INFECTED BLOOD INQUIRY

CLOSING SUBMISSIONS

Saunders Law Core Participants

References

Witness – name/day

Transcript – [T/date/page/line(s)]

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Contents

Part 1: Introduction

1. These submissions are made on behalf of the four Saunders Law Core Participants ("Saunders CPs"): **Mr AK**, **Paul**, **Robert James** and **Mr AH**. The sentiments, values and beliefs that bind this group together are reflected in **Robert's** words in his witness statement:

> *"I believe the state has failed me and other haemophiliacs in this infected blood scandal. They have failed by first removing the dignity of the groups that became most affected by HIV and viral hepatitis; promoting and reinforcing a stigmatised view of those groups; failing to prevent this stigma from affecting the decision making of those in positions of knowledge and authority; failing to acknowledge and implement risk reduction strategies; and ultimately failing to stop a significant number of vulnerable and disabled people in its care from becoming infected with debilitating and frequently fatal infections. From the first appearance of AIDS, there were suggestions it was 'a judgment from God' and that people with the syndrome deserved to die from it. This perception came on top of state-legitimised stigma against gay people, drug users, sex workers and migrants. Immediately, it led to a separation between those with HIV that were infected through blood products and others with the condition. This implicitly divided all people with AIDS as either innocent and worthy of care [haemophiliacs] and others as guilty and worthy of blame [gay men, sex workers, IV drug users]. This division denied those deemed guilty of their human dignity and ultimately demeaned those deemed innocent. Those of us infected through blood or blood products were routinely exceptionalised and separated from the general service provision for people with HIV. I feel strongly that this haemophilia-exceptionalism affected the initial risk perception in the early stages of AIDS; the approach to the management of blood products; the provision of clinical care to those affected with AIDS, and the availability of community support services. From the onset, the HIV and AIDS epidemic was fundamentally characterised by stigma. The groups that were initially publicised as being "high risk" were gay*

men, injecting drug users and sex workers The perception of guilt and innocence led to a long-standing separation of people with haemophilia and HIV from the wider HIV sector. Many with haemophilia and HIV themselves advocated for this separation, for fear that they would be tainted by association with homosexuality and drug users. But in effect, this separation left many haemophiliacs in a silo - with poorer and less cutting-edge HIV services. I think this has also happened in a less pronounced way for those with hepatitis C. Those infected with HIV through blood products and the small number through blood transfusions were - and still are - painted as innocent victims by the media. The notion of innocence can be seen as a defence against the worst excesses of prejudice and an attempt to induce sympathy from those with homophobic views. But it is a privilege that is only available to a few and stands in opposition to the universality of human dignity. People infected with HIV through sex or sharing needles know that descriptions based on blame exclude them and instead, holds them personally responsible for HIV and AIDS".[1]

2. The Saunders CPs submit that the State's failures to protect the right to life, the right to be free from degrading and inhuman treatment, the right to health, dignity, and bodily autonomy, and the right to enjoy those rights free from discrimination, of people with haemophilia infected with HIV and/or HCV during the 1970s and 1980s fall within the scope of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), the U.N. Convention on the Rights of Persons with Disabilities ("CRPD") and the European Convention on Human Rights ("ECHR"). These Conventions were not incorporated at relevant times, but they provide a framework for understanding the Saunders CPs' claims that the State's acts and failures violated human rights norms.

[1] Robert James [WITN1004002] [2/3-3/6].

3. For the Saunders CPs, then, this Inquiry is concerned not merely with a tragic and catastrophic medical accident and cover up, but also with gross violations of the fundamental rights of those infected and affected.

4. Those violations can be seen in the State's failures to, among other things, (a) ensure proper systems for risk assessment, standard setting, and pharmacovigilance in the face of virological threats from HTLV-III (later HIV and AIDS) and Non-A, Non-B ("NANB") (later hepatitis C), that were known of, or ought to have been known of at an early stage, and (b) ensure a proper system for gathering and conveying information to patients (or their parents/carers), including information as to risk, and securing patients' (or their parents'/carers') informed consent to the administering of blood products. Rather, the State inappropriately and unsafely outsourced to individual actors such as clinicians and powerful pharmaceutical companies, the regulation and delivery of treatments which at a very early stage were known to carry the risk of serious harm and death: risks that ultimately materialised in the case of thousands of people with haemophilia.[2] These failures resulted in acts - for which the State is responsible - that violated the most highly protected of human rights through the administration of dangerous and life threatening treatments.

5. Additionally, the stigmatising of those with HV/AIDS during the 1980s, in particular, was by itself a violation of the right to dignity of those affected. It also played a role in impeding the provision of information, transparency, the acquisition of consent and access to treatment). Paradoxically, it was at times the most stigmatised of groups, the most marginalised in society (gay men and drug users), who were best informed, better able to manage their treatment, the best supported because they had to look after themselves.[3] Their involvement as

[2] These submissions refer to the impact on people with haemophilia because the Saunders CPs all contracted their infections as a result of the administering of Factor VIII but they wish to acknowledge those others infected and affected as a result of the administration of treatment for other conditions.
[3] Dr Winter makes these observations about the genesis of patient involvement, for example: "*the gay patients with HIV changed the nature of practice in the sense that they, in many ways, were a new generation of*

patients in their own care (*patient involvement*), played a huge part in their relatively good outcome after infection. Those people with haemophilia who accessed treatment outside the haemophilia centres, at Genitourinary Medicine ("GUM") Clinics [4] - largely shunned and stigmatised places for their association with gay men with AIDS – had better outcomes.

6. During the critical periods - the 1970's and 1980's - a diverse range of medical experts played a role in the treatment of people with haemophilia for whose decisions the State was ultimately legally responsible. These included academic virologists, transfusionists, treating haemophilia doctors and public health specialists. These years were a crucial time in treatment and care, with Factor VIII being hailed as a "*wonder drug*"[5], all but replacing the innovation of cryoprecipitate. The spectre of hepatitis– jaundice, serum hepatitis, hepatitis B (HBV) and later non-A, non-B hepatitis (NANB)–, however, was an ever-present possibility, with the risk ultimately recognised as an inevitable but for most involved, an acceptable, consequence of necessary treatment. The early news from the United States suggested strongly that there was a risk that HTLV-III (later HIV and AIDS[6]) might be communicated through blood products was, again, either ignored, played down, or regarded as a risk worth taking by clinicians and others with responsibility for ensuring the safe delivery of blood products and treatment. The proper and early acknowledgement of risk might have caused those with an interest in promoting the *"wonder drug"* to pause, assess and mitigate but instead suggestions of the same were met with the mantra of "*no conclusive proof*"[7] of risk and this approach permeated the management of risk across the United Kingdom. In particular, those to whom the State largely devolved its responsibilities

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patients who came along to doctors, quite rightly, and said, 'Hang on a minute. This is my life, my illness. I want all the facts and I want to do all the decisions', all of which is completely correct." [T/2.10.20/18/11-19/23].

[4] Sexual health clinics (genitourinary medicine (GUM) clinics).

[5] Presentation from Counsel to the Inquiry on the Oxford Haemophilia Centre [T/9.10.20/152/6]

[6] Later, human immunodeficiency virus and acquired immunodeficiency syndrome.

[7] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/8/4-6]

(including the UK Haemophilia Centre Doctors' Organisation[8] ("UKHCDO") which was granted *de facto* control over the regulation and delivery of treatments), were driven by arrogant and self-regarding hubris.

7. The State's responsibility in law, in so far as relevant to these submissions, is addressed in Part 2 but the fact of it was, in truth, acknowledged at a fairly early stage in this Inquiry when **Lord David Owen** gave evidence. **Lord Owen** accepted, as he was bound to do, that the Minister of State for Health in office at material time retained what was described in the Inquiry as "*political responsibility*" for decisions on clinical matters and safety.[9]

8. These issues will be explored fully below. However, it is important to note at the outset that it is a matter of considerable regret and disappointment to the Saunders CPs that the Inquiry has chosen not to more fully investigate the role of the pharmaceutical industry.[10] It is difficult to believe that the, no doubt, phenomenal profits that were to be made by the industry out of the promotion and sale of treatments that were known at an early stage to carry with them the risk of fatal infection, would not have affected their response to such dangers. The extent to which the money to be made from blood products may have motivated a lack of transparency and mitigating measures on the part of pharmaceutical industry will perhaps now never be known.

9. Finally, by way of introduction, the Saunders CPs emphasise that in these submissions they do not recite or refer to every piece of evidence that might relate to their key concerns. They highlight some selected extracts that shed light on the overall approach they take to the issues raised in this Inquiry.

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[8] A registered charity since 1991 (1032606) https://register-of-charities.charitycommission.gov.uk/charity-search/-/charity-details/1032606/charity-overview.
[9] Lord David Owen [T/22.9.20/155/7-12].
[10] There were few witnesses called and less by way of scrutiny than was seen with other actors.

10. The words NANB and hepatitis C, and HTLV III, AIDS and HIV, are used interchangeably. This reflects the changes in names given to these viruses over time.

Part 2: The Law

11. At the time of the events with which this Inquiry is concerned, the ECHR, the ICESCR and CRPD did not form part of domestic law. Further, the Human Rights Act 1998 ("HRA") does not have retrospective effect.[11] At all material times, these instruments bound the U.K. as a matter of international law since the U.K. has been a party to these Treaties since 1951,[12] and 1976,[13] and 2009,[14] respectively. Nevertheless, they are not binding in U.K. domestic law.[15]

12. However, this is a public Inquiry, not litigation, and it is not said that this Inquiry should suggest any legal liability arises under these instruments. Instead, it is said that they act as an appropriate framework for considering the extent to which the State has acted conformably with international human rights norms. These are norms that all liberal democracies are expected respect. It is through the prism of human rights that the Saunders Law CPs consider that the issues arising in this Inquiry should be viewed. It is on that basis that the rights in international law are drawn to the attention of the Inquiry and the Inquiry is invited to bear them closely in mind.

International Covenant on Economic, Social Rights and Cultural Rights (ICESCR)

13. It is submitted that the Inquiry can have regard to the ICESCR as a means of exploring the issues raised by this Inquiry. This is because the actions of the State that this Inquiry is exploring fall within the broad scope of the ICESCR.

14. Article 2, ICESCR provides that:

> *(1) Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation,*

[11] *In Re McKerr* [2004] 1 WLR 807.
[12] Signature 1950.
[13] Signature 1968.
[14] Signature 2007.
[15] *R(SC) v SSWP* [2022] AC 223, for a discussion on their status in domestic law.

especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

(2) The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

…..

15. Article 12, ICESCR obliges States parties to:

(1) *recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*

(2) *The steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:*

……

(c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

16. The Committee on Economic, Social and Cultural Rights (the Covenant's monitoring body) recognises that:

"Health is a fundamental human right, indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health, conducive to living a life in dignity".[16]

[16] Paragraph 1.

17. Article 12 does not confer a right to be healthy.[17] Article 12 instead imposes an obligation on States to "*take steps, ...to the maximum of [their] available resources, with a view to achieving progressively the full realisation of the rights…*"[18], including the right to health. State responsibility is therefore adjudged having regard to the limits of its resources. The specific steps required have been considered by the Committee on Economic, Social and Cultural Rights and it has identified three aspects to States' obligations under the ICESCR: *to respect; to protect; and to fulfil*:

    a. *Respect* involves refraining from interference in the enjoyment of the right of the covenant.
    b. *Protect* requires governments to work at preventing third parties from interfering with enjoyment of the right.
    c. *Fulfil* requires them to proactively facilitate, provide for and promote the enjoyment of the right through appropriate legislative, administrative, financial, judicial, promotional and other measures in order to achieve full realisation of the right to health[19].

    In addition, the Committee identified the essential elements of the right to health: (i) availability; (ii) accessibility (including economic accessibility); (iii) acceptability; and (iv) quality.[20]

18. The ICESCR (as with other international and regional human rights instruments) imposes positive obligations on State parties to secure compliance with the duties under it, as is apparent from the above.

