentives and/or oversight on public authorities to comply, or comply within the time frames envisaged by the legislation is required;

(d) Mandatory annual publication of the number of all FOI requests received by public authorities; their responses/replies or non-replies/responses or outstanding requests remaining; the timescales for such replies; and whether the applicant has appealed, pursued the request further, and/or raised the request with the ICO;

(e) Whether greater powers of enforcement should be provided to the Information Commissioner's Office, to ensure greater adherence by public authorities to the requirements of the FOI Act 2000;

(f) Whether there should be punitive measures imposed (fines, publication of non-compliance lists) on public authorities in the event of significantly poor or

[581] Wednesday 09th November 2022, pg 27, ln 3

consistently poor performance and/or failures to meet the statutory targets, to incentivise maintenance of high standards, and better serve the public interest.

(g) Whether individuals as well as organizations should be held to account for non-compliance under the FOI Act 2000.

Q. Recommendation for reforms to decisions on convening Public Inquiries

783. It is common ground among Core Participants that the current discretion afforded to ministers in determining whether a Public Inquiry should take place, and the lack of structured decision-making – even under the 2005 Act – has for too long deferred any proper investigation into the infected blood scandal.

784. Core Participants suggest a number of ways to cure this, none of which we object to.[582] Our own proposal is that there should be a formal consultation in respect of the process of convening a Public Inquiry, and:

(a) whether (and if so when) there should be an entitlement to the same; and

(b) how the convening of Public Inquiries can be put on a fairer, more consistent and more transparent footing, removing them from the discretion and inclinations of politicians.[583]

785. This should include consideration of the proposal that Public Inquiries should not be sponsored by a government department where that department is at risk of criticism or a potential core participant.

R. Recommendations in respect of action relating to criminal liability and disciplinary tribunals

786. While recognising that s.2(1) of the Inquiries Act 2005 prohibits determination by the IBI itself of criminal liability, there is such strong feeling amongst the infected and the affected (who note that criminal proceedings have occurred in other jurisdictions) that the Inquiry will are invited to pass all relevant papers, evidence and information to the relevant prosecuting authorities in the four nations to allow them independently to consider whether criminal proceedings should be brought.

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[582] Leigh Day, recommendation 29; Thompsons – the Patient Safety Commission for Scotland; Haemophilia Society, paragraph 6.
[583] See "Towards Justice: Law Enforcement & Reconciliation" (Cumberland Lodge) https://www.cumberlandlodge.ac.uk/read-watch-listen/towards-justice-law-enforcement-reconciliation-cumberland-lodge-report

787. In this regard, the infected and affected represented by Collins Solicitors endorse the submissions made by Milners Solicitors with respect to the offences that may have been committed, the vital public interest in addressing the questions of law raised in their submissions, and the conclusions of fact and law they reach therein.[584]

788. Similarly, the Inquiry will be invited to recommend that the GMC undertake an independent review of the conduct of doctors (practising, retired and deceased) who were engaged in Factor 8 product patient trials, advising governing bodies and societies (e.g. UKHCDO, Haemophilia Society, ACVSB, licensing bodies, the DoH) on the safety and use of blood products and administering unlicensed factor concentrate products on a 'named patient' basis.

789. In addition, we endorse the suggestion of Thompsons Solicitors that the GMC conduct a probe into its own tribunal process with a view to its improvement, in particular in relation to patient involvement.[585]

S. Other

S1. Generally, in respect of issues raised by *devolution*:

790. It shall be the responsibility of the United Kingdom government to implement these recommendations in the event that any devolved administration is unable to do so. The present situation in Northern Ireland demands that the United Kingdom government fund and support the implementation of all recommendations in respect of Northern Ireland.

791. There shall be parity between the nations of the United Kingdom in respect of all support given to the infected & affected. This recommendation requires all nations to 'level up' to the best practice in any single nation. This requires (for example) England to implement specialist psychosocial support in the way that Wales, Scotland and Northern Ireland have done; it requires Scotland to adopt the electronic record keeping illustrated by Southampton NHS Trust in England.

792. As set out in chapter xx, we endorse the parity suggested by Sir Robert Francis in respect of future financial support.[586]

S2. vCJD

[584] We note that prosecution was considered by Strathclyde Police; see POSC0000035.
[585] SUBS0000036

[586] Francis report, CITATION, paragraph 9.88, pages 115116.

793. In respect of *vCJD* –

(a) patients who were notified that they were at risk of vCJD should be offered a tonsil biopsy to confirm whether they have in fact contracted vCJD;

(b) as suggested by Watkins & Gunn, there should be a review of whether the public health measures that resulted from the notification are still necessary;[587]

(c) as suggested by Thompsons Solicitors, the specialist support schemes should liaise with Professor John Collinge's team on vCJD counselling.[588]

S3. Burden of proof where medical records missing

794. We support Leigh Day's recommendation 21 in respect of support schemes. However, we say that where medical records have been lost, the burden of proof should be *reversed* and not merely a lower standard of proof applied.

S4. MHRA, regulatory and licensing reforms

795. We support the reforms that others suggest, including those who gave evidence in the last two weeks of the Inquiry.[589]

S5. Historical records relating to the Alliance House Schemes

796. The historical records relating to the Macfarlane Trust and other Alliance House schemes are currently held by Russell Cooke solicitors. Provision should be made for their preservation and safekeeping. The infected and affected should be involved in the making of the decision.

S6. Liaison with US Embassy

797. Some Core Participants urge that UK authorities liaise with the American authorities to correct the anomalous position experienced by some infected Core Participants wishing to enter the United States. Some of those infected with HIV who applied for a public health visa waiver with or who travelled to the USA before repeal of the law requiring people with HIV to have a waiver for entry (in 2009), still face inconvenience when entering the USA and are the subject of extra checks by the Immigration Authorities. They have attempted to have the designation removed, but without success.

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[587] Watkins & Gunn, paragraph 9.
[588] Thompsons, paragraph 6.9.

[589] Thompsons, paragraphs 19.2 and 20.1; Watkins & Gunn, paragraphs 30 to 34; Saunders, paragraph 23; Milners, paragraph 7.

S7. Recombinant therapy for von Willebrand Disease

798. People with severe Von Willebrand disease, who are still being treated with plasma-based factor products, should be given the option to transfer to a safer recombinant substitute.

Conclusion

799. Of the various recommendations outlined above, we have identified the following as being most crucial to our clients:

(a) Apology
(b) Memorials
(c) Improved patient treatment and information
(d) Consent
(e) Record-keeping
(f) DWP and HMRC implications
(g) Coroners
(h) Taskforce

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Chapter 17 - Inquests, Coroners and Death Certification

800. The Inquiry has heard evidence from Core and other Participants regarding their experiences of laying to rest infected partners, parent(s) and offspring. We have heard of the surrounding stigma attached to these demises, and their difficult dealings with undertakers and/or the Coronial system, manifest in the registered 'Causes of Death' recorded on Record of Inquest Forms, and Death Certificates, which are public records.

801. Cause of Death is also used for mortality statistics and should be accurate, as identified by the WHO 'Medical Certification of Cause of Death'.[590] Such states *'mortality statistics are much more meaningful if all details available in the deceased person's records regarding the precise diagnoses are incorporated into the death certificate'*[591]. The 2001 Home Office review following the Shipman Inquiry recommended *'brief information about .... the patient's clinical history should be recorded* [on the death certificate].[592]

802. However, only recently in June 2022, has the Government announced its intention towards the recommended statutory 'medical examiner' system with a. view to commencing in April 2023 https://www.england.nhs.uk/establishing-medical-examiner-system-nhs/ .

803. Some Participants have felt that through prejudice and/or a misguided desire to 'spare the families', inaccurate or misleading recording of the 'Causes of Death' and/or Inquest 'Verdict' (now 'Conclusion') has occurred which does not reflect the true position. These are submissions on the current position, with future suggestions for the Chair to consider.