19. The right to health also envisages protection from discrimination as is provided for by Article 2(2) of the ICESCR. Therefore, the "*right to health*" may be described

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[17] General Comment 14: *The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)* Committee on Economic, Social and Cultural Rights, Twenty-Second Session, adopted 11 August 2000, paragraph 8.
[18] Article 2 (1), ICESCR.
[19] General Comment 14, para 33.
[20] General Comment 14, para.12.

as an integrated corpus of so called first and second-generation rights, in the promotion of wellness.[21]

20. General Comment 14 (2000)[22] promulgated by the Committee on Economic, Social and Cultural Rights confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in ICESCR (mentioning HIV/AIDS in terms[23]). These include, *inter alia*:

    a. To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; …
    b. To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs; and…
    c. To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.

21. Article 12(2)(c) and (d) are most relevant to the issue of HIV/AIDS and the circumstances of the U.K. from the 1970s onwards. Two areas of domestic UK law during the 1970's and 1980's conceivably were tools capable of protecting the right to health, as expressed in art 12 (2) (c) and (d) of the ICESCR: (i) the duty of care

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[21] So-called "first generation rights" are civil and political in nature, which are individualistic and involve restraints of the State over the individual. So-called "second generation rights" are economic, social and cultural in nature and are related to equality. The component parts for realising the right to health, arguably include freedom from discrimination, which is itself, a first generation right.
[22] E/C.12/2000/4.
[23] Paragraph 12.

in negligence at common law; and (ii) the public law notion of *Wednesbury* reasonableness. However, these do not contemplate the rights embraced by the ICESCR with the broad obligation to protect the right to health of people with haemophilia under Article 12 (2) (c) and (d) and would not, therefore, adequately secure the rights protected under the ICESCR.

22. It is submitted that examining the acts and failures of the State during the years that are being investigated by this Inquiry through the lens of the ICESCR, will require consideration of the failure to meet the *"pledge"* to ensure self-sufficiency in blood and blood products. This was first and foremost an issue of risk mitigation, that was critical for maintaining public health and protecting the right to health of haemophiliacs. Though self-sufficiency has sometimes been cast as a mere political aspiration involving the allocation of resources from Government, the ICESCR would regard it as a substantive obligation given the requirements of Article 2.

23. In relation to HIV and HCV, core obligations would also include: facilitating or providing early reliable public health information, in particular to people with haemophilia receiving blood products, about the risks associated with Factor VIII, including the risk of NANB in the 1970s and AIDS in the 1980s, and the enhanced risks associated with commercial, U.S. products. The central role for the State in this regard was two-fold: (i) providing an authoritative and centralised channel for disseminating such public health information to people with haemophilia about virological risks; and (ii) putting steps in place to mitigate imminent virological risks, ranging from self-sufficiency to the selection of alternative treatment (including cryoprecipitate) for people with haemophilia.

24. Instead, as is explored below, the Government in essence abandoned its role, delegating responsibility to individual clinicians and the UKHCDO. The UKHCDO essentially became a proxy for the CMO. Dominant figures in the UKHCDO played an outsized role in thought leadership around imminent virological threats. In relation to the second, efforts at self-sufficiency almost

ground to a halt; and effectively, no steps were taken to pursue alternatives to the increasing use of commercial factor concentrates. There was no rigorous comparative analysis between continued use of commercial factor VIII and its alternatives that were capable of mitigating risks (e.g. cryoprecipitate).

25. Further, the ICESCR provides for the right to non-discrimination. Non-discrimination was not afforded to people with haemophilia. They constituted a particularly vulnerable group at special risk of infection, and so were disproportionately disadvantaged by the State's failures in relation to the transmission of HCV and HIV through blood and blood products.

Convention on the Rights of Persons with Disabilities

26. The CRPD is obviously highly relevant. Key provisions include the following:

> Article 1
> The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.
> Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.
> Article 2
>
> "….Discrimination on the basis of disability" means any distinction, exclusion or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the

political, economic, social, cultural, civil or any other field. It includes all forms of discrimination, including denial of reasonable accommodation;

"…Reasonable accommodation" means necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms.

Article 3

The principles of the present Convention shall be:

(a) Respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons;

(b) Non-discrimination;

(c) Full and effective participation and inclusion in society;

(d) Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity;

(e) Equality of opportunity;

(f) Accessibility…

Article 4

1. States Parties undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. To this end, States Parties undertake:

(a) To adopt all appropriate legislative, administrative and other measures for the implementation of the rights recognized in the present Convention;

(b) To take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices that constitute discrimination against persons with disabilities;

(c) To take into account the protection and promotion of the human rights of persons with disabilities in all policies and programmes;

(d) To refrain from engaging in any act or practice that is inconsistent with the present Convention and to ensure that public authorities and institutions act in conformity with the present Convention;

(e) To take all appropriate measures to eliminate discrimination on the basis of disability by any person, organization or private enterprise;

(f)…

(i) To promote the training of professionals and staff working with persons with disabilities in the rights recognized in the present Convention so as to better provide the assistance and services guaranteed by those rights.

Article 5

1. States Parties recognize that all persons are equal before and under the law and are entitled without any discrimination to the equal protection and equal benefit of the law.

2. States Parties shall prohibit all discrimination on the basis of disability and guarantee to persons with disabilities equal and effective legal protection against discrimination on all grounds.

3. In order to promote equality and eliminate discrimination, States Parties shall take all appropriate steps to ensure that reasonable accommodation is provided.

4. Specific measures which are necessary to accelerate or achieve de facto equality of persons with disabilities shall not be considered discrimination under the terms of the present Convention.

Article 8(1)

States Parties undertake to adopt immediate, effective and appropriate measures:
(a) To raise awareness throughout society, including at the family level, regarding persons with disabilities, and to foster respect for the rights and dignity of persons with disabilities;
(b) To combat stereotypes, prejudices and harmful practices relating to persons with disabilities, including those based on sex and age, in all areas of life;

Article 15
1. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation
2. States Parties shall take all effective legislative, administrative, judicial or other measures to prevent persons with disabilities, on an equal basis with others, from being subjected to torture or cruel, inhuman or degrading treatment or punishment.
Article 25

States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for

persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall:

(a) Provide persons with disabilities with the same range, quality and standard of free or affordable health care and programmes as provided to other persons, including in the area of sexual and reproductive health and population-based public health programmes;

(b) Provide those health services needed by persons with disabilities specifically because of their disabilities, including early identification and intervention as appropriate, and services designed to minimize and prevent further disabilities, including among children and older persons;

….

(d) Require health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent by, inter alia, raising awareness of the human rights, dignity, autonomy and needs of persons with disabilities through training and the promulgation of ethical standards for public and private health care;

(e) Prohibit discrimination against persons with disabilities in the provision of health insurance, and life insurance where such insurance is permitted by national law, which shall be provided in a fair and reasonable manner;

27. As can be seen, the focus of the Convention is dignity, equality and autonomy, values that the Saunders CPs consider must inform the approach of this Inquiry. Those are interests that were seriously impaired by the treatment afforded people with haemophilia by reason of the State's failures.

The European Convention on Human Rights (ECHR)

28. Article 2, ECHR guarantees the right to life. It provides that:

> *Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.*

29. Article 2(1) imposes two particular obligations. The first is a negative obligation prohibiting a State from depriving life; and the second is a positive duty to ensure that right to life is protected. Beyond these defined obligations, the ECtHR and the domestic courts have stated that there are further obligations implied within Article 2(1). The first is a substantive duty to take the necessary measures where there is deemed to be a *risk to life*. The second is a procedural duty to undertake a prompt and effective investigation into allegations that an individual's Article 2 rights have been infringed. [24]

30. In respect of the positive protective obligation under Article 2, it is triggered where,

> *It [is] established to the [court's] satisfaction that the authorities knew or ought to have known at the time of the existence of a real and immediate risk to the life of an identified individual or individuals…..and that they failed to take measures within the scope of their powers which, judged reasonably, might have been expected to avoid that risk.*[25]:

31. The duty applies whether the source of the risk to life is a public or private person or body.[26] This means that if the State knew or ought to have known of the risk to

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[24] See discussion in *R v Her Majesty's Coroner for the Western District of Somerset and Middleton* [2004] 2 AC 182; *R (Gentle) v Prime Minister* [2008] 1 AC 1356.
[25] *Osman v UK* (1998) 29 EHRR 245, para 116.
[26] *Oneryildiz v Turkey* (2005) 41 EHRR 20.

life posed by Factor VIII, then it was bound act upon that knowledge within the parameters identified in *Osman*.

32. Secondly, the duty to undertake a prompt and effective investigation into allegations that an individual's Article 2 rights have been infringed, [27] requires that an investigation,

> *"ensure as far as possible that the full facts are brought to light; that culpable and discreditable conduct is exposed and brought to public notice; that suspicion of deliberate wrongdoing (if unjustified) is allayed; that dangerous practices and procedures are rectified; and that those who have lost their relative may at least have the satisfaction of knowing that lessons learned from his death may save the lives of others."*[28]

33. Article 3, ECHR provides that: *"No one shall be subjected to torture or to inhuman or degrading treatment or punishment."* Similar positive and implied obligations arise under Article 3 as those under Article 2.[29]

34. Article 8, ECHR protects the right to respect for private life. It also imposes positive obligations in some circumstances.

35. In the context of health, the values and interests protected by Articles 3 and 8 are engaged. They are both important for matters that arise in this Inquiry because they embrace notions of autonomy, bodily integrity and dignity. It is submitted that they provide a good framework, and sometimes a better framework than an *"ethics"* framework, for securing respect for human rights.[30]

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[27] See discussion in *R v Her Majesty's Coroner for the Western District of Somerset and Middleton* [2004] 2 AC 182; *R (Gentle) v Prime Minister* [2008] 1 AC 1356.
[28] *R (Amin) v Secretary of State for the Home Department* [2003] UKHL 51 [2004] 1 AC 632 at [31].
[29] *DSD v Commissioner of Police of the Metropolis* ([2018] 2 WLR 895.
[30] See the discussion in A. Constantin, *"Human Subject Research: International and Regional Standards"* (2018), Health and Human Rights. Vol. 20(2),137-148.

36. Article 14 provides that:

> *"The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."*

37. Article 14 applies where the facts fall within the ambit of a Convention right (its application does not presuppose a breach of a *"substantive"* right)[31]. The concept of discrimination under the ECHR is wide. It covers direct and indirect discrimination and forms of institutional discrimination.[32] It also imposes positive obligations in some circumstances, including to ensure *"special vigilance"* and *"vigorous reaction"* in the case of invidious forms of discrimination.

38. As to protected *"status,"* this will include health conditions and disabilities.[33]

39. These frameworks and rights reflect human rights norms that are highly relevant to the events that are the subject of this Inquiry.

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[31] *Abdulaziz, Cabales and Balkandali v United Kingdom* (1985) 7 EHRR 471, para 71; *Wandsworth v Michalak* [2002] EWCA Civ 271; [2003] 1 WLR 616, para 20, *per* Brooke LJ.
[32] *Thlimmenos v Greece* (2000) 31 EHRR 411; *DH v Czech Republic* (2008) 47 EHRR 3.
[33] *Botta v Italy* (1998) 26 EHRR 241.

Part 3(i): Knowledge of Risks and Response

Introduction

40. The evidence received in this Inquiry demonstrates, and the Inquiry should find, that at all material times, and in particular by the time the Saunders CPs most likely contracted Non-A, Non-B hepatitis ("NANB") ("HCV") and/or HTLV-III (HIV and AIDS[34]), firstly, the *risk* of their transmission (and indeed of other unknown viruses[35]) through blood and blood products was, or ought to have been, known. Secondly, the relationship between large pool and commercial factor products from the U.S. (paid donors), and the increased risk of transmission of viruses was also known, or ought to have been known. Thirdly, the response to those risks was wholly inadequate.

41. The period covered by these submissions in the case of HCV is the 1970s through to the 1980s (leading up to the official naming of HCV in 1989[36]), and in the case of HTLV-III (HIV and AIDS[37]), the period beginning 1980. While there are similarities between the issues that arise in the case of HCV and HIV/AIDS, there is a difference between the two that should be borne in mind. In both cases steps could have been taken to reduce risk. However, in the case of HIV, the risk of transmission of HIV through blood and blood products in the U.K. could probably have been close to eliminated[38] if the use of commercial blood products from the U.S. was stopped immediately upon U.K. doctors becoming aware that there was a risk, however small, that those blood products could transmit a potentially deadly contaminant.[39] The position for HCV was different because by the time

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[34] Later, human immunodeficiency virus and acquired immunodeficiency syndrome.
[35] Robert James [WITN1004001] [4/ 10].
[36] 'Story of Discovery: Hepatitis C: from non A, non B hepatitis to a cure', National Institute of Diabetes and Digestive and Kidney Diseases, 9 June 2016, see: https://www.niddk.nih.gov/news/archive/2016/story-discovery-hepatitis-c-from-non-a-non-b-hepatitis-cure
[37] Later, human immunodeficiency virus and acquired immunodeficiency syndrome.
[38] Or kept to tiny numbers.
[39] Robert James [WITN1004001] [17/ 36]

the presence of a NANB hepatitis virus became suspected, it had made its way more widely into the U.K. blood stream and testing was not 100% accurate. Nevertheless, as explored below, the incidence of transmission of HCV could have been significantly reduced if adequate measures had been introduced on discovery of risk and risk factors.[40]

42. A selection of the evidence relating to the state of knowledge and the response of some key actors is addressed below. But, in summary, the evidence demonstrates conclusively that the risk of known viruses (HAV and HBV) being communicated through blood and blood products was widely known by U.K. clinicians at the latest by the mid-1960s ("post-transfusion hepatitis"). By the 1970s, it was recognised that unknown viruses could be transmitted by infected blood and blood products, and the risk of transmission increased with larger donor pools and, additionally, where blood was sourced from paid donors. [41] By 1981, reports were being made of AIDS in patients with haemophilia and no other risk factors.[42] By July 1982, at the latest, it was known by the Department of Health and Social Security ("DHSS") and the Chief Medical Officer ("CMO") that there were safety concerns around American Factor VIII (deriving in significant part from paid donors) because of the risk of contamination by an undetectable virus (AIDS). [43] By later in 1982, it had become known to very senior haemophilia clinicians,[44] and by the beginning of 1983, at the latest, it was known by U.K. haemophilia clinicians generally that people with haemophilia were at risk of AIDS through use of Factor VIII.[45]

[40] Robert James [WITN1004001] [10 - 15/ 22 – 33].
[41] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/37 – 75].
[42] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/81 – 84].
[43] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/85 – 90].
[44] Presentation from Counsel to the Inquiry on knowledge of risk / Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/142/2 – 6].
[45] Presentation from Counsel to the Inquiry on knowledge of risk /Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/23.9.20/101 – 122], [T/24.9.20/1 – 148] and [T/30.9.20/1 – 111].

43. That knowledge fell within the scope of ICESCR, Articles 2, 3, 8 and 14, ECHR[46] and the CRPD requiring appropriate action to secure the health of people with haemophilia, safeguard lives and protect against the risk of degrading and inhuman treatment, loss of bodily autonomy and dignity, and against the risk of discrimination.

44. However, the response to that knowledge was almost universally inadequate at best, and otherwise characterised by hubris, indifference, an absence of empathy, deliberate obfuscation, and in some cases duplicitousness.

45. Philosophers have described this condition: *"I knew, but I didn't believe it, and because I didn't believe it, I didn't know"* (Raymond Aron).[47] As Franz Fanon put it:

> *"Sometimes people hold a core belief that is very strong. When they are presented with evidence that works against that belief, the new evidence cannot be accepted. It would create a feeling that is extremely uncomfortable, called cognitive dissonance. And because it is so important to protect the core belief, they will rationalize, ignore and even deny anything that doesn't fit in with the core belief."*[48]

46. Or put more prosaically by one doctor:

> *"They held the line to the point where it almost became like denial, a denial problem, into 1983. I think to continue to propose that there was no conclusive evidence that AIDS was caused by an infectious agent was simply, in retrospect of course, untenable…[T]hey saw all the*

[46] Council of Europe, Committee of Ministers, '*Recommendation on the Committee of Ministers to Member States, on preventing the possible transmission of acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products*', No. R (83) 8, 23 June 1983, see: https://rm.coe.int/native/09000016804f2fdc

[47] Quoted in film by Claude Lanzmann, '*The Jan Karski Report*', at 21:35, see: https://youtu.be/JQ7Y1dc6sbQ?t=1297 .

[48] Frantz Fanon, 'Black Skin, White Masks' (2008) Grove Press, U.S.

downsides of not having prompt and convenient treatment, and they'd just been given, if you like, within the last ten years, this supply of treatment of concentrate that could -- they knew had the capacity to eradicate those problems of haemophilia. So their attitude was conditioned by their experience of the disease."[49]

47. The fact that this situation was allowed to develop was because, as the Inquiry as heard, leading haemophilia doctors dominated the national response to the risk posed to people with haemophilia from factor concentrates, and therefore NANB and AIDS. There was much reliance on the principle of clinical freedom, which meant that individual haemophilia doctors within UKHCDO were left to their own devices in discerning risk to patients and responding to them. The UKHCDO, as the forum for haemophilia doctors that also included many Reference Centre Directors, was in essence a *de facto* policy and operational unit for the virological response in relation to people with haemophilia.

48. For many of the key clinicians the *"wonder drug"* in which they had expressed so much enthusiasm, and which they regarded themselves as having delivered to grateful patients, was worth the risks they were not fully willing to countenance. This was especially when it would require them to confront the fact that their patients shared in common a condition that appeared to primarily impact on highly stigmatised groups, namely homosexual men and drug-users. Regrettably, many of them continued to deny risk, relative risk or knowledge of risk for some time, and in some cases in evidence to this Inquiry. Some examples are given below.

49. The result was that, whereas the precautionary principle would have demanded the immediate withdrawal of Factor VIII, or at a minimum, U.S. commercial products even if that meant a resort to cryoprecipitate for some, there was barely

[49] Dr Bevan [T/12.1.21/98/13-18 and 99/21-25 and 100/1-2].

a response until the discovery of widespread infection of people with haemophilia with HCV and HIV.

50. The account below is not intended to be a comprehensive review of the evidence but picks out some illustrative matters.

What Was Known, by Whom and What was Done?

(a) Clinicians

NANB (Hepatitis C)

51. By 1965[50], hepatitis B ("HBV") ("post-transfusion hepatitis") had been identified, and the risk of its transmission through blood and blood products had been recognised. [51] At that stage, and until the early 1990s, diagnosis of the presence of the virus in blood donations relied on proxy markers (e.g.HBsAG).[52] Nevertheless, the tests allowed for significant risk reduction.[53] Thus, research conducted in the U.S. and published in 1972 indicated that if only blood shown HBsAG *"negative"* had been used it would have reduced the rate of *"post-transfusion hepatitis by 25%"*[54] (that is, allowing for the fact that not all blood tested would reveal the

[50] Though as early as 1950, the World Health Organisation ("WHO") had noted the "conveyance of hepatitis serum by blood and blood transfusions and… human blood derivatives," (Robert James [WITN1004001] [4/11]; and Fourth Report of the Committee on Programme, adopted at 7th plenary meeting, 25 May 1950, see: https://apps.who.int/iris/bitstream/handle/10665/100102/WHA3_108_eng.pdf?sequence=1&isAllowed=y)

[51] Robert James [WITN1004001] [4/11]; and Blumberg BS, Alter HJ, Visnich S, 'A "new" antigen in leukaemia sera', Journal American Medical Association (JAMA), 1965, 191, 541 – 546, see: https://jamanetwork.com/journals/jama/article-abstract/654843.

[52] Robert James [WITN1004001] [4/11 and 5/12]; Nishikawa H, Osaki Y, 'Clinical Significance of Occult Hepatitis B Infection in Progression of Liver Disease and Carcinogenesis', *J Cancer* 2013; 4(6):473-480. doi:10.7150/jca.6609, see: https://www.jcancer.org/v04p0473.htm .

[53] Robert James [WITN1004001] [4/11 and 5/12]; Nishikawa H, Osaki Y, 'Clinical Significance of Occult Hepatitis B Infection in Progression of Liver Disease and Carcinogenesis', *J Cancer* 2013; 4(6):473-480. doi:10.7150/jca.6609, see: https://www.jcancer.org/v04p0473.htm .

[54] Robert James [WITN1004001] [6/14]; and H J Alter, P V Holland, R H Purcell, J J Lander, S M Feinstone, A G Morrow, P J Schmidt, 'Posttransfusion hepatitis after exclusion of commercial and hepatitis-B antigen-positive donors, Ann. Intern Med, November 1972, 77(5)/ 691-699, see: https://pubmed.ncbi.nlm.nih.gov/4628213/

presence of HBV[55]). This same study looked too at the impact of using blood from paid donors compared to voluntary donors and found that excluding commercial (paid) donors would have reduced the risk of hepatitis by 70%.[56].[57] These are matters that U.K. clinicians and those with responsibility for securing the safe supply of blood and products knew or ought to have known.

52. By the time factor concentrates came to be used in the U.K in 1976[58] the risk of transmission of HBV through blood was, therefore, known,[59] and indeed there were outbreaks of HBV among those to whom factor concentrates were administered. Testing for HBV antigens (HBsAG) was in use by the English Blood Transfusion Service by 1977 and in use by the Scotland Blood transfusion Service before 1978,[60] and, as referred to above, this was important for reducing risk significantly, but because of the limits of the antigen tests, it could not have eliminated risk entirely.[61] Other mitigating strategies were also available, however; most particularly not using products deriving from paid donors.

53. By the 1970s too, evidence began to emerge indicating the existence of another hepatitis causing agent that was assumed to be a virus[62] (NANB). The incidence of

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[55] Using the viral, surface, antigen test then only available.
[56] Robert James [WITN1004001] [6/14]; and H J Alter, P V Holland, R H Purcell, J J Lander, S M Feinstone, A G Morrow, P J Schmidt, 'Posttransfusion hepatitis after exclusion of commercial and hepatitis-B antigen-positive donors, Ann. Intern Med, November 1972, 77(5)/ 691-699, see: https://pubmed.ncbi.nlm.nih.gov/4628213/.
[57] Robert James [WITN1004001] [6/14]; and H J Alter, P V Holland, R H Purcell, J J Lander, S M Feinstone, A G Morrow, P J Schmidt, 'Posttransfusion hepatitis after exclusion of commercial and hepatitis-B antigen-positive donors, Ann. Intern Med, November 1972, 77(5)/ 691-699, see: https://pubmed.ncbi.nlm.nih.gov/4628213/.
[58] Christopher Bishop [T/4.11.2021/2/15-20].
[59] Robert James [WITN1004001] [7/16]; Craske J, Dilling N, Stern D, 'An outbreak of hepatitis associated with intravenous injection of Factor-VIII concentrate', 2 August 1975, The Lancet, Volume 306, Issue 7927, 221-223; and Haemophilia and HIV Life History Project, C1086/22/01-04 and C1086/12/01-06.
[60] Robert James [WITN1004001] [6/15]; Levine PH, McVerry BA, Attock B, Dormandy KM, 'Health of the Intensely Treated Haemophiliac, with Special Reference to Abnormal Liver Chemistries and Splenomegaly, July 1977, Volume 50, Issue 1, 1-9, see: https://www.sciencedirect.com/science/article/pii/S0006497120666204 ; and Burrell CJ, Black SH, Ramsay DM, 'Antibody to hepatitis B surface antigen in haemophiliacs on long-term therapy with Scottish Factor VIII, Journal of Clinical Pathology, April 1978, Volume 31, Issue 4, 309-312.
[61] Robert James [WITN1004001] [6/15]
[62] Robert James [WITN1004001] [7/16]

NANB infection and its relationship to blood transfusion was observed as early as 1974 following a study covering the period 1969-72.[63] With the development of tests for hepatitis A ("HAV") and HBV in the 1970s,[64] it became (or should have been) clear, that NANB and ultimately other unknown hepatitis-like viruses, could be transmitted by blood.[65] [66] It soon became clear too, that as with HBV, the size of the plasma pool (with multi-donor concentrates *"inevitably infected with NANB]"*[67]) [68] was significant for determining the extent of the risk.[69] Further, It was also known by the late 1970s, at the latest, that, as **Dr Jones** (Newcastle Haemophilia Centre) described it, *"the risk of hepatitis had been linked particularly to commercial concentrates prepared from the blood of paid donors, and they know that these risks still exist despite the increased sensitivity of donor tests for hepatitis B."*[70] This meant that though cryoprecipitate was known to transmit hepatitis, it appeared to do so at a lower rate when U.S. factor products were not used.[71]

54. It was also clear by then that NANB could cause serious liver disease.[72] As **Professor Tuddenham** (Royal Free Hospital haemophilia centre[73], member of

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[63]Prince MA et al, 'Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis B Virus', 3 August 1974, The Lancet, 241-246. See: https://www.infectedbloodinquiry.org.uk/sites/default/files/WinterPN/WinterPN/PRSE0001431%20-%20The%20Lancet%20%27Long-incubation%20post-transfusion%20hepatitis%20without%20serological%20evidence%20of%20exposure%20to%20hepatitis-B%20virus%27%20by%20Prince%20et%20al%20-%203%20August%201974.pdf ; A history of the development of knowledge post-war can be found in Robert James [WITN1004001] [4-9/10-20]; and see to the Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20].