Current Position

804. Provision is made for a Coroner to report and investigate a death under the Coroners & Justice Act 2009, for the purposes of ascertaining (s.5): Who, How, When and Where the deceased came by their death, for purposes of making a 'determination' under s.10 to make findings of the particulars required to register a death under the Births & Deaths Registration Act 1953, and Rule 34 of the Coroners (Inquests) Rules 2013.

805. 'How' has been interpreted by the Courts[593] to mean '*By what means*' a death occurred, save in the case of an Article 2 Inquest, which is larger in scope, when 'How' is interpreted as '*By what means and in what circumstances*'[594]. A Coroner's conclusions

[590] RLIT 0001100_005 at Pg. 6
[591] RLIT0001100_006 at Pg. 6
[592] DHSC0041464_015_0003 at Pg. 3
[593] R v HM Coroner for N. Humberside & Scunthorpe, ex parte Jamieson [1996] QB 1
[594] R (Middleton) v HM Coroner for West Somerset [2004] 2 AC 182.

should necessarily be brief, neutral and clear, without expressing opinion[595], and without seeking to attribute criminal or civil liability on the part of a named person[596].

806. Under rule 34 of the Coroners (Inquests) Rules 2013 [597] a Coroner (or jury) '*must make a determination and any findings required under section 10, using Form 2*'. Form 2 is appended as a Schedule to the CIR 2013; and sets out a pro forma 'Record of an Inquest'. Box 3 sets out the '*How, when and where*' provisions, and Box 4 the '*Conclusion as to death*'. There are further notes (i) and (ii) provided for Boxes 3 and 4.

807. At the Coroner's discretion, there are currently different forms of conclusions available to any Coroner / jury:

    a. a **short form conclusion** (a specific description of up to 3 words taken from the list set out in note (i) to Box 4, in Form 2 of the CIR 2013 schedule e.g. accident or misadventure or unlawful killing); or

    b. a **narrative conclusion** (a short descriptive conclusion paragraph, or answers to specific questions put to a jury); and

    c. there is the option to combine both under note (ii) providing for a narrative conclusion 'as an alternative, or in addition to one of the short form conclusions' – often termed a **hybrid conclusion**.

808. The presumption (absent a jury) is that a Short Form conclusion is to be preferred, albeit brief Narrative conclusions (which do not offend section 5 or 10) have become more prevalent, being seen to address the concerns of bereaved families more fairly, as interested parties to an Inquest. They should nevertheless address issues central to the possible cause of death, which may entail jury guidance from a Coroner.

809. From the evidence heard during this Inquiry, if an Inquest were to consider a short form conclusion only, it appears to us that those falling for consideration would be:

    i. Unlawful Killing[598] Restricted to the criminal offences of: Murder, Manslaughter (including corporate manslaughter) and Infanticide, with all elements of the

[595] S.5(3) of the CJA 2009
[596] S.10(2) of the CJA 2009
[597] Made pursuant to s.45 of the CJA 2009
[598] See further the 'Chief Coroner– Law Sheet No.1'

offence to be proven to the criminal standard of proof.[599] [600] [601] [602] For this short form conclusion, a Coroner must (a) be satisfied there is sufficient evidence upon which a jury properly directed, could properly reach that conclusion; and (b) also be satisfied that it is safe on the evidence to leave that conclusion to the jury. However, in a medical context '*Mistakes, even very serious mistakes, and errors of judgment, even very serious errors of judgment, and the like, are nowhere near enough for a crime as serious as manslaughter to be committed*'[603]. Albeit there may be potential for corporate manslaughter, under the Corporate Manslaughter and Corporate Homicide Act 2007, which is the subject of separate submissions by others, though it is understood this Act is not retrospective and applies only from 2008 onwards.

ii. Misadventure: Where death has arisen from a deliberate act (the administration of factor concentrates or a transfusion) which '*unexpectedly and unintentionally went wrong*'[604]. We suggest, that from the state of government and clinical knowledge which the Inquiry has uncovered, it may not have been unexpected:
   (a) in relation to NANBH during the 1970s and 1980s, that death may follow;
   (b) in relation to HIV through 1982 and 1983, that death may follow.

iii. Open conclusion, where no other short form conclusion has been proved, but this is discouraged, save where 'strictly necessary'.

810. We note that currently, under rule 24 of the Coroners (Inquests) Rules 2013:
   (1) A coroner may admit the findings of an Inquiry, including any Inquiry under the Inquiries Act 2005, if the coroner considers them relevant to the purposes of the inquest.
   (2) Before admitting such inquiry findings as evidence, the coroner must announce publicly that—

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[599] **Murder** - person is guilty of murder if s/he kills a person unlawfully (not in self-defence or defence of another or accidentally) and at the time intended either to kill him or cause him some really serious bodily harm (murderous intent) – this last element is considered unlikely.

[600] As stated in *R v Adomako* [1995] 1 AC 171 (HL) **Gross negligence manslaughter** (at common law) requires - (1) The existence of a duty of care (based on ordinary principles of negligence) owed to the deceased, (2) a breach of that duty of care, (3) the risk of death (not just the risk of serious injury) was a reasonably foreseeable consequence of the misconduct: *Reeves v Commissioner of Police for the Metropolis* [2001] 1 AC 360, 393 (HL), (4) the breach caused the death, and (5) having regard to the risk of death involved, the misconduct was grossly negligent so as to be condemned as the serious crime of manslaughter.

[601] Under section 1 of the Corporate Manslaughter and Corporate Homicide Act 2007, **Corporate Manslaughter** is committed by an organisation (or other body listed in the Act), if the way in which its activities are managed or organised causes a person's death and amounts to a gross breach of a relevant duty of care owed to the deceased. A breach of a duty of care is gross *'if the conduct ... falls far below what can reasonably be expected of the organisation in the circumstances*': section 1(4)(b).

[602] **Unlawful act manslaughter (at common law)** are: (1) A deliberate act which is unlawful (eg an assault); (2) The act is a dangerous act in that it is, from an objective standpoint, one which a sober, reasonable and responsible person of the perpetrator's age and gender, would inevitably realise is an act which is likely to cause the deceased some physical harm, albeit not serious harm; (3) The unlawful, dangerous act causes death (even though death or harm of any kind is not intended). [*Archbold* 19-112 and *DPP v Newbury* [1977] AC 500]

[603] See *R v Misra* [2005] 1 CrAppR 21 [25] (CA)

[604] Chief Coroners Law Sheet No.1 (21st September 2021)

(a) the findings of the inquiry may be admitted as evidence;

(b) the title of the Inquiry, date of publication and a brief account of the findings; and

(c) any interested person is entitled to see a copy of the Inquiry findings if he or she so wishes.

A proposal for an additional Short Form / Mandatory Narrative Conclusion

811. It is submitted the foregoing short-form conclusions are ill-suited to the circumstances of those who have died following receipt of contaminated blood or blood products.

812. We contend that in the future, in such cases, a narrative conclusion should be mandated in addition to underlying causes of contaminated blood or blood products being identified on the medical cause of death boxes.

813. An anonymised example of a Narrative Conclusion in a recent Inquest, which we commend to the Chair as one which serves the purpose of having properly investigated the death, is set out below.

> " *.... Z had mild haemophilia A. Between [date] and [date] he was treated on Y occasions with Factor VIII concentrate, a product developed to treat haemophilia. At least one of the Factor VIII treatments he was given was contaminated with hepatitis C.*
>
> *In [year], Z was diagnosed with hepatitis C. As a result of the infection with hepatitis C he suffered a variety of mental and physical symptoms which impacted on [details of impact]. There was little or no support available and the stigma of the virus created isolation, frustration and sadness at the loss of a life imagined.*
>
> *Z subsequently developed cirrhosis, a recognised complication of hepatitis C. He was also diagnosed with cancer of the liver and portal hypertension. Both conditions are complications of cirrhosis. In [date] he presented with his first variceal bleed. In [date] he had a second variceal bleed. On the night of [date], Z was admitted to hospital due to him vomiting blood. He was stabilised and an endoscopy revealed further bleeding varices which were banded. He had sepsis and was treated with antibiotics, but it progressed. Save for basic observations on the Early Warning Score system, there are no notes by medical staff between ... and ... when it had become apparent that Z's condition had significantly deteriorated. It is therefore not possible to say what if any observations took place in this period, and how rapid the deterioration was. Despite a transfer to the Intensive Care Unit, Z died in the early hours of [date].*
>
> *Z's death is the direct consequence of being given Factor VIII between [dates] which was contaminated with hepatis* C".