[64] Albeit with their limitations, described above.

[65] [DHSC0200111].

[66] [RLIT0000228]; Robert James [WITN1004001] [7/16]; See also Prince et al, *Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis B Virus* (3 August 1974), The Lancet, 241-246; Purcell et al, *Non-A, non-B hepatitis* (1976) Yale Journal of Biology and Medicine, 243-250; International Forum (1977) Vox *Sang*, 32:246-363;

[67] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/71/9]

[68] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/71/6-11].

[69] [RLIT0000228]; Robert James [WITN1004001] [7/16] ; See also Prince et al, *Long-Incubation Post-Transfusion Hepatitis without Serological Evidence of Exposure to Hepatitis B Virus* (3 August 1974), The Lancet, 241-246; Purcell et al, *Non-A, non-B hepatitis* (1976) Yale Journal of Biology and Medicine, 243-250; International Forum (1977) Vox *Sang*, 32:246-363.

[70] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/59/13-17].

[71] [DHSC0200111].

[72] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/68-73]

[73] From 1978 with Dr Kernoff as co director (Professor Edward Tuddenham, [T/22.10.20/2/18-20]) and then with Dr Lee too 1983 director (Professor Edward Tuddenham, [T/22.10.20/13/12-13])

UKHCDO, Reference Centre Director, Medical Advisory Panel of the Haemophelia Society[74]) acknowledged in evidence, by 1978 both he and **Professor Kernoff** (Royal Free Hospital and Chairman of the Haemophilia Working Party of the NETRc Association of Haematologists[75]) were aware that NANB was a clinically significant condition with potentially serious long-term consequences.[76] However, the extent of the harm was often underplayed to maintain confidence in concentrate. Thus, in 1974, **Dr Jones** (Newcastle Haemophilia Centre) for example wrote that *"[h]aemophiliacs seem to have a high resistance probably developed as a result of repeated blood transfusions. Although many have the antibody, few have had severe jaundice due to serum hepatitis"*,[77] without mentioning NANB[78] at all. [79] [80][81][82] Shortly afterwards, [83]**Dr Jones** wrote to colleagues *"confidential[ly]"* that the link between commercial concentrate and hepatitis had been proved and that it carried the risk of jaundice. However, he concluded "*it was generally agreed that the advantages and indeed the necessity of concentrate outweighed the risk of hepatitis*".[84] At around the time, he was writing to colleagues describing the risk of hepatitis contamination as *"very worrying"*[85].

55. By the end of the 1970s, **Dr Jones** and apparently his colleagues "*were in no doubt that haemophiliacs exposed to multi-donor concentrates were inevitably infected with non-A non-B hepatitis and that a substantial proportion of them could go on to develop chronic*

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[74] Professor Edward Tuddenham, [T/22.10.20/6/15]. He also worked under Professor Bloom from 1972 to 1975 Professor Edward Tuddenham, [T/22.10.20/7/16-19]
[75] Professor Edward Tuddenham, [T/22.10.20/103/19]
[76] Professor Edward Tuddenham, [T/22.10.20/59/2-15]
[77]Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/32/16-19]
[78] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/33/9-15].
[79] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/30/20-24]
[80] However, there was often a dissonance between what he said to patients and what he said to colleagues. For example, in the first edition of his book - *"Living with Haemophilia"* – published in 1974, which would have been and was read by patients. (Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/30 – 34])
[81] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/33/9-15].
[82] At around the time, he was writing to colleagues describing the risk of hepatitis contamination as *"very worrying"* Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/36/21-23]
[83] In 1975. Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/40/7].
[84]Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/42/6-9].
[85] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/36/21-23].

liver disease."[86] **Dr Mayne's** account that *"the risk that non-A, non-B hepatitis could progress to chronic hepatitis was known in 1977 but the full significance of its effects was not appreciated, elaborated and investigated until the mid to late 1980s"*[87] is unconvincing and ought not to be accepted.[88] **Dr Mayne** also stated that she *"had observed these abnormal liver function tests for so long without there being any apparent clinical ill-effects that [she think she] could have been lulled into false sense of security"*[89] and that in 1976 *"treatment was considered to be both effective and safe"*.[90] She went on to suggest that patients had not been put off using concentrates[91] since *"freedom from pain was of paramount importance to them."*[92] As with **Dr Jones**, in actuality she regarded the risk worth taking. The implicit suggestion that she was somehow reassured by patients' wish to have concentrates is disingenuous. As the evidence overwhelmingly demonstrates, patients were largely not informed of the risk (see, Part 3(ii) below) and her account about this was incredible.[93]

56. The reluctance to acknowledge what was apparent is also evidenced by the account of **Dr Winter** (Kent Haemophilia Centre). **Dr Winter** accepted that though in the 1970s, HBV was known to be a serious condition with potential long-term consequences, there was an unwillingness to accept that NANB would be a serious problem because of the benefits of factor concentrates.[94] Thus, he said:

> *"Patients kept saying to us 'I've never felt as well as this, I never want to change, this is the treatment I've always wanted'. So I think there*

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[86] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/71/6-11].
[87] [WITN0736011]; Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.03.21/174/ 21-25 and 175/1-3].
[88] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/30.3.21/170/-5-6]. In her HIV litigation report, Dr Mayne stated that *"the patients themselves became aware of the risks of hepatitis during the mid-1970s"* because of the World in Action documentary in 1975: Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/30.3.21/170/5-6].
[89] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/179/6-10].
[90] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/180/16-17].
[91] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/170/11-15]
[92] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/170/17-19].
[93] The Inquiry will recall the observations about the World in Action documentary and Sr Brian's intervention: Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/180/22-25].
[94] Dr Mark Winter [T/1.10.20 / 41/2-25 and 42/1].

was a feeling across the haemophilia doctors that we've noted this. It looks like there's a third virus… If it is, it doesn't seem to be doing any harm… All of that changed radically around about 1978/79… because their [studies] showed that most of these patients had very significant chronic liver disease."[95]

57. Again, **Dr Colvin** (Royal London Hospital) gave evidence that he expected that he and his colleagues knew by the late 1970s that there may be an association between NANB hepatitis and chronic liver disease.[96] He nonetheless described the *"wishful thinking"* that NANB hepatitis would take a significantly different course to HBV[97]. This was attributed to a reluctance to believe that there were any problems with treatments which were able to offer patients *"proper haemophilia care"*.[98]

58. In summary, by the 1970s, then, it was recognised that viruses, including HAV and HBV, but also NANB, could be transmitted by infected blood and blood products and that increased risk was associated with larger plasma pools and the use of paid donors. This meant that it was or ought to have been understood that the risk of transmission of viruses, including unknown viruses, could be mitigated by the taking of particular, readily identifiable, steps; testing, the use of small plasma pools and voluntary donors (and not, therefore, U.S. Factor VIII).

AIDS (HIV)

59. As is well known, earlier indicators of the presence of AIDS were found in the United States' Centres for Disease Control ("CDC") and Prevention Reports: the *Morbidity and Mortality Weekly Reports* ("MMWR"). The MMWR first reported in June 1981 on the phenomenon of a rare lung disease (pneumocystis carinii pneumonia), along with other unusual infections, in five previously healthy young

[95] Dr Mark Winter [T/1.10.20 / 40/ 25 and 41/1-24].
[96] Dr Brian Colvin [T/6.10.20/39/19-25 and 40/1]
[97] Dr Brian Colvin [T/6.10.20/49/20]
[98] Dr Brian Colvin [T/6.10.20/42/1]

homosexual men. The infections pointed to impaired immune function.[99] This appears to be the first report in a clinical/public health journal of what came to be known as AIDS. Thereafter, in July 1981, the MMWR reported on kaposi's sarcoma and pneumocystis in 26 homosexual men New York City and California.[100] Then in August 1981, the MMWR recorded a follow up on kaposi's sarcoma and pneumocystis and discovered 70 additional cases since the July report. Of all cases, 107 were male and 94% of those whose sexual orientation was known, were homosexual or bisexual. 40% of those reported by this stage had died by the time of the report. [101]

60. Further reports followed as evidence continued to emerge. Thus, in June 1982 the MMWR reported on a cluster of kaposi's sarcoma and pneumocystis carinii pneumonia among homosexual men in Los Angeles and Orange Counties, California.[102] Hypotheses as to the cause of the immunodeficiencies, that were understood to be the immediate cause of these infections, included that as yet unidentified infectious agents were being sexually transmitted among homosexual men, alternatively that sexual contact with infected men did not directly result in acquired cellular immunodeficiency but was simply indicative of certain ways of living ie. there was another factor relating to a lifestyle (the example of amyl nitrate and other drug use was given).

61. However, by July 1981 a further matter had come to the attention of the CDC. The MMWR reported for the first time the incidence of immunosuppression in three patients with haemophilia who had no other known risk factors for (what soon became termed) AIDS. All three patients (two of whom had by the time of the report died) were reported to have had pneumocystis carinii pneumonia and all three had received frequent injections of Factor VIII concentrate.[103] Further, in

[99] [CGRA0000242].
[100] [OXUH0002849].
[101] [CGRA0000424].
[102] [RLIT0001690]
[103] [CGRA0000428]

December 1982, the MMWR reported on a 20 – month -old infant who had required multiple blood transfusions at birth and had developed unexplained cellular immunodeficiency and opportunistic infections. Donor tracing revealed that one of the baby's doners had died of AIDS in August 1982 (*"the San Francisco baby case"*).[104]

62. By 1982, then, there was evidence coming from the U.S. indicating that AIDS, a fatal disease, was not as a result of an infection affecting homosexual men only but that it was transmissible to adults and children through blood products, including Factor VIII. That evidence came to the attention of the Consultant Adviser in Blood Transfusion to the CMO at the DHSS, **Mr Gunson** (also a Regional Transfusion Director[105]), almost immediately. While it may not be obvious that a U.K. specialist would be reading the MMWR (although there would be no automatic reason why not given the importance of the subject), it is clear that **Mr Gunson** read widely (including the Lancet, the BMJ, the New England Journal and Vox Sanguinis as well as two U.S. blood journals). [106] **Mr Gunson** confirmed in his evidence in the HIV litigation that he *"first became aware of the emergence of HIV/AIDS from the information in the Scientific Literature from the USA."*[107] So, he plainly acquainted himself with the U.S. literature. Additionally, he said that he: *"first suspected the link between haemophiliacs and AIDS during 1982, when there were instances of haemophiliacs contracting immune deficiency."*[108]

63. Thus, a DHSS minute dated 16 July 1982 recorded **Mr Gunson** as having reported that there was likely to be *"considerable publicity"* over the following couple of weeks *"concerning the safety of American Factor VIII"*, referring to, among other matters the fact that a number of people with haemophilia in the U.S. had

[104] [CGRA0000304]
[105] Presentation from Counsel to the Inquiry on Dr Harold Gunson [T/11.11.21/99-102] among other roles.
[106] Presentation from Counsel to the Inquiry on Dr Harold Gunson [T/11.11.21/115/2-9]
[107] Presentation from Counsel to the Inquiry on Dr Harold Gunson [T/12.11.21/13/19-21].
[108] Presentation from Counsel to the Inquiry on Dr Harold Gunson [T/12.11.21/14-15]

contracted what came to be identified as AIDS.[109] This must be a reference to the evidence referred to in the July MMWR (see above). It was noted too that the "*voluntary unpaid donor system*" adopted by the U.K. was safer than the U.S. system ("*where drug addicts are tempted to give blood simply for the money*") but that "*about half of the Factor VIII bought from commercial companies is imported from the USA*".[110]