814. Alternatively, we propose an addition to the Short Form conclusions set out in Form 2 of the Schedule to the CIR 2013. Such an additional Short Form conclusion might be: "*Illness / Disease acquired from contaminated blood or contaminated blood products.*"

Further Submissions

815. We propose that under any new system, the deaths of haemophiliacs with potential liver disease are immediately referred to Medical Examiners required to certify cause of death, to provide reassurance to affected families that there will be independent scrutiny into the death of their loved ones. If the system of medical examiners is not operational by the time the Inquiry reports, then such deaths should be referred to the Regional National Medical Examiners for England and Wales or its equivalent, with oversight from the National Medical Examiner.

816. Furthermore, as stated herein, Core Participants have given evidence of being troubled by Form 99 recorded 'Causes of Death' registered on Death Certificates and Records of Inquests (/Inquisition Forms) as not accurately reflecting the true position or circumstances of death, omitting references to "HIV/AIDS" or AIDS-related illnesses" and specifically the absence of any reference to contaminated blood or blood products.[605]

817. While in some cases this may have occurred to avoid potential stigma arising in the 1980s surrounding HIV deaths, the evidence to the Inquiry has been that in many of those cases it was done without the family's request or consent. There are concerns that it may have been done in some cases to hide the association between the death and the provision of contaminated blood or blood products. This may reflect a practise of trying to avoid referral to a Coroner, as highlighted[606] in a Joint Report of the Royal College of Physicians and Royal College of Pathologist, published in the Journal of Royal College of Physicians of London on the 4th October 1982.

818. Following the conviction of the Manchester GP, Harold Shipman, for the death of 15 patients, the Home Office instituted a comprehensive Report for the Review of Death Certification in 2001.[607] Paragraph 11 of its executive recommendations highlighted:

> "*… This review of death certification procedures cannot be considered in isolation. The procedures are closely connected with the arrangements for the registration and investigation of deaths ..... We therefore recommend that the results of this Review should be taken into account by the Shipman Inquiry, the Home Office Fundamental Review of the Coroners' System ....".* Patently, there is an acknowledged clear association arising.

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[605] WITN1673001, WITN1206001 WITN1506001 WITN1574001 WITN1144001 WITN1208001 WITN1210001 WITN5267001

[606] HOME0000058_028_0006 at Pg. 6

[607] DHSC0041464_015

819. Section 5 therein (at paragraph 5.1) records the '*Purposes of death certification'* as including to: *"..to support relatives and others with a valid interest in the medical cause of the death..*" and *"...to ensure that unnatural deaths, which require further investigation, are properly investigated ..*".

820. Core Participants now question whether such records might now be retrospectively amended or rectified following any publication of the current Inquiry's Report, to take account of its historical findings, so that an accurate, full and fair cause of death may be retrospectively recorded. This will be at the instigation of those affected, seeking to correct the same, rather than a generic wholesale blanket exercise into the death certificates of every haemophiliac and/or transfused patient in the last 50 years. The Inquiry is respectfully invited to consider the concerns expressed and mechanisms for resolution.

821. It is submitted that much turns on which process a Coroner has chosen, to investigate the death.

a. If a post-mortem has occurred, which leads the coroner to determine that no further investigation is warranted, as a natural death has occurred, a Form 100B process will be adopted, as required by under s.4(1) of CJA 2009. It is considered this process may be re-opened by a Senior Area Coroner under s.4(3) of the CJA 2009, in the event of 'new evidence' coming to light. It is envisaged this process of re-opening the Inquest could (at least initially), be a paper exercise, taking account of the Inquiry's report, any medical notes or inferences that may be legitimately drawn from the surrounding facts of the Deceased's treatment/s.

b. If, on the other hand, a Coroner has determined (in their discretion) a Post-Mortem was not necessary, and adopted the Form 100A process deeming investigation was unnecessary, it will likely have been determined a 'natural death'. In such circumstance, the decision made in the exercise of that discretion may only be challenged by way of Judicial Review in the Divisional Court [608]. The absence of a post-mortem distinguishes it from the Form 100B process and precludes the application of s.4 of the CJA 2009.

c. Finally, a Coroner may decide an investigation is required, regardless of whether a post-mortem has been yet sought or not, and will formally open an inquest to decide what further investigations are required, or may give directions for a pre-inquest hearing to occur. A conclusion following such Inquest may only be challenged by way of Judicial Review in the Divisional Court.

[608] For example – see Margaret Terry v Alan Craze (HM Coroner for East Sussex)[2001] 5th Feb, EWCA Civ 148. Albeit that this case was decided under the previous 1988 legislation.

822. Thus, as things stand, to review cause of death, either a Senior Area Coroner re-opens the Record of Inquest (if Form 100B process was used) or a judicial review is required.

823. We submit the process of full judicial review is time-consuming and costly, and that the Chair should recommend there be a review of the legislation, with a view to changing the law under the Coroners & Justice Act 2009 or the Coroners (Inquests) Rules 2013 to remove the necessity for judicial review in these particular and limited circumstances.

824. Alternatively, and short of changing the law, the Chair might recommend an expedited process could be recommended in the Divisional Court, with government / DoH commitment: (i) not to challenge any judicial review in these circumstances, and (ii) to consent to an Order remitting the matter back to the relevant Coroner's Court area for a further consideration, initially on the papers. This would provide a huge step towards clarity, vindication, and closure for those affected.

825. Once the Record of Inquest has been amended, the Death Certificate may be reconsidered. A Death Certificate may not be changed once issued – all that can be done is a note added to the original entry in the register of deaths, and an updated certificate be then issued, showing that additional note. An application for is required to be made to the relevant registrar for the register of deaths, upon payment of a fee, usually by the person who originally registered the death (although it can be applied for by anyone able to show the information given at the time of registration was wrong/inaccurate).

Chief Coroner's Guidance

826. A significant and helpful development since the introduction of the CJA 2009 and the Office of Chief Coroner has been the publication of a series of 'Chief Coroner's Guidance' and 'Law Sheet' documents to assist the Coronial processes. Whilst these are expressly said not to be a codification of the law on Inquests, they are well-respected, widely referred to, and helpful guides.

827. By way of illustration, Guidance Notes have previously been provided on issues such as 'Sudden Cardiac Death – Inherited Heart Conditions'.

828. We submit that the Chair should consider recommending that the Chief Coroner considers assessing the desirability of providing a Guidance Note on '*Death caused or contributed to by likely receipt of contaminated blood or blood products'.*

829. Such guidance could be produced in light of, and referring to, the Inquiry's Report (when published). It might be produced after consultation with (i) the Coroners' Society of England & Wales; (ii) 'Inquest'; and/or (iii) RLR from the Inquiry.

830. It might usefully address matters including:

a. A summary of the historical perspective of the Contaminated Blood scandal, and current ongoing consequences in terms of infection;

b. identification of the Infected Blood Inquiry, its report, recommendations, and a reminder of rule 24 of the Coroners (Inquests) Rules 2013, which permits such report to be admitted in evidence in any inquest;

c. details of illnesses which can be attributed to infection with contaminated blood or blood products, and the treatments endured for such illnesses;

d. how to address missing documentation and medical records, and the presumptions that might reasonably be made in their absence (often with medical institutions unable to produce the same);

e. the desirability of Narrative conclusions and/or availability of any additional Short Form conclusion if forthcoming. Example narratives should be provided.

f. the provision of information to bereaved families on available support in the coroner's area;

g. Powers under rule 28 for Prevention of Future Deaths, in relation to pharmacovigilance matters.

h. The separate 'Yellow Card' (and 'Black Triangle') systems of reporting, that permit Coroners (amongst others) to report to the MHRA, where medicines (Blood Products) are deemed to have had an adverse effect on a patient. Note too, the distinction that safety of 'Blood' per se, is dealt with by SABTO;

i. steps to be taken, in the event a bereaved family member / interested party seeks to review or re-open a previous conclusion (/verdict), which makes no reference to the administration of contaminated blood or blood products, in circumstances where there is evidence that such may be relevant to the cause of death. The desirability of dealing with any remitted applications on paper, given provision of appropriate material to do so, and the availability of the findings of the Inquiry under rule 24.

831. Finally, we note from the most recent tranche of evidence to the Inquiry that there may be calls for the compulsory reporting of all transfusion infections or adverse occurrences. We draw the Chair's attention, to the provisions under s.7(2)(c) of the CJA 2009: that a Jury must be summonsed where death has been caused by a 'notifiable poisoning or disease'. This may seem to be engaged under the provisions of s.7(4) that '*notice is required under any Act to be given to (a) a Government Department, or (b) an inspector or other officer of a government Department.*'

832. Thus, if a blood transfusion or provision of blood products has occurred, which has led to death, and this is deemed / required (in the future) to be notifiable, as opposed to voluntary reporting for example to SHOT or another Public Health government department, then a Jury will be required at any Inquest.

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Chapter 18 - Compensation

Introduction

833. We repeat what we say at the beginning of our chapter on non-financial recommendations. Infected and affected Core Participants want three things from this Inquiry**: closure, reassurance** and financial **security**.

a. **Closure** through the findings of fact in the Inquiry's final report. Previous chapters have made submissions on the conclusions that the Chair should draw.

b. **Reassurance** through regular health monitoring and care, and the rebuilding of damaged trust relationships with government and NHS actors (including apology, reparation and making amends according to the Inquiry's recommendations) so that this kind of scandal can never happen again. Those matters are addressed in the chapter on non-financial remedies.

c. **Financial security**: this chapter deals with Compensation.

834. As the Chair well knows, High Court Judges regularly recognise in their judgments in claims in tort for catastrophic personal injuries or clinical negligence the impossibility of turning back the clock or undoing all the effects of a tort, and recognise that a financial award of damages can never truly compensate an individual for suffering a life-changing injury.

835. As we set out below, this Inquiry is, however, in the fortunate (and better) position that it can improve on the remedies available to a Court. By the interaction between (i) giving closure through its conclusions; (ii) non-financial remedies; and (iii) compensation it can and should achieve something closer to the concepts of reparation, restoration, restitution (in a non-legal sense) and perhaps even redemption[609]. Professor Sir Jonathan Van Tam evocatively referred to this as the possibility of creating a *"new future"*.

836. In July 2022 we put forward our submissions in respect of interim payments[610], and we build on what we said then.

837. For ease, in this Chapter we refer to the Report of Sir Robert Francis KC entitled *"Compensation and Redress for the Victims of Infected Blood – Recommendations for a*

[609] Adopting the language of Revd David Armstrong of St Botolph's, in the annual Haemophilia Service of Thanksgiving and Remembrance, but intended in a secular sense (of being rescued or released by another from a disastrous situation)
[610] Now at SUBS0000026

Framework" simply as "the Francis Report" and to the scheme of compensation he proposed in that report as "the Francis Framework".

838. At the end of this chapter we address the consequences of the Government not yet having published its response to the Francis Framework.

Language matters: support / compensation / responsibility

839. Language is important. "Support" – which is what has been provided to date – connotes something which was intended to do little more than lift its recipients out of poverty. "Charity" connotes something which is offered, rather than due or required.

840. The Inquiry has heard repeated evidence of how offensive the language of "support schemes", "support payments", "charitable help" and "*ex gratia* support" has been to the infected and affected. There is (as we have demonstrated above and the Inquiry has understood) a genuine claim to have been grievously wronged by actions for which the State bears ultimate responsibility[611].

841. Repeated assertions that *legal* responsibility has never been established (with the exception of those who succeeded in *A v National Blood Authority*) are technically correct, but serve only to diminish the *moral* responsibility which has been accepted by so many witness to the Inquiry and to belittle the genuine entitlement of the infected and affected to redress. That language turns them, or at least the limited number of those eligible, into recipients of charity dispensed only due to the magnanimity of the State. That is simply wrong.

842. We note, but do not set out all the evidence the Inquiry has heard, that as the Inquiry has proceeded there has been a growing recognition of the moral responsibility, and of the appropriateness of compensation rather than (merely) support. Examples include:

a. The then-Secretary of State for Health, Matt Hancock, accepted when he gave evidence to the Inquiry that there was a moral responsibility on Government to address the impact of what happened.[612]

b. Previously in September 2020 Penny Mordaunt MP (then Paymaster General) had written to the (then) Chancellor Rishi Sunak: *"I expect Sir Brian to make recommendations about levels of financial support and* ***it is inevitable that the Government will need to provide substantial compensation****. The costs are likely to be high, and I firmly believe that we should begin preparing for this now - before the inquiry reports."*

[611] See our introductory chapter and the reference by Lord Kenneth Clarke to the Secretary of State for Health having ultimate responsibility for his department, officials and ministers (transcript 27.7.21 p.211)
[612] Transcript 21.5.21 p.126

c. Justin Fenwick KC considered that terms on which the HIV litigation was settled reflected the shared belief on both sides that none of those infected would survive for long.

d. Sir Rupert Jackson considered that it was *"unfortunate that the government of the day did not face up to its moral responsibility ..."*

e. Sir Robert Francis said in evidence: *"A lot of decisions that seem to have been taken about support ... have been around a wish to avoid accepting legal liability when actually what needed to be looked at was the moral case for looking after people."*

f. We adopt and endorse Sir Robert Francis' analysis of the evidence and material on moral responsibility at §§4.7 - 4.74 of his report. He concludes at §4.74 that *"It is my firm conclusion that a special case is demonstrated here for* ***compensation*** *to be made available ..."* We agree.

g. Moreover there is a unanimous groundswell of public opinion (insofar as that can be deduced from newspaper articles, newspaper editorials in papers of all political leanings and representations made by elected Members of Parliament of all parties) for full and complete, proper compensation to be paid.

843. Mr Hancock accepted in his oral evidence on 21.5.21[613] that there was a distinction between support schemes and compensation and that what had been put in place so far were support schemes. Well aware of the distinction, he said: *"should the inquiry's recommendations point to compensation, then* ***of course we will pay compensation****."*

844. We submit that the infected and affected should never have been made to go cap-in-hand to various iterations of Trusts and Schemes which approached their applications for help with a critical lack of sympathy and understanding. They should never have been made to feel like (or have been treated as) beggars, whingers, scroungers or burdens on the State.

845. For the future, then, the language of "compensation", as opposed to "support" is therefore vital. Compensation flows from proper recognition that a wrong has been done. What the Inquiry recommends, therefore, should be compensation.

What is 'compensation' in common law?

846. In common law in all four nations, the purpose of an award of damages by way of compensation in tort (e.g. for personal injuries) is, so far as possible, to put the injured person back in the position as if the negligence had never occurred.

[613] Transcript 21.5.21 pp.149-150

847. The principles are long-standing, and will be well-known to the Chair, but have recently been reconsidered and re-stated by the Privy Council in the case of *Attorney-General of St Helena v AB* [2020] UKPC 1. The appeal focussed on general damages for PSLA in St Helena, but paragraphs [22] to [24] are relevant for us.