64. **Professor Tuddenham also** became aware of the July MMWR at around the time it was published,[111] as did **Dr Bevan** (St Georges Hospital, Tooting) who indeed read it at the time of publication and learnt of the *San Francisco Baby case*, again at the time the MMWR published details of it.[112] For **Dr Bevan** then, "*[p]eople with haemophilia were at risk of blood-borne infection because of their exposure to pooled plasma from many donors, so the association, as I understand it between blood product usage and AIDS seemed quite likely to me*". [113]

65. **Dr Jones** became aware of the 1981 MMWR and the "*San Francisco baby case*" by no later than September 1982,[114] at a meeting of the Haemophilia Reference Centre Directors, and by 1983 he knew that AIDS had reached the U.K.. He described the feeling at the beginning of the AIDS epidemic: "*there was a – a harmful agent out there which if it did cause disease, it was a deadly disease, and these people were going to die extremely quickly*".[115]

66. Further, in Autumn 1982 the risk of the transmission of AIDS by use of Factor VIII was drawn to the attention of **Professor Bloom** (Cardiff Haemophilia Centre). As

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[109] Presentation from Counsel to the Inquiry on knowledge of risks [T/23.9.20/87/10-15].
[110] Presentation from Counsel to the Inquiry on knowledge of risks [T/23.9.20/88/10-15].
[111] Professor Edward Tuddenham [T/22.10.20/62/11-19].
[112] "it was published as a supplement. A kind of digest of MMWR findings were published in the Journal of the American Medical Association, as far as I remember, and this was a journal I did read, it was one of my kind of chronic reading lists, so I had read that and I was aware of it and I was alarmed by it, as you'd expect". Dr David Bevan [T/12.1.21/62/12-25 and /63/1-25].
[113] Dr David Bevan [T/12.1.2021/63/2-6].
[114] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/91/24-25 and 92/1-2].
[115] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/ 95/17-20].

the Inquiry has heard, **Professor Bloom** played a very significant role in the events that transpired. He was described to the Inquiry as *"perhaps the most important figure in shaping the response of haemophilia clinicians to the risk of AIDS"*[116] and *"a world authority on haemophilia. He was very well informed."*[117] It was also noted that he appeared to receive more information than other clinicians working in the field of haemophilia, and he seems from UKHCDO minutes, to have been shaping the debate throughout. His views at least, and necessarily their conveyance, were, then very influential indeed. Professor Bloom was also importantly one of the key actors who actively denied the risks of AIDS when the risks had become clear. And it was Professor Bloom's views that *"dominated"* during the early 1980s.[118] In October 1982, **Immuno** wrote to **Professor Bloom** in these terms: *"I am sure you are aware three cases of PCP were reported in haemophiliacs receiving Factor VIII concentrate. This caused concern about the transmission of the disease by Factor VIII or possibly other blood product*s."[119] Notwithstanding what he knew, in January 1983 Professor Bloom advised the Haemophilia Society, that it had not been proven that AIDS was transmitted through blood products and there was *"no need for the haemophiliac community to be unduly concerned."*[120]

67. Then in January 1983, the New England Journal of Medicine published an article by **Desforges** in which she noted both the role Factor VIII played in improving the quality of life and health enjoyed by people with haemophilia but noting too that *"[t]he risk associated with exposure to plasma from multiple donors….ha[d] long been a concern in the care of these patients primarily because of evidence of virus-induced liver disease."* [121] By then, they were also *"becoming aware that treating hemophiliacs with*

[116] Presentation from Counsel to the Inquiry on the Cardiff Haemophilia Centre [T/8.10.20/37/4-6].
[117] Professor Christopher Ludlam [T/1.12.20/15/9-11].
[118] Professor Christopher Ludlam [T/3.12.20/58/2-3].
[119] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/142/2-6],
[120] Presentation from Counsel to the Inquiry on the Cardiff Haemophilia Centre [T/30.9.20/ 15/20-21].
[121] [OXUH0002853]

Factor VIII preparations may exact a high cost…[122]."[123] She summarised her concerns as follows:

> *"[t]he present program has been extremely successful and would be given up by physicians and patients only with great reluctance. Yet it is time to consider doing so, even though we may not have enough evidence to demand such a radical change. The fact that haemophiliacs are at risk for AIDS is becoming clear. If the use of cryoprecipitate will minimise this risk the current home infusion programme needs to be revised. … Unfortunately, the data are consistent with the greater potential for AIDS in the population treated with concentrate. Physicians involved in the care of hemophiliacs must now be alert to this risk. Preventing the complications of the present treatment may have to take precedence over preventing the complications of haemophilia itself".*[124]

68. The Inquiry can safely conclude that this article would have been read by key haemophilia clinicians in the U.K., or at least they would have been made aware of the substance of its contents at the time of, or shortly after, its publication. **Professor Bloom**, **Dr Craske**, **Dr Mayne** and **Dr Kernoff** were certainly aware of it by 24 January 1983 (and were aware that fractionation companies were aware of the problem[125]), and of the high mortality rates.[126] This was the date on which the London Airport (**Immuno**) meeting took place and at which all Reference Centre Directors (except **Professor Tuddenham**) were in attendance.[127] At that meeting, it was noted that 10 people with haemophilia had been affected by AIDS in the U.S.; the youngest was age 7.[128] All cases had had prolonged treatment with Factor

[122] [CGRA0000428]
[123] [OXUH0002853]
[124] [OXUH0002853]
[125] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/31.3.21/16-17].
[126] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/31.3.21/16-17].
[127] [PRSE0002647]; Professor Edward Tuddenham [T/22.10.20/62-64]
[128] [PRSE0002647]; Professor Edward Tuddenham [T/22.10.20/62-64]

VIII. [129] A reference was also made to the *San Francisco baby case"* and to the **Desforges** article. [130]

69. Further, **Professor Ludlam** (Edinburgh Royal Infirmary, member of UKHCDO and a member of the Reference Centre Directors group[131]) was confident that he was *"certainly"* aware of it in early 1983 and that he considered that **Desforges'** conclusion that the fact that people with haemophilia were at risk for AIDS was *"becoming clear"*.[132]

70. **Dr Jones** was also clearly familiar with the **Desforges** article, and very shortly after its publication, since he referred to it in his 1983 publications[133] and indeed acknowledges in his witness statement that *"it was read and discussed most carefully"*.[134] It can be assumed that this was read more widely among U.K. haemophilia specialists since they were already discussing the issue among themselves and so, no doubt, just like **Professor Ludlam**, they will have been keeping up to date with relevant publications shedding light on the issues. [135] Similarly, though her evidence was extremely evasive, it seems likely that **Professor Lee** (Royal Free Hospital) would have been aware of it since she accepted that there was some evidence at the latest in January 1983 that blood products might transmit AIDS (*"If you -- you know, if you have people with haemophilia*

[129] [PRSE0002647]; Professor Edward Tuddenham [T/22.10.20/62-64]
[130] [PRSE0002647]; Professor Edward Tuddenham [T/22.10.20/62-64]
[131] Professor Christopher Ludlam [T/1.12.20/15/19-21 and 16/8-11]
[132]Although, notwithstanding he agreed with the conclusion, he sought minimise its significance no doubt because she raised the prospect of a resort to cryoprecipitate. Professor Christopher Ludlam [T/2.12.20/11/5-14].
[133] See, the Lancet editorial 2 April 1983 [PRSE0002723] and 10 December 1983 [HSOC0001285]; and Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/112-113].
[134] Presentation from Counsel to the Inquiry on Newcastle Haemophilia [T/3.2.21/123/2-3].
[135] "Professor Bloom asked Dr Craske if he had any information about the acquired immune deficiency syndrome following reports from the United States and the possible relationship of the syndrome with blood products and hepatitis. Dr Craske said he would find out more about this and agreed to try and have some information available for the Haemophilia Centre directors at the Manchester meeting." Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/93/4-11].

having this strange syndrome…"[136] though the position she, unconvincingly stated, was not *"cut and dried"*[137]).

71. A month after the **Desforge** article, in February 1983, AIDS was discussed at a meeting of Reference Centre Directors (including **Professor Tuddenham** and **Dr Kernoff**) for the first time. **Professor Bloom** was in attendance and noted that the incidence of AIDS higher than first thought and additionally patients with haemophilia who had received American concentrates might be at risk.[138] It was also noted that by then approximately 12 cases of AIDS were thought to have occurred in people without haemophilia in the United Kingdom.[139] **Professor Tuddenham** gave evidence that he was "*highly puzzled*" as to what was causing the syndrome.[140] However, it was presumed at that stage to be transmissible by direct contact means and therefore that it was likely to be a virus, and it was clear that the haemophilia population was at risk.[141] Nevertheless no plan or recommendations were drawn up at that stage.[142]

72. Further, there was no discussion about informing patients of the risk or of possible changes to treatment.[143]

73. **Dr Gunson** also knew of the evidence emerging from the U.S. indicating a link between Factor VIII and AIDS since he wrote to **Dr Walford** (Principal Medical Officer at the DHSS) on 17 February 1983 (apparently following a trip to the U.S.), enclosing some information for her on the AIDS situation and stating: *"I think that we will have to carefully watch this situation and perhaps when I come back from Washington at the end of February, we could meet to discuss it, because the most important recommendation that is coming from the USA is the question of whether there should be*

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[136] Professor Christine Lee [T/21.10.20/17/2-6].
[137] Professor Christine Lee [T/21.10.20/16/25].
[138] Professor Edward Tuddenham [T/22.10.20/87-8].
[139] Professor Edward Tuddenham [T/22.10.20/88/5-11].
[140] Professor Edward Tuddenham [T/22.10.20/89/2-4].
[141] Professor Edward Tuddenham [T/22.10.20/89/4-8].
[142] Professor Edward Tuddenham [T/22.10.20/89/9-14].
[143] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/117/5-10]

an increased usage of cryoprecipitate, and if this philosophy takes off in the UK it will have considerable implications for the Regional Centres and for the plasma supply situation."[144] It is apparent too, then, that the Department of Health and Social Security (DHSS) were aware of the risk. Indeed, **Dr Walford** acknowledged in her witness statement that she became aware of the *San Francisco Baby* case in late 1982 or early 1983[145]; her response is dealt with under "Accountability" in Part 3(iv) below).

74. The issue also began to be picked up by the mainstream media, with articles shown from April and May 1983 linking the transmission of AIDS to blood products.