> 22. The core function of PSLA damages, like any other type of damages for the commission of a tort, is that identified by Lord Blackburn in *Livingstone v Rawyards Coal Co* (1880) 5 App Cas 25, 39:
>
> > "where any injury is to be compensated by damages, in settling the sum of money to be given for reparation of damages you should as nearly as possible get at that sum of money which will put the party who has been injured, or who has suffered, in the same position as he would have been in if he had not sustained the wrong …"
>
> In Heil v Rankin [2001] QB 272, after citing that passage, Lord Woolf MR continued, at para 23, as follows:
>
> > "23. This principle of 'full compensation' applies to pecuniary and non-pecuniary damage alike. But, as Dickson J indicated in the passage cited from his judgment in Andrews v Grand & Toy Alberta Ltd, 83 DLR (3d) 452, 475-476, this statement immediately raises a problem in a situation where what is in issue is what the appropriate level of 'full compensation' for nonpecuniary injury is when the compensation has to be expressed in pecuniary terms. There is no simple formula for converting the pain and suffering, the loss of function, the loss of amenity and disability which an injured person has sustained, into monetary terms. Any process of conversion must be essentially artificial. Lord Pearce expressed it well in H West & Son Ltd v Shephard [1964] AC 326, 364 when he said:
> >
> > > 'The court has to perform the difficult and artificial task of converting into monetary damages the physical injury and deprivation and pain and to give judgment for what it considers to be a reasonable sum. It does not look beyond the judgment to the spending of the damages.'
> >
> > 24. The last part of this statement is undoubtedly right. The injured person may not even be in a position to enjoy the damages he receives because of the injury which he has sustained. Lord Clyde recognised this in Wells v Wells [1999] 1 AC 345, 394H when he said: 'One clear principle is that what the successful plaintiff will in the event actually do with the award is irrelevant.'"

23. An important part of the purpose of PSLA damages is that they should

> reflect what society as a whole considers to be fair and reasonable compensation for the victim or, as the Supreme Court of Canada put it in Andrews v Grand & Toy Alberta Ltd [1978] 2 SCR 229: "reasonable solace for his misfortune."
>
> 24. This is captured in Sir Thomas Bingham MR's observation in John v MGN Ltd [1997] QB 586, 611, 614, that:
>
> > "Any legal process should yield a successful plaintiff appropriate compensation, that is, compensation which is neither too much nor too little. That is so whether the award is made by judge or jury … Nor is it healthy if any legal process fails to command the respect of lawyer and layman alike …"

848. Common law compensation therefore:

a. Seeks to put the party who has been injured, so far as money can, in the same position he would have been in if he had not sustained the wrong.

b. Should reflect what society as a whole considers to be fair and reasonable compensation for the victim.

c. Should be such as to command the respect of the lawyer and the layman alike.

849. The compensation that we invite the Chair to recommend for the infected and affected should be the same,but can and should be tailored to their unique and particular circumstances as they are known in detail to the Inquiry.

The purpose and nature of compensation following this Inquiry

850. Many of the infected and affected who gave oral evidence spoke eloquently of being deprived of the life they had been meant to lead, including being deprived of their financial independence.

> *"Nobody here wants to be on a benefits system, we just want to live our life"* (Anon – transcript 16.10.19)
>
> *No scheme will ever give us independence* (Tony Farrugia – transcript 18.10.19)
>
> *Just financial dignity, that's all we ask for really* (Alan Burgess – transcript 28.10.19)

851. They should therefore have restored to them their financial independence.

852. As the Francis Framework proposes, they should be entitled to choose between (or combine):

a. The comfort and future security of knowing that they will not be cast adrift financially by vagaries of the benefits system or changes in administration or changes in policy by future governments.[614] In other words, if they want it, it should give them the long-term confidence of a guaranteed annual stream of (index-linked) income.

b. Being freed from regular interactions with the State (through the proposed successor to the support schemes) and be returned to the independence they would otherwise have had. In other words, if they want it, they should be entitled to a lump-sum award to reflect their past loss and their likely future loss.

The Francis Framework generally

853. Sir Robert Francis was instructed by the Government as an independent reviewer. He has immense experience of medico-legal work, has himself conducted significant Inquiries and is impartial.

854. Having instructed him to report, there is no reason for the Government not to follow his recommendations – if and insofar as they are adopted and recommended by the Chair in his Report.

855. In broad terms, and subject to the aspects of clarification set out below, we agree with and endorse the Francis framework. Where we do not mention an aspect of his report, we agree with it.

856. The broad effect of Sir Robert's proposed framework is that many aspects of the application process and award will be dealt with as if they were a common law assessment of damages in a personal injuries or fatal accident claim (similar to how the Criminal Injuries Compensation Board operated, when it was first set up). This is likely to allow the framework to be recognised by those it is intended to benefit as being right and objectively fair (if it proceeds in the same way and is determined by the same principles as a Court process would), but is likely to require legal assistance for applicants, a level of specialist legal knowledge on the part of those who initially deal with and adjudicate on the applications and access to an experienced and specialist legal appeal tribunal (or, more effectively – a right of appeal to the High Court) if an applicant is not satisfied with the

[614] Mr Hancock recognised this when he said in evidence: *"I would absolutely give a commitment to anybody receiving a payment, any of the beneficiaries infected or affected, that I would expect that tœontinue for their lifetime."*

initial adjudication (again similar to the original Criminal Injuries Compensation Scheme or, we understand, to how the scheme works in the Republic of Ireland).

857. We recognise that a scheme based on the Francis Framework and run in this way will take time to process complex applications, but that is to be set off against our submission (below) that interim payments should be made to wider classes of applicants (thereby removing at least some of the immediate financial hardship); the fact that a large number of applications will not be complex; many potential applicants may be entirely satisfied by an interim payment and uprated annual payments; and our contention that having legal advice and representation for applicants is likely to speed and smooth the process, rather than slow it. On balance, therefore, we the Chair to recommend a more individual and bespoke system for the assessment of awards, analogous to the process of an assessment of damages.

858. We also observe that the Francis Report provides an overview of what his proposed compensation framework should do, but does not purport to be a finely-detailed model scheme. We have points of clarification and concern to make about a number of aspects, which we set out below. For some we have suggested solutions. Some we flag up to the Chair as being issues on which he himself might make recommendations. In light of the complexity of some of those issues, we strongly invite the Chair to recommend that (as was done in the Republic of Ireland) the fine details of the scheme be worked out by a process of negotiation and co-operation between the Government and suitable representatives of the infected and affected community (ideally also involving RLRs with experience of PI and clinical negligence law) – all of whom will have an interest in achieving and agreeing as fair, workable and practicable a scheme as possible, as swiftly as possible.

859. Clarity on Sir Robert's proposal that Estates may bring claims for the injury and losses suffered by the deceased needs to be provided swiftly, as grants of probate take time to obtain and core participants will need to take steps to prepare for the introduction of the compensation scheme.

860. We have points of clarification and concern relating to:

a. To whom should the framework apply
b. National scope
c. No-one should be worse off
d. The level of the general damages-type awards
e. The form of the award
f. The experience and quality of the assessors
g. Legal representation for applicants
h. Simplicity
i. Those who lost parents as children

j. The evidence of Keith Carter
k. Increased insurance and life assurance costs
l. Ongoing payments / pension loss / past and future loss of earnings

(a) To whom should a Compensation Framework apply?

861. Sir Robert recommended that compensation in some form or other be available not only to those presently beneficiaries of the support schemes, but also to parents who lost children, those who lost parents, and to carers. We concur wholeheartedly. As a matter of fact they have suffered and have incurred financial hardship resulting from the illness and death of those infected[615]. Time is not on their side, particularly those who were parents of boys who died in the 1980s and 1990s, who are now all of advanced years and have never had their situation recognised adequately or at all.

862. We observe that the very fact of the non-recognition of these three groups under the previous and current support schemes has itself been divisive, and damaging to those individuals.

863. We note that when the Chair pointed out (during the course of Mr Hancock's evidence) that when MFT was set up in 1988, clause 4 of its objects included *"parents and children ... of such persons".* Mr Vineall (accompanying Mr Hancock) replied *"Well I wasn't aware of that piece of information, I have to say"* and the subsequent exchange between Mr Vineall and Mr Richards KC was this:

> Q: Why is the scheme drawn … so narrowly that only certain categories of relative can receive support?
> A: The only thing I can say is that those are the boundaries we've always drawn around the scheme.
> Q: That's a statement of status quo, rather than a reason, is it not, Mr Vineall?

864. In 2019, Nadine Dorries, then a junior minister in the DoH, wanted to include other family members such as parents[616] within the four nations' schemes.

865. In his list of dependants at p.74 of his report, Sir Robert aligns potential dependants able to bring claims under his Framework with those who are identified as dependants under s.1(3) of the FAA 1976. In doing so, he replicates a list which has come under criticism for many years as being illogical. The 2010 Civil Law Reform Bill (which would have extended eligibility for dependency damages to any person who was financially

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[615] Although, as we note and comment on below, the Francis Framework as currently proposed excludes the affected (bereaved spouses and bereaved parents, for example) from claiming for their own financial loss (e.g loss of earnings). We say this is wrong, and invite the Chair to recommend that they be able to claim such losses.
[616] EIBS0000047

dependent on the deceased) was shelved by the coalition government in January 2011. As a result, there are a number of illogicalities remaining in the list under the FAA, e.g.

a. a person who has cohabited with the deceased for 1.9 years may not claim (as not having reached the 2-year threshold under s.1(3)(b)), whereas a divorced wife may (s.1(3)(a)) or someone who had been married only for one day may (s.1(3)(a));

b. any child of the deceased may claim, however remote their relationship may be (s.1(3)(e)), whereas any child of a cohabitee could not, even if there had been cohabitation for far longer than the threshold two years and even if the cohabitee's child had been part of the deceased's household for all that time (s.1(3)(f) requires such a child to be treated as a child of the family *in relation to a marriage or a civil partnership* in order to be a dependant).

We submit that it would be preferable to define a dependant for the purposes of the compensation framework simply as any person who can establish that they were or would have been financially dependent on the deceased. This will not open legal floodgates, as any award will still require proof of the nature and extent of such dependency.

(b) National Scope

866. There must be only one, single compensation framework across the whole UK. The mechanics of whether it is centrally funded or contributed to from the budgets of the four nations is of no concern to most of our Core Participants. What matters is that there is a scheme which (both in making lump sum awards *and* in paying annual payments) treats those in all four nations exactly equally and is guaranteed to do for the future.

867. In the Francis Report it is anticipated that bereaved relatives should be awarded compensation for their bereavement and dependency loss on the same basis as under the Fatal Accident Act 1976[617]. There was no express reference by Sir Robert to Scots law, and it may be that he did not appreciate that there is a material difference in the damages which may be awarded in such claims between Scotland and England. We will defer to representations which we anticipate will be made on behalf of the Thompsons Core Participants in respect of Scots law, but in fatal claims under Scots law there is a head of general damages for the loss of society of a relative[618]. See the recent English case of *Haggerty-Garton v ICI*[619] in which Scots damages law was applied to a deceased mesothelioma claim in the High Court and loss of society damages totalling £230,000 were awarded to the widow and three children.

[617] See §9.111 – Bereavement Award and §9.112 – Bereaved Family Financial Loss Award
[618] s.4 Damages (Scotland) Act 2011
[619] [2021] EWHC 2924 (QB), Ritchie J.

868. In a nation-wide scheme intended to achieve fairness it would be wholly wrong for those who (fortuitously) live (or were infected) on one side or the other of the border to get more or less than someone living (or infected) on the other side.

869. Sir Robert intended that the level of awards under his proposed compensation framework should be such as to discourage individuals from instead pursuing civil claims for damages in the Courts. We wait to see what is said on behalf of the Thompsons Core Participants but, if there is a head of loss which is compensable in Scotland but not England, we anticipate that it will be said that awards under the Francis Framework should include such a head of loss. And, if so, we contend that for reasons of parity for all applicants in all four nations. In other words, to deter Court proceedings but maintain consistency across the four nations, a 'highest common denominator' approach should be adopted. We will develop this point in oral submissions as appropriate.

(c) No-one should be worse off

870. This is important. The ongoing annual payments should be set at such a level as to equal or exceed the maximum in any of the four nations. And there should be an undertaking to raise them annually in line with a suitable index, probably CPI.

(d) The level of the general damages-type awards

871. Sir Robert bases his figures for these awards on the Judicial College Guidelines for the Assessment of Damages in Personal Injury Cases which, as the Chair well knows provide guidance for Judges by categorising and updating reported judicial awards, so that judicial consistency of awards of damages can be achieved and recourse need not be had in every case to reams of previous individual reported decisions.

872. We see some merit in Sir Robert's approach of 'banding' the general-damages-type awards for injury impact and for social impact / stigma. In a sense, he is doing no more than providing 'brackets' akin to those in the JC Guidelines.

873. As lawyers we recognise the effect of cases such as *Sadler v Filipiac* [2011] EWCA Civ 1728 – that where an individual suffers multiple injuries of different types with overlapping consequences, the award of general damages is not simply the mathematical total of the sums which would have been awarded for each had they been suffered separately. In other words an award for injury A + injury B should be more than the award for either A or B alone but less than simply (A+B). Sir Robert applies that approach to the suffering of multiple diseases and suggests that one-half of the award for the 'less serious' disease be added to the full award for the 'more serious' disease (as he described

them). We do not agree. We refer to the lay and expert evidence the Inquiry has received about the *compounding effect* of co-infection (and the side-effects of treatment for co-infection) in individuals and we contend that the appropriate measure of damages for suffering A and B is in fact (A+B) or a sum only marginally discounted from (A+B).

874. The equivalents of common law general damages (the injury impact award and the social impact award ought to be uprated for inflation from the figures used in the Francis Report, as that is the legal principle which applies to general damages awards at common law.

a. It is apparent from p.151 (Appendix 5) of his report that Sir Robert derived his ranges of figures for the Impact award which appear in his grid at p.103 of his Report from the 15th edition of the JC Guidelines. That edition (the first under the editorial stewardship of Mrs Justice Lambert) was published in 2019 and contained figures based on RPI as it stood at June 2019.
b. At that date, RPI was 298.6
c. Today it is 356.2 (that is the figure for October 2022, released on 16.11.22).
d. That is a rise of **19.3%**.
e. The next RPI release by the ONS will be on 14.12.22. In oral submissions on 17.1.23 we will be able to take it into account, and also the release expected in mid-January 2023.
f. Increases in RPI must continue to be added to the award figures between the date of our submissions and the date of the Report, and then between the date of the report and the date of inception of any Compensation Scheme.
g. Because there will be such future changes, we do not provide a revised version of the full table at §9.35 (p.103) of the Francis report. We will be happy to do so at the date of our oral submissions. For now, we merely note that the lowest figure in that table (for the mild version of Disease A as Sir Robert described it) would rise from £50,000 to £59,560 and the largest (for severe co-infection) would rise from £315,000 to £375,795.
h. Each of the figures in the table for the impact of stigma and social isolation at §9.48 (p.107) should also be uprated by (currently) 19.3%.

875. Similarly, the awards uplift for loss of prospects of forming a partnership (put at £10,000 - £20,000 at §9.53), and for loss of the chance to have children (§§9.57-9.59) are based on the JC Guidelines and should also be uprated by 19.3% (as at today's date).

876. Further, we contend that the 10% uplift for *Simmonds v Castle*[620] – which, according to the footnote on p.151, Sir Robert specifically chose to omit – should be added to the figures in addition to the RPI uprating. Sir Robert's justification for not including the *Simmons* uplift is set out at p.151 but (i) legal representation will be required, so it should be added, and (ii) not adding it would lead to a marked disparity between the framework award and

[620] [2012] EWCA Civ 1288– introduced as part of the Jackson costs reforms

the level of common law damages, which would run contrary to Sir Robert's avowed intention that the levels of awards under a compensation framework should be set at such a level as to be comparable to common law damages[621] and therefore deter individuals from making civil claims.

(e) The form of the award

877. We welcome Sir Robert's suggestion at §9.74 that awards should be flexible – so that a living applicant could be offered their choice of a lump sum award or take (suitable) elements on a periodical payment (index-linked annual payment) basis. This reflects one of the most enlightened reforms of damages in civil claims[622], and is often used to provide long-term security for seriously-injured claimants. Although sparse on detail in his report, we infer that Sir Robert assumes that the applicant will be able to choose to ask for periodical payments for ongoing future financial loss and that such a request, if made, ought to be accommodated.