75. Further evidence indicating the risk posed by AIDS to patients receiving Factor VIII was brought to the attention of **Professor Bloom** around this time. This included, in May 1983, evidence of the Cardiff patient (a 20-year-old man) (**Professor Bloom's** patient) whose infection fitted the criteria for AIDS[146] having previously received U.S. Factor VIII concentrate. Details were contained in a communicable disease report in relation to the week ending 6 May 1983. This noted that this was the first report of AIDS in a patient with haemophilia in the UK known to the Communicable Disease Surveillance Centre ("CDSC"). [147] In a letter dated 9 May 1983 from **Dr Galbraith** (at the CDSC) to the DHSS confirming **Professor Bloom's** case of AIDS in Cardiff and another in Spain linked to U.S. Factor VIII concentrate, **Dr Galbraith** wrote:

> *Last week …a case of AIDS in a haemophiliac in Cardiff who had received USA Factor VIII concentrate was reported. The case fits the recognised criteria for the diagnosis of AIDS. In The Lancet of 30 April three cases in haemophiliacs in Spain are reported; I have confirmed that they received USA Factor VIII concentrates. In the same issue of The Lancet, the tally of 11 reported cases in*

[144] Presentation from Counsel to the Inquiry on Dr Harold Gunson [T/12.11.21/16/8-22]
[145] [WITN4461001/169/71.2]
[146] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/17/19-20].
[147] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/14/11-12].

haemophiliacs in the USA is recorded and a paper describes a case in a multiply transfused child in the USA… 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".[148]

76. **Dr Galbraith** explained the rational, as follows: 1. The AIDS epidemic in the USA is probably due to a transmissible agent. 2. The agent is probably transmitted by blood and blood products. 3. 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 because (a) the earliest cases of AIDS reported in the USA developed symptoms in 1978 and, therefore, USA blood products manufactured from donations before 1978 are very unlikely to have been contaminated. Indeed, the earliest reported date of onset of AIDS in a person with haemophilia is October 1980. (b) Most of the reported cases of AIDS had been diagnosed in 1981 and 1982 (c) The incubation period is long, between several months and two years, maybe as long as four years, and therefore one would not expect to see many cases due to USA blood products until a year or more after 1981/82 donated blood products had been given. 4. Factor VIII concentrate of pooled products would appear to have a high risk of being contaminated with AIDS agent because homosexuals and drug abusers are known to be frequent blood donors and each plasma pool from which it is manufactured is collected from as many as 1,000 donors. 5. There is apparently no known means of ensuring that blood or blood products are free of the AIDS agent. 6. He emphasised that few cases did not mean low risk, and pointed in particular to an apparently long incubation period.[149] He noted too,

[148] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/16/24-25 and 17/1-3].
[149] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/18/19-21].

chillingly, that *"the mortality rate of AIDS exceeds 60% one year after diagnosis and is expected to reach 70%"*.[150] [151]

77. Blood products donated in the U.S. after 1978 were not, of course, withdrawn.

78. **Professor Bloom** would have been aware of these points. As seen, his case was referred to in terms (the Cardiff case). Notwithstanding this, in July 1983, the subcommittee of the Committee on Safety of Medicines, comprising, among others, **Professor Bloom**, **Dr Galbraith**, who presumably had been prevailed upon to change his mind, and **Dr Gunson**, concluded (with **Professor Bloom** apparently leading the discussion on this) that a return to cryoprecipitate for treatment could not *"at present be recommended"* because *"(a) it is probably impossible to satisfy UK needs in this way; (b) even if needs could be satisfied it would involve a major rethink of UK policy for preparing blood products; (c) the perceived level of risk at present does not justify serious consideration of this solution."*[152] Nor, the meeting concluded, could U.S. preparations be withdrawn from the U.K. market on grounds of supply,[153] leaving much, it was decided, to the judgment of individual doctors.[154] Further, the minutes of a meeting of all haemophilia centre directors in October 1983 record, **Professor Bloom** expressing the view was that there was *"no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS"*.[155] The meeting concluded with the agreement that patients *"should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in the same*

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[150] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/20/5-7].
[151] He also noted an incubation period of between several months and 2 years. Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/18/9-11].
[152] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/ 33/13-24].
[153] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/34/1-2].
[154] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.2020/34 /15-16]. Including as to the treatment of children with mild haemophilia. Ibid [T/24.9.2020/34 /4-8].
[155] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.2020/54/9-12].

way". [156] **Professor Bloom** was sanguine about the risk, considering it inherent in the appropriate treatment for haemophilia and at which he, metaphorically, shrugged his shoulders. Thus, in his letter to a patient in 1992, he describes patients contracting HCV as *"yet another aspect of the bad luck to which the haemophilia population has been exposed."*[157] He no doubt took the same view of AIDS.

79. In the meantime, again notwithstanding what was known, **Dr Jones** wrote a letter to colleagues in the Northern Region, dated 26 May 1983, casting doubt on whether the Cardiff case could truly be seen as a case of AIDS.[158] Further, and typical of the responses to these warnings, **Dr Jones** downplayed the risk of AIDS and emphasised the benefits of factor concentrates. Thus, in the same letter he wrote:

> *If this is true then even if the agent has been recently introduced, one would expect to see many more cases amongst the haemophilic populations most exposed to Factor VIII concentrates from the suspect areas. …[T]he effects of withdrawal of Factor VIII concentrate treatment for our haemophiliacs would mean the cessation of home therapy and prophylaxis and the withdrawal of elective surgery."*[159]

80. **Dr Jones** is also believed to have written an editorial in the Lancet in April 1983[160] in which doubt is cast on the relationship between AIDS and factor products. [161]

81. Similar evasive responses are seen from **Professor Lee**. Thus, on 16 November 1983 she wrote to **Dr Rizza** that she had a *"nasty feeling"'* that NHS

[156] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.2020/54/18-22].
[157] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/30.9.2020/170/8-9].
[158] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/108/20-23].
[159] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/109/8-11].
[160] [160] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/112/2-11].
[161] [PRSE0002723]; Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/112/2-11].

concentrates were going to turn out safer (than U.S. products).[162] She confirmed in evidence that that nasty feeling arose from her realisation that it was the donor pool rather than the fractionation methods which were causing the immunological abnormalities[163] (and thus that they were going to have a large number of patients with AIDS). However, thereafter she adopted the *"1 in 1,000"*[164] - that had conflated incidence and risk, contrary to *"a fundamental principle of epidemiology"*.[165] Further, and even more startling, in a co-authored a study, part funded by **Armour**, by **Professor Lee**, **Dr Rizza** and others, submitted on 4 June 1984 -that is slightly over 6 months after the letter to **Dr Rizza** –the authors concluded that *"[f]ractionation procedures used to prepare clotting factor concentrates, and the amounts of concentrate used, are more likely to be causally related to these immunological abnormalities than the origins of source donor plasmas"*.[166] When asked in evidence about the discrepancy **Professor Lee** was unable to answer convincingly, stating that it *"must have been the predominant conclusion at that time"*.[167] The Inquiry might properly ask itself whether the answer might be found in the involvement of **Armour**. There was an unhealthy – and some might say, improper - relationship between clinicians (by no means all) and the pharmaceutical industry. As **Professor Tuddenham** described it, pharmaceutical companies afforded *"lavish entertainment"* and the like on doctors because of an expectation that they might gain influence.[168] The same is true of research funded by the pharmaceutical industry that might be affected by *"conscious and unconscious bias"*.[169]

82. In the case of **Dr Jones**, even when he came to explicitly acknowledge risk, he did nothing to address it. Thus, in a November 1984 letter to the Royal Victoria Infirmary's administration department, **Dr Jones** stated that he had become

[162] Professor Christine Lee [T/21.10.20/50/25 – 50/1].
[163] Professor Christine Lee [T/21.10.20/51/2-11].
[164] Professor Christine Lee [T/21.10.20/35/19-22].
[165] Professor Edward Tuddenham, [T/22.10.20/100/13].
[166] Professor Christine Lee [T/21.10.20/52/ 22-25 and 53/1].
[167] Professor Christine Lee [T/21.10.20/53/2-14].
[168] Professor Edward Tuddenham, [T/22.10.20/133/23].
[169] Professor Edward Tuddenham, [T/22.10.20/133/ 15-16].

aware of seroconversion (indicative of AIDS) commonly seen in people with haemophilia who had received non-heat-treated NHS concentrate.[170] However, only a few days later, on 29 November 1984, he wrote to **Professor Bloom** that: "*For the moment I intend to go on using the non-heat-treated NHS product from Elstree. In view of cumulating evidence of possible contamination in both the Elstree and Edinburgh products, I might have to change my mind about this before April when Richard Lane assures me that heat-treated material will be available from his plant.*"[171] He also advised patients to use up their present stocks despite the fact that commercial companies had agreed to take up the non-heat-treated material without incurring any cost[172]. It appears that was not until December 1984 that a policy was introduced for children to continue using cryoprecipitate[173]. By this time, all the Saunders CPs, including **Mr AH** who was a still a child, had most likely contracted HIV.[174]

83. Similarly, despite what she knew as early as January 1983, **Dr Mayne** continued to use concentrates, and there is no evidence that patients were asked to reduce their usage in the first half of the 1980s. In her written statement, Dr Mayne said *"even with the benefit of hindsight, I cannot envisage otherwise. In reality, the choice was stark – stop treatment with concentrates with all the risks and disruption that would entail for patients or continue with treatment in light of the information then available."* [175] This is extraordinary given that she well knew treatment with concentrates was to subject patients to the real risk of a potentially fatal infection. She stated too that a return to cryoprecipitate

[170] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/132/3-25 and 133/1-16.
[171] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/134/20-25 and 135/1].
[172] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/136/11-14].
[173] Presentation from Counsel to the Inquiry on Newcastle Haemophilia Centre [T/3.2.21/138/24-25].
[174] Mr AH was diagnosed with HIV in 1985.
[175] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/31.3.21/63/7-14]. Also, in a report produced by Dr Mayne in 1988, she described '*a revolutionary concentrate*' being introduced in 1967 called cryoprecipitate which patients were 'ecstatic' about despite many developing hepatitis B, see [RHSC0000067_002]; and Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/30.3.21/29/21-22].

was *"greeted by an emphatic refusal from the patients concerned"*.[176] The veracity of this evidence is doubtful given the lack of information transmitted to patients (see Part 3(ii)) and **Dr Mayne's** treatment choices throughout the first half of the 1980s.

84. **Professor Tuddenham** gave evidence that by October 1983 (the date when **Professor Bloom** held the meeting with Centre Directors above) there was *"very strong circumstantial evidence that they are transmitting AIDS"*.[177] However, **Professor Tuddenham** confirmed that the Royal Free did not change its approach to treatment until December 1984, when it introduced heat-treated concentrates and delayed elective surgery.[178] Even then, Royal Free chose to require patients to exhaust their existing stock before switching products.[179] As **Professor Tuddenham** agreed *"if there's a risk, it should be met by immediately stopping using the at-risk product"* and that cryoprecipitate would have been an obvious alternative[180][181] but nevertheless the risk was tolerated.

85. As well as treating clinicians, there were other key institutions that were cognisant of the risks posed by NANB and AIDS and did not act upon that knowledge in ways that might have reduced risk. These include the blood service, the pharmaceutical industry and, albeit shouldering less responsibility, the Haemophilia Society. Observations on the state of their knowledge, and the responses, are made below.

(b) Blood Services

86. It is axiomatic that as the risks of NANB and AIDS and were to be found in blood and blood products, the custodians of those services might have been

[176] Presentation from Counsel to the Inquiry on Belfast Haemophilia Centre [T/31.3.21/56/19-20].
[177] Professor Edward Tuddenham, [T/22.10.20/106/22-25].
[178] Professor Edward Tuddenham, [T/22.10.20/75/11].
[179] Professor Edward Tuddenham, [T/22.10.20/78/7-10].
[180] Professor Edward Tuddenham, [T/22.10.20/78/18-20].
[181] He asserted however that these decisions were left to **Professor Kernoff** on his own. Professor Edward Tuddenham, [T/22.10.20/48/16].

expected to have played a leading role in apprehending and responding to risks. Strictly speaking, they were not involved in patient care with people with haemophilia in the way that haemophilia doctors were. With more distance from patients, the blood transfusions services might have offered robust and entirely objective intelligence around the virological risks of AIDS and NANB, based on empirical evidence. By and large they did not.

87. Instead, practitioners within the blood services though they knew, or to have known early on, of the risks were largely silent on the risks posed by NANB and AIDS and sometimes positively misleading. The public perception of AIDS, in particular, and its association with male homosexuals and drug users, in part shaped the way that the risks to people with haemophilia were investigated and knowledge developed. In part it was too, the belief that Factor VIII was a *"wonder drug"* that was better for patients than reversion to cryoprecipitate, and additionally supply concerns. Further, the absence of a unified national regulatory system directed at ensuring blood security, meant there were numerous missed opportunities to study and respond to risks consistently across the blood services. The Blood Transfusion Service was a *"fragmented and disorganised shambles"*, as **Professor Cash** described it, in 1987, [182] There was also a lack of guidance from the CMO in circumstances where haematologists would have welcomed centralised directions[183]. The absence of centralised guidance meant there was major variation in care: *"You'd be utterly bemused by the different way in which ten patients could be treated by ten different doctors. I mean, it was astonishing, and something that will surely come out of this Inquiry is the great variability of care that patients received"*.[184] The context for this was the prevailing practice of granting *"clinical freedom"*[185] to haemophilia doctors at the time.[186]

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[182] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/3/9-10].
[183] Dr Mark Winter [T/1.10.20/114/3-7].
[184] Dr Mark Winter [T/2.10.20/28/10-16].
[185] Dr Mark Winter [T/2.10.20/11/16] and [T/2.10.20/145 14-16 - 146/1-8].
[186] Dr Mark Winter [T/2.10.20/11/16] and [T/2.10.20/145 14-16 - /146/1-8].