878. We note however that Sir Robert refers to periodical payments at §9.74 only in the context of future care but then refers at §9.105 to the possibility of taking "future losses" (without defining what such losses are but following his identification of some of them at §9.102) as either a lump sum (on a multiplier x multiplicand basis) or as periodical annual payments. However he had previously at §9.88 suggested that applicant should be entitled to an annual (and tax-free) £10,000 p.a. to broadly reflect those losses listed at §9.102.

879. We endorse applicants being given the choice of whether to take future care costs as a lump sum or periodical payments. And given the choice of whether to take the value of the additional "future losses" as a tax-free annual payment or to capitalise them as a lump sum with a multiplicand of £10,000 and a multiplier (at the prevailing Ogden rate) reflecting the individual's life expectancy.

880. We do note some lack of clarity in Sir Robert's report over whether future loss of earnings can be taken as a lump sum or periodical payment, and we deal with that below.

881. Periodical payments are a relatively specialist aspect of English damages law and we contend that this highlights the need for those who apply to be legally represented, the need for those who initially assess and adjudicate on the applications to either have substantial legal experience themselves or to be able to refer complex applications to leally trained assessors at the first instance, and for there to be a right of appeal to an independent panel composed of experienced practising specialist PI or clinical negligence lawyers.

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[621] §9.25

[622] s.2 Damages Act 1996 and CPR 41.4 *et seq*

(f) The experience and quality of the assessors

882. In light of the issues raised above and below, the successful operation of any compensation scheme will, require a considerable number of highly-skilled, legally trained, medically-informed, sympathetic assessors.

883. They must all have read and be aware of the Inquiry's report and recommendations and the history of the contaminated blood scandal.

884. There will have to be sufficient of them already in post and trained to deal swiftly and effectively with an influx of claims when the scheme is implemented.

885. Among them there will have to be legally-qualified assessors experienced in PI and clinical negligence cases available to identify and assist with points of law and practice, as many aspects of the proposed Francis Framework replicate the common law approach to an assessment of damages.

886. A right of appeal (to the High Court) will be necessary. It would be sensible and expedient simply to have one stage of appeal to the Court, rather than an intermediate level of appeal to a different tribunal which would risks wasting time and cost.

(g) Legal representation for applicants

887. As so many aspects of the Francis Framework replicate the common law assessment of damages, this will be essential if applicants are to know and properly understand what they might be entitled to and how to obtain and produce the right supporting evidence.

888. As the Chair has already observed, the involvement of experienced lawyers familiar with the work and in particular familiar with the contaminated blood scandal should lead to a saving of time and a streamlining of applications and evidence. In many cases, experienced lawyers should be able to present earnings arguments on the basis of factual evidence, comparators and published tables and data without having to obtain expert employment evidence.

(h) Simplicity

889. While we advocate a scheme running along the principles of a common law assessment of damages, we note and endorse some of the aspects in which it might be simplified, or assumptions might be made, as Sir Robert said in his oral evidence:

a. He would discourage any need for bespoke life expectancy evidence for each applicant (or each surviving bereaved dependant), instead preferring the simpler and more straightforward approach of using averages derived from life tables and multiplier tables in publications such as PNBA's "Facts & Figures".

b. He would discourage any bespoke evidence about the duration of working lives, again preferring the simplicity of using averages and the PNBA tables.

(i) Those who lost parents as children

890. We refer in earlier chapters to the obvious suffering of those who, as children, lost parents. The Inquiry has a supplementary report from the psychosocial experts on childhood bereavement.

891. Similar issues and considerations arise in respect of claims on behalf of those who themselves suffered injury when they were children.

892. The Chair has, as his questions to Keith Carter showed, an understanding of the particular difficulties and uncertainties involved in bringing clinical negligence and personal injury claims in relation to the losses suffered by children.

893. This, we suggest, highlights the need for legal representation so that the claims of these groups can properly and fully be advanced.

(j) The evidence of Keith Carter

894. Mr Carter gave evidence and suggested that in many cases the use of an expert employment consultant would be necessary in order properly to understand an individual's likely 'but for' career trajectory and probable earnings.

895. We concur that such evidence might well be necessary in some cases but suggest it should not be necessary in all, or the majority. Reflecting the approach towards expert employment evidence in the Courts, many cases can be advanced and properly considered on the basis of factual evidence about the individual, their school, family, siblings, abilities, expectations etc and calculations undertaken from that factual foundation, by experienced lawyers, with the benefit of earnings tables and statistics.

896. We suggest that there should be scope under a compensation scheme to adduce expert employment evidence in suitable cases, but that it will not be necessary is every case.

(k) Increased insurance and life assurance costs

897. The Inquiry heard from many factual witnesses describing their inability to get life assurance, travel insurance or other types of insurance, or to get them only at highly inflated premium rates. The statement from James Dalton of the ABI (WITN7327001) suggests that such products are available, or are available without greatly-increased costs, but gives scant detail.

898. In the circumstances, and in light of the factual evidence the Inquiry has received, we suggest that the Inquiry recommends a lump-sum uplift in the guaranteed annual payment of the order of magnitude suggested by Sir Robert in the second bullet point under §9.88.

(l) Ongoing payments / pension loss / past and future loss of earnings

899. At §9.90 Sir Robert recommended ongoing support should continue for the infected and those of the affected who already benefit from support schemes, should be consistent across the four nations, be guaranteed for life and raised to 5% above national median earnings, index-linked to ASHE 80th centile.

900. He made no recommendation about retrospective levelling-up of any historical inequalities in support payments, preferring instead to treat all past support payments as 'charitable receipts' not to be set off against his proposals for compensation, and to leave historical matters where they lay. Presumably this was a function of him being asked to devise a compensation framework to be used for the future.

901. The Francis report does not specifically consider pension loss. The Chair explored with Keith Carter some aspects of pension loss and heard evidence which should lead the Inquiry to conclude that there will be an element of pension loss for every infected and affected person who would (but for these events) have been in employment, or who would (but for these events) have been in better paid employment than they actually are. But the evidence of Mr Carter serves also to demonstrate that, while a loss is in principle established, it is going to vary immensely from person to person and be immensely difficult to quantify (having to be based, as it would be, on proof of a "but for" scenario), possibly requiring expert evidence which would be both expensive and time-consuming.

902. At common law, if a loss is established but it is difficult to quantify, the Court nonetheless does its best to quantify it, even on the basis of a rough-and-ready 'jury award'. On that approach, adopting a measure of (say) an additional 5% (so taking annual payments to 10% above national median earnings) might be considered as one way to take account of pension contributions which an employer might otherwise have made (the investment of which the applicant would have benefitted from had they been in work). Alternatively, the Chair might conclude that receipt of the guaranteed annual payments for

life (by definition therefore including the period when the individual would in the 'but for' scenario have been retired) reflects compensation for the loss of pension which would have been payable in that period in any event.