88. **Mr Gunson**, Consultant Adviser in Blood Transfusion to the CMO at material times (from 1980[187]), among holding many other roles,[188] was a key player in the response to the risks associated with blood products and NANB and AIDS. .[189] He was also exceptionally well qualified to understand and respond to risk. As early as 1978, **Mr Gunson** was taking a lead role in the management of risks posed to blood safety. As early as 1978, **Mr Gunson** was member of a WHO Expert Committee on Biological Standardisation. This Committee prepared a report in the same year, on *"Requirements for the collection, processing and quality control of human blood."*[190] This report contained information about the collection of blood and blood components, and the selection of donors. It advised that: "*Before each donation questions shall be asked to determine that the donor is in normal health and has not suffered, or is not suffering from, among other things, 'infectious diseases': Donors shall have a negative history of viral hepatitis, of close contact with an individual with hepatitis within the past six months, of receipt within six months of human blood or any blood component or fraction that might be a source of transmission of viral hepatitis within the previous six months and that any donor should be permanently excluded if a previous blood donation given by him was the only unit of whole blood or of a blood component administered to a patient who developed hepatitis within six months and who received no other blood fractions capable of hepatitis transmission during this period.*[191] Further, it stated that "*Donor population showing a prevalence of acute or chronic hepatitis higher than that found in the general population should be avoided for collection both of single donor products (whole blood and its components) and of plasma for pooling for the manufacture of plasma fractions known to be capable of transmitting hepatitis, such as clotting factor concentrates."*[192] Similarly, the report advised that countries with *"a low*

[187] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/11.11.21/100/20]
[188] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/11.11.21/98-100].
[189] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/11.11.21/110-113].
[190] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/5/24-25].
[191] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/6/22-25 – 7/1-19].
[192] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/7/25 – 8/1-3].

incidence of hepatitis should not use whole blood or blood products obtained from source material collected from an area in which there is a high incidence of hepatitis."[193] As to HBV surface antigen testing, the report stated that: "*National health authorities shall develop policies designed to prevent the transmission of other infectious diseases based on the prevalence of [other (sic)] diseases in the donor population and the susceptibility of recipients to the same diseases."*[194] As to donors for plasmapheresis, in addition to these matters, *"donors participating in a more frequent plasmapheresis programme shall be examined by a licensed physician on the day of the first donation, or no more than one week prior to the first donation. This examination shall include urine analysis and blood sampling for liver function tests"*.[195] As explored below, these steps were not taken to address HBV or NANB (or "other infectious diseases") for several years.

89. In relation to NANB, there was inexcusable delay in introducing testing. As to HBV and NANB, the need for care and proper testing, was identified early on (including in the 1978 WHO report above). Though there was a relatively early attempt, in 1981, by **Mr Gunson** and **Mr Mclelland** (Director of the Edinburgh Transfusion Centre[196]) to establish a prospective study to investigate transfusion-associated NANB, this attempt did not succeed. [197] In April 1987, **Mr Gunson** submitted an application to the DHSS for a grant for a multi-centre study of ALT and anti-HBc screening of donations (surrogate testing) in England. [198]The plan was to test 12,000 donors in a period of six months and, by interviewing the donors with elevated ALT levels and those who were anti-HBc positive, to determine rates and any aetiological factors contributing to elevated ALT values and the significance of anti-HBc positive donors. [199] The

[193] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/8/4-7].
[194] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/8/10-14].
[195] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/5-9].
[196] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/20/13-14]
[197] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/42/13-21]
[198] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/43/5-16].
[199] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/43/5-16]

DHSS approved the application in April 1988 and the trial proceeded. [200] In January 1989, **Mr Gunson** decided that the proposed Chiron (HCV) test could be trialled using 1,000 of the samples from the multi-centre surrogate testing trial where the samples either had raised ALT or anti-HBc results.[201] However, at a meeting on 24 February 1989 of the UK Advisory Committee on transfusion-transmitted diseases, at which **Dr Gunson** attended, *"[i]t was agreed that there should be no recommendation to institute ALT testing until the current study was completed in England. However, there was a degree of inevitability about the introduction of the test which was required by regulatory authorities in other countries to determine the acceptability of fractionated plasma products."*[202] Thus, in February 1989, there was no decision to introduce surrogate testing though its introduction was regarded as inevitable. In his statement for the hepatitis litigation, **Dr Gunson** said that he did not believe that the National Blood Transfusion Service ("NBTS") needed to introduce surrogate testing for NANB, whether by screening for raised ALT levels or anti-HBc, at any time between 1988 and 1991 because he did *"not believe that recipients of blood or blood products derived from donors who had not been so screened …were receiving a product which was less safe than they were entitled to expect"* [203] Some surrogate testing was introduced in an apparently haphazard way (**Dr Cash**'s letter dated 12 January 1990 suggests he found out about plans to introduce routine ALT donation testing of plasmapheresis donations[204] on 1st April 1990 by chance[205]). In November 1989, a decision was made that routine testing would only be introduced when a confirmatory test was available, when the U.S. Food and Drug Administration ("FDA") had approved the test, and then when urgent tests had been done.[206] The desire for FDA approval was to avoid the

[200] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/43/19]. A recipient study did not get ethical approval (unsurprisingly). Ibid. [T/12.11.21/45/6-8].
[201] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/47/8-15]
[202] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/48/2-8].
[203] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/49/1-7].
[204] Something the WHO report had adverted to in terms. [SHPL0000163_033].
[205] [NHBT0000027_011]; Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/49/19-23].
[206] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/53/21-25 and /54/1-2].

"embarrassment" of the FDA not approving the test when it had been developed in the U.S.[207] That embarrassment did not arise, it was said, when using the second generation test because that had been properly tested in the U.K.[208]; that is, it can be inferred that if there had been early and thorough research on the effectiveness of ALT and anti-HBc testing, such testing (which it was anticipated might reduce HCV infection rates by 20%-60%[209]) would have been introduced earlier. Routine testing was, not, however, introduced until 1991.

90. As to HIV, as already noted above, **Dr Gunson** knew almost immediately after U.S. reports of the link between Factor VIII and AIDS; that is, by no later than 16 July 1982. He was also aware that large proportions of Factor VIII were procured from commercial companies in the U.S.[210] He later confirmed that within one year of his appointment in October 1981 as Consultant Adviser, "*the relationship between AIDS and the transfusion of blood and its products was proven*".[211] This is consistent with the contemporaneous evidence as described above. However, later, in his statement for the HIV litigation, he stated that:

> *"During 1982 it was not, in my view, proven conclusively that Factor VIII concentrates were the cause of AIDS contracted by haemophiliacs. Again, to quote Dr Peter Jones, in his presentation at the meeting in 1986, reported 'however, when in July 1982, the [U.S.] Centers for Disease Control …reported unusual opportunistic infections in three men with haemophilia, the possibility of a viral aetiology was thought less likely than an immune response to the constant barrage of extraneous denatured protein involved in treatment'."*[212]

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[207] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/56/3-9].
[208] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/56/10-17].
[209] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/53/17-18].
[210] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/88/10-15].
[211] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/11.11.21/104/17-20].
[212] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/10/17-11 and 11/1-2]

91. However, whichever way he saw it, or put it, it matters not: the fact is that **Dr Gunson** understood that *"one way or another"*[213] Factor VIII concentrates were the cause, or created the risk, of AIDS. And what was known, or ought to have been known, was that steps needed to be taken to protect against the risk posed by Factor VIII. Notwithstanding this, there was considerable resistance to changing anything in order to alleviate (and perhaps eliminate) risk.

92. Thus, in a report produced by them dated 27 April 1983, **Dr Gunson** and **Dr Barbara** (Head, Microbiology for the North London Blood Transfusion Centre) noted that they had *"followed carefully the information from the USA on AIDS"* but that there had been no reported cases of AIDS as a result of transmission through blood products at that point (in the U.K.).[214] They decided, therefore, to make no recommendations *"with respect to donor screening and use of cryoprecipitates"* and that *"until further information is available, the Working Party [of which **Dr Gunson** and **Dr Barbara** were a part] will not recommend changes to present practices for donor selection or use of blood products."*[215] Despite, then, knowing of the risk of infecting a patient with a deadly disease (or exciting a deadly immune response), through blood products, **Dr Gunson** and **Dr Barbara** decided that there was no need to do anything at all.

93. A similar approach was taken in Wales where the first infection in Cardiff was identified.

94. Thus **Dr Napier** (Medical Director, Welsh Regional Blood Transfusion Service) attended a meeting convened by the Welsh office Medical Services Health Professional Group in May 1983 at which **Mr Bloom's** Cardiff case was

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[213] Sir Brian intervention: Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.21/13-17].
[214] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11.22/18/24-25 and 19/2-4]
[215] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson, [T/12.11.21/19/1-7]

discussed. The Welsh Chief Medical Officer, **Dr McAvoy** from the communicable disease surveillance centre, and **Professor Bloom** were also in attendance. **Dr Napier** said this:

> *"It was important to keep the problem in perspective. There was complete awareness of the evolution of the problem which in America has seemingly developed as a result of two coincidental factors, an increased use of blood and its products within an increasingly permissive society where homosexuality is tolerated and drug abuse common... Given that the reported incidence of AIDS in the UK is very low we might be confident that we are not collecting potentially contaminated blood."*[216]

95. As Dr Napier fairly acknowledged in evidence: "*it seems perhaps that we might have been reluctant to accept or understand this aetiology at the time. But it was all a very new and evolving understanding, and I think at that stage there was -- there were quite a lot of arguments about what the true cause of the clinical syndrome of AIDS was.*"[217] At about the same time (3 May 1983), **Dr Napier** broadcast through a local newspaper "*a plea to the public not to panic over speculation concerning possible links between the mystery disease AIDS and blood transfusions*" stressing that "*there is no proof as to how it is transmitted*".[218] The article also reported him to have said: "*We've been aware of this disease for some time and it has not caught us out unaware*" and "*it is important to remember that we do not take blood from anyone who is harbouring any sort of infective problem*".[219] In his oral evidence, Dr Napier commented that this "*reflected the thinking that was around within the transfusion community at the time*" but that in hindsight it was unfortunate that he made the statement.[220]

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[216] Dr Tony Napier, [T/1.12.2021/5/3-9 and 5/22-25].
[217] Dr Tony Napier, [T/1.12.2021/6/8-14].
[218] Dr Tony Napier, [T/1.12.2021 9/24-25 - 10/1-6].
[219] Dr Tony Napier, [T/1.12.2021/10/25 and 11/5-8].
[220] Dr Tony Napier, [T/1.12.2021/11/15-21].

96. Then in a letter to the then CMO (**Sir Henry Yellowlees**), dated 9 June 1983, **Mr Gunson** wrote that "*press publicity… has resulted in a reconsideration of this problem and the formulation of the policy outlined above.*"[221] It is quite unclear why press coverage, and not a rigorous assessment of risk, should affect policy. It is not clear whether as a direct result or otherwise, but some rudimentary screening was introduced (asking donors whether they were homosexual etc[222]) but nothing more.

97. Again, in a memo drafted by **Dr Gunson** to the then **CMO** in October 1983, he wrote, "*With respect to AIDS, it is too early to anticipate the effects in the UK, but it is important that every opportunity is taken to investigate possible ways in which the blood donor population can be screened*".[223] The greater use of cryoprecipitate was however, strongly resisted. Thus, in a letter to **Dr Walford** dated 16 May 1983, **Dr Gunson** outlined the recommendations made by the Council of Europe, stating, "*You can see what they are leading to is the greater use of cryoprecipitate… Although I put forward the UK view of this product the consensus was against us. Like you, I do not think BPL could change to freeze-dried cryo rapidly and the logistic problems would be considerable*".[224]

98. There is no doubt that the stigma attached to AIDS created by the knowledge that risk groups were homosexuals and drug users affected those in the blood services, as with others. There was a reluctance to believe it could affect people falling outside those cohorts (the innocent) and this informed the response to what ought to have been a growing and urgent response to risk. Thus, **Dr Colin Entwistle**: (Consultant Director, Oxford Blood Transfusion Centre in essence acknowledged that the response to the risk of AIDS to people with haemophilia might have been shaped by the perception that only persons

[221] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson, [T/12.11.21/23/25 – 24/1-3].
[222] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11/27/15-25 and /28/1-6].
[223] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/11.11.21/152/16-20].
[224] [224] Presentation from Counsel to the Inquiry on the work of Dr Harold Gunson [T/12.11/25/17-24].

engaged in *"dangerous activities"* would be affected: *"I think one has to remember that 1982 was a very different social situation to what we have today… The public conception of AIDS… was that it was a condition which was primarily linked to persons with certain practices… and was not a matter involving the general public… it was only as time went by… it was realised that AIDS was becoming a more serious problem and that the general public, which included blood donors, would have to take this on board… we had to draw up guidelines for donors which would not scare them rigid"*.[225] He said that, before September 1983, *"it is fair to say… not an awful lot was known as to who actually could be involved, apart from so-called at-risk groups"*.[226]

(c) Pharmaceutical companies

99. As observed at the outset, the Saunders CPs regret the paucity of evidence before this Inquiry on the role of the pharmaceutical companies. But it is submitted nevertheless that the available evidence clearly demonstrates that the risk of AIDS and HCV posed by the transmission of blood and blood products was known by those within the pharmaceutical industry very early on. Without investigation it is any event obvious that that would be so; it is not something they would overlook. **Professor Tuddenham** gave evidence that the Factor VIII industry alone is presently worth $10 billion.[227] There is unlikely to have been any great enthusiasm from pharmaceutical companies for withdrawing a product that produced so much revenue, but much incentive to be on top of emerging knowledge of the risk such products posed.

100. As early as 1973 it was clearly known by the pharmaceutical industry that for safety, the testing of Factor VIII[228] for hepatitis was required (albeit risk

[225] Dr Colin Entwistle [T/6.12.21/75/11-12 and 74/9-25 – 75/1-7].
[226] Dr Colin Entwistle [T/6.12.21/76/6-8].
[227] Professor Edward Tuddenham [T/22.10.22/131/11-12].
[228] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/66/20-25].

could not be completely excluded).[229] It was also known by the industry that the size of the donor pool was relevant to risk.[230] Notwithstanding this, testing was not introduced and nor was it by 1976 when Factor VIII was launched in U.K. by Armour.[231][232] Further, **Immuno** (and perhaps other companies) was seeking a U.K. license to source plasma from the U.S. ,[233] from paid donors and obtainable from large urban areas[234] where they were already sourcing blood.[235] This is so notwithstanding that internal documents demonstrate that **Immuno** knew that plasma sourced in the U.S. and collected in large urban areas carried a significantly higher hepatitis risk.[236] However, sourcing blood in this way reduced the cost for **Immuno** and it appears that **Immuno** considered, from their experience in the U.K., that the U.K. would buy a less safe product for patients in the UK because it was cheaper.[237] On 6 April 1979, at a meeting of the Haemophilia Reference Centre, it was noted that **Immuno** Factor VIII products were being sold at two prices: the cheaper preparation being made from U.S. plasma – the implication being that the cheaper product carried the higher risk of hepatitis – though **Immuno** had said *"that their action was aimed at making available to clinicians material which may carry less risk of transmitting hepatitis"*.[238] That can only have been untrue.

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[229] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/68/5-8].
[230] [230] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/70/19-25 – 71/1-8].
[231] Mr Christopher Bishop [T/4.11.2021/2/18].
[232] After the World inaction programme broadcast on 1 and 8 December 1975. By 1978 such a license had been granted. Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T 23.9.2021/85/20-23].
[233] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/80/17-25 – 81/1-5].
[234] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/84/11-17].
[235] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/84/24-5 – 85/1]
[236] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.2021/87/9-11].
[237] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/83/4-8].
[238] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/100/17-25 - 101/1-12].

101. At material times, there existed a voluntary Code of Practice for the Pharmaceutical Industry. There were various editions but its fourth edition was dated January 1974.[239] It referred to: *"... members of the Association of the British Pharmaceutical Industry have agreed to voluntarily observe the principles set out in a Code of Practice for the Pharmaceutical Industry; a Code which regulates the standards of conduct to be followed in the marketing of medicines intended for use under medical supervision."*[240]. It emphasised 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[241] and that *"Information about medical products should accurately reflect current knowledge or responsible opinion [and] Information about medical products must be accurate, balanced and must not mislead either directly or by implication [and]… Information must be capable of substantiation, such substantiation being provided without delay at the request of members of the medical profession."*[242] It is apparent from above that this was not happening. Thus, in May 1983, Armour wrote to all Haemophilia Centre Directors:

> *"Despite the fact that there is a little evidence to associate plasma component therapy with the transmission of AIDS, Armour, through its affiliate organisation, Plasma Alliance, has had programmes in operation for several months, which have been designed to help prevent the utilisation of plasma obtained from members of high risk groups associated with AIDS in the production of clotting factor concentrates."*[243]

[239] Mr Christopher Bishop [T/4.11.2021/10 /8-23].
[240] Mr Christopher Bishop [T/4.11.2021/10/12-18].
[241] Mr Christopher Bishop [T/4.11.2021/11/23-25 - /12/1-3].
[242] Mr Christopher Bishop [T/4.11.2021/12/10-20].
[243] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21/60/17-25 - 61/1-2].

102. There was ample evidence of risk and Armour were still collecting blood from at risk populations, and indeed they were seeking U.K licenses for that purpose.[244]

103. In February 1983, Armour wrote to all Haemophilia Centre Directors plainly in an effort to provide reassurance in the hope that Haemophilia Centre Directors would continue to use Armour products. The action comprised "*a more aggressive programme*" including[245]: communication with donors in the form of written and oral information and questions; presenting donors with a factsheet "*describing the high risk groups thus far identified with AIDS, the seriousness of the syndrome, and the possible link to the treatment of haemophilia*"; questioning of donors by trained processors as to their being members of high risk groups and the presence of any signs that might be indicative of AIDS; requiring donors to affirm in writing that they are not members of the high risk groups involved; and physical examinations performed by plasma centre attending physicians.[246] The *aggressive programme* did not extend to withdrawing Factor VIII, not sourcing blood from the U.S, or not pursuing license applications for licences to sell blood sourced from the U.S. [247]

104. Further, there was no routine system of warning through labels across the various pharmaceutical companies. The way in which risks were expressed on the product label for Kryobulin for example, varied over the years. The product licence was approved in March 1973, with a warning that the risk of "*homologous serum hepatitis cannot be entirely excluded*".[248] This warning was criticised in 1975 by **Dr Dane** of Middlesex Hospital after a 14-month old child

[244] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.09.21/144/10-16].
[245] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21/64/7].
[246] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21/64/16-25 – 65/1-5].
[247] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21/66/15-19].
[248] [248] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/68/5-8].

became infected with HBV following the use of Kryobulin.[249] The Association of the British Pharmaceutical Industry Data Sheet Compendium 1978 data sheets from 1981 to 1986 include references to hepatitis risk but make no reference to HIV or AIDS whatsoever.[250]

105. When compulsory screening was introduced, Armour resisted any suggestion that it was necessary for safety, no doubt so that they could continue to supply products without suggesting externally that there was any risk. Thus, in a meeting on the subject of Factor VIII in the U.S. on 27 February 1986, it was agreed that: *"there is no problem with Factorate drawn from unscreened donors…. at least in theory, by screening, we will improve the product even more and we should do as much as we can to implement those improvements as quickly as possible.*[251]" Finally, the meeting determined that *"there was no reason to cause any problems in terms of the normal day to day delivery of Factor VIII to our customers, etc, based on all the information available to date…. In other words, it is a voluntary withholding and not a withdrawal from the market."* [252] The observation of Sir Brian is here adopted: *"The curiosity of it is that it's proposing to introduce a screening, which is bound to be expensive, it is proposing to not- effectively to recall or withhold batches which have not been screened, which is going to be expensive and lead to the loss of product already manufactured, all on the basis that there is no evidence that it has any effect at all, which is -- just makes me curious about the document".*[253] This was a company knowing that it had to take action to reduce the risk to them, but did not want to acknowledge the risk inherent in their products and wished to keep the costs to a minimum, and so while insisting that it was not necessary to screen, did so anyway.

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[249] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/24.9.21/4/8-18].
[250] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/24.9.21/21/8-15].
[251] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21 /96/21-22 and 97/13-16].
[252] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21 /96/8-25; 97/1-25 and 98/1-4].
[253] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Armour and Bayer [T/29.9.21 /99/8-16].

106. The approach of pharmaceutical companies in 1983 is exemplified, too, by Cutter U.S.' interactions with the DHSS in the U.K. In June 1983 Cutter U.S. corresponded with the DHSS regarding measures being taken in relation to AIDS. This correspondence revealed that Cutter was asserting that there was an absence of "*persuasive data*" on AIDS and that this was complicated by "*sensationalist and erroneous reporting in press*".[254] They stated that the "*facts about AIDS are limited*", that it was "*not known whether it is a virus*" and that it "*can only be assumed AIDS can be transmitted by certain blood products. This has not been shown.*"[255] Thus, there was again an effort to minimise existence of risk in their external relations.

(d) Haemophilia Society

107. The Haemophilia Society deserves special mention. It should have been an advocate for people with haemophilia, ferreting out risks related to AIDS and NANB and putting pressure on those who could effect positive change to do so. It was largely ineffectual in this respect. It relied heavily – almost exclusively – on mainstream clinicians, including UKHCDO[256], and on the pharmaceutical companies for guidance. Much of the Haemophilia Society's activities in the field of NANB and AIDS comprised rubber stamping the expressed views of leading haemophilia clinicians within the UKHCDO. These were the very bodies that were not confronting risk, minimising it and producing misleading information. **Mr Watters**, General Secretary (1981-94) at the Haemophilia Society, frankly agreed that there was information during the developing AIDS crisis which was not shared with the Society by the UKHCDO and that Executive Committee members

[254] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Bayer [T/30.9.21/139/2-5].
[255] Presentation from Counsel to the Inquiry on pharmaceutical companies involved in blood products: Bayer [T/30.9.21/139/9-17].
[256] Dr Tony Napier [T/1.12.21/3/25 – 4/1-8]. y

were not necessarily challenging clinicians.[257] Instead *"the Society was more interested in maintaining a friendly relationship with those powerful clinicians."*[258]

108. **Mr Watters** also agreed that the Society depended very heavily on the views of **Professor Bloom** in shaping its own direction of travel. Thus, for example, following an Observer article in January 1983 regarding the link between commercial concentrates imported from the US and a *"devastating and mystifying disease'*, Mr Watters contacted **Professor Bloom** for guidance.[259] **Professor Bloom** responded that the cause of the new disease was unknown, and it had not been proven that it was transmitted through contaminated blood products. **Professor Bloom** further stated that there was *"no need for the haemophilic community to be unduly concerned"*.[260] This was not true as **Professor Bloom** did and must have known.

109. One source of misinformation so far as patients were concerned was the Haemofact leaflet produced by the Haemophilia Society and providing advice for people with haemophilia. **Mr Watters**, General Secretary (1981-94) at the Haemophilia Society agreed that the Haemofact would have been the main way in which the Society communicated to members about risks, although the editor did not have any medical qualifications and any information requiring verification would have been referred to the Chairman of the UKHCDO. The Society relied largely on **Professor Bloom** for information which it relayed to its members.[261]

110. As is now known, those Haemofact leaflets were a source of misinformation on NANB and AIDS. This is picked up in Part 3(ii) below but included the notorious

[257] Mr David Watters [T/9.2.21/33/14-25 – 34/1-9].
[258] Mr David Watters [T/9.2.21/43/3-5].
[259] Mr David Watters [T/9.2.21/87/2-23].
[260] Mr David Watters [T/9.2.21/91/10-15].
[261] Mr David Watters [T/9.2.21/85/1-25 – 86/1-11].

1 in a 1000 fallacy. [262] Further, **Dr Kernoff**[263] is quoted in a 1 January[264] 1983 Haemofact dismissing the possibility of an epidemic of AIDS amongst patients with haemophilia as *"ludicrous