903. Conceptual difficulties arise, however, for any applicant who chooses to try to establish what Sir Robert has described as an 'Additional Claim for Future Loss of Earnings' (report, §9.94). Note that he suggests that only an infected person may claim a financial loss award, not an affected person[623]. The interaction between Sir Robert's guaranteed annual payments for life and the common law approach to future loss of earnings and pension loss will need to be thought through.

a. Sir Robert titles §9.94 *"Additional Loss of Earnings"* (our emphasis)[624]. It is not clear whether he is suggesting that all applicants *must* receive his proposed increased annual payments and may claim (to be capitalised and paid once-and-for all on a lump sum basis, or as an additional annual payment) only the excess or slice by which they can prove their future net earnings would have exceeded that annual figure. Or whether he considers that an individual who could prove that they would have had future earnings greater than that level could elect to have their full annual loss used as the multiplicand and take their full future loss of earnings solely as a lump sum (calculated on a multiplier x multiplicand basis) in their hands now, disentitling themselves from future receipt of the guaranteed annual payments.

b. We can see that some individuals might want to 'cut their ties', take their compensation on a once-and-for-all lump sum basis, and have nothing further to do with annual payments from the state (as we know some claimants prefer to do in PI and clinical negligence litigation, cutting their ties with the tortfeasor / insurer).

c. If Sir Robert anticipates (as he appears to do elsewhere in his report) that an applicant would be entitled to take their future care costs and their future other financial expenses on a lump sum (multiplier x multiplicand) basis if they want, then it seems illogical to preclude them from doing so in respect of future loss of earnings and instead to insist that they remain tied to the state (the presumed tortfeasor) for life for at least part of their future losses.

d. Respect for individual autonomy surely suggests that if an individual wants to capitalise and take as a lump sum their full future earnings loss (whether using

[623] We suggest that this is wrong. Take for example the case a bereaved spouse or a bereaved parent who is rendered unable to work by the deep psychiatric reaction to the death of their spouse or child. Subject to the necessary safeguards of proof of genuine psychiatric condition, medical and legal causation, and loss– why should they be excluded?

[624] He does not appear to consider pension loss, but it should be part and parcel of future loss of earnings

the guaranteed annual payment as the multiplicand or using such greater sum as they may be able to prove) then they should be entitled to do so.

e. If able to take *full* future loss of earnings as a lump sum, then within such a calculation, there may be variability of earnings between different years and there may be periods of years to which different multiplicands will apply. To provide consistency, and security for the applicant, there would have to be a provision that the annual figure of (net median earnings +5% or +10% if including lost pension contributions) would be a "floor" below which no annual multiplicand for any future year of loss should drop for the purposes of a lump sum calculation.

f. Following that approach through begs the question of what happens for that individual (who has chosen to take full loss of future earnings as a lump sum) after the date of assumed retirement, i.e. what about pension loss? Should they be able to use the guaranteed annual figure as the multiplicand for every future year of likely life after their assumed date of retirement, and claim it a s a lump sum? Or should the calculation of additional future loss payable as a lump sum simply stop at the individual's assumed retirement age, and (assuming they live to that age) they then become entitled to receive annual payments at the guaranteed minimum level? Should they be entitled to take (either as a lump sum or as an annual payment) the amount by which they may be able to prove their 'but for' pension would have exceeded the annual guaranteed sum? Again we suggest that arguments of autonomy ought to enable the individual to capitalise their post-retirement financial loss, receive it as an immediate lump sum, and 'cut their ties' on all aspects of compensation once and for all.

904. In calculating any future loss of earnings award on a lump sum basis, it is assumed that Sir Robert's proposed "discount for accelerated receipt" should be understood to mean the use of the Ogden multiplier as applicable from time to time (currently in fact a negative discount rate of -0.25%). We invite the Chair so to recommend.

905. We also raise issues for clarification in respect of past loss of earnings.

a. Sir Robert recommends (§9.94) that an *infected* person[625] be able to claim for past loss of earnings. He qualifies this by identifying it as *"past and future loss of earnings over and above the tariff sums described above"*

b. It is not clear how this will work, as the "tariff sum" is the current netted-down value of (median earnings +5%).

[625] We reiterate the point made above that, subject to s afeguards of proof, an *affected* person ought also be permitted to claim past loss of earnings

c. He is not, as we understand it, proposing that the 'tariff sum' be paid retrospectively to infected applicants.

d. It is not clear whether he is suggesting that sufficient data from ONS and its predecessors is available to produce a table identifying what median earnings were for every year back to the 1970s – in order to provide a threshold above which applicants must prove they would have earned in order to be entitled to anything. We do not know if it is.

e. At §9.95 he appears to suggest that infected applicants should be entitled to claim past earnings loss assumed (if no clearer case can be proved) to have been at *"national average earnings for that class of employment"* or at national median earnings.

f. We suspect that there is unintentional ambiguity at §9.94, and that what Sir Robert means is that:

    i. for the past, an individual can claim their loss of earnings, however small or large that loss may be, by reference to evidence or to statistics; and
    ii. for the future they can claim loss of earnings over and above the tariff sum.

g. We contend that interest should be paid on past financial losses on the same basis as in personal injury claims (see §9.127).

906. For both past and future earnings, the calculation of loss should use (as appropriate) male or female earnings statistics, as more accurately reflecting the individual's true loss.[626]

The issue of unconscionable delay, and a proposed solution

907. We have set out elsewhere in detail (in the chapter on government lack of candour) and will not repeat here the unconscionable delay and prevarication on the part of the Government in making public any response to the recommendations of the Francis Report. As at the date of writing these submissions, we have still not had such a response.[627] We make points elsewhere about how that inaction gives the impression of treating the infected and affected with contempt, prevents the Chair and the Inquiry team from engaging with and probing the response, and it therefore protects (and, we infer, was intended to protect) the Government from public scrutiny.

[626] As Keith Carter said in his oral evidence
[627] It is difficult, therefore, to know what the Interim Payments are 'interim' to.

908. Practically, however, that lack of response suggests that – contrary to Sir Robert's hope and expectation – a compensation scheme will not be "ready to roll" as soon as the Inquiry reports.

909. We therefore propose two, inter-linked solutions to this problem.

a. Early in his consideration of the evidence and the submissions from RLRs, the Chair should (after forming his views on those issues of conduct and responsibility necessarily underlying any conclusion that compensation should be paid[628], and after giving those he intends to criticise the appropriate opportunity under R.13 to respond) – ahead of publication of his final Report dealing with all other issues – publish a further Interim Report, setting out his full and final recommendations for a compensation framework or scheme. That would allow the government to respond, and preparations for the implementation of the scheme to begin in earnest. Time matters, and it would allow the wheels to be set in motion for compensation to be paid at the earliest opportunity to those who deserve it. It would also allow – if necessary – the Chair to reconvene oral hearings before the completion and publication of his final report if aspects of the Government's response to the final recommended compensation framework or scheme warrant scrutiny in the formal and public forum of a further Inquiry hearing.

and

b. A further interim recommendation should be made immediately for interim payments to be paid to the two groups excluded from interim payments so far excluded:

iii. parents who lost their child(ren);
iv. children who lost their parent(s).

The exclusion to date of those two of those groups from any support scheme is striking and unjustifiable. Their suffering is obvious and their urgent need is evident precisely because they have been excluded from any scheme so far and have received nothing towards their loss. Sir Robert Francis recognises this and recommends that children and parents should fall within his category of affected person, so they would, ultimately, be able to claim under his proposed scheme.

[628] The very fact of making an interim recommendation for interim payments (unopposed by those representing Government) connotes that the Chair concluded (and/or that the RLRs for the Government conceded) that there would be a sufficient finding of culpability to enable compensation to be paid.

910. In our July submissions on interim payments[629] we proposed a logical rationale within the Francis Framework for entitlement to interim payments of £100,000 to groups other than those already entitled, which was whether:

a. it can be demonstrated with some confidence that their ultimate entitlement under the Framework would exceed £100,000;
b. they can be said to have the same level of need as the living infected;
c. they can be identified as a group and paid with (relative) administrative ease. (Although on this point we do not accept that current registration with one of the current schemes, so as to facilitate payment, should be the determinant - if it is considered that a recipient *should* benefit, then a short administrative delay is still better than having to await the conclusion of the Inquiry, the setting up of the compensation scheme, and however long it takes to 'queue' in that scheme.)

911. We do not here repeat the rationale and detail set out at §§12-21 of our Submissions on Interim Payments, but respectfully refer the Chair back to them. As we set out there, interim payments to children who lost parents and to parents who lost children could be made through the Estates of those who have died.

912. In the alternative, a blunt and simple solution would be to allow those who lost children, and those who lost parents, to register as individuals under their current national support schemes simply for the purposes of using those schemes as the vehicle by which to deliver an interim payment to them as individuals, with a set-off later against any entitlement they may later establish directly as individuals or indirectly through Estates.

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[629] SUBS0000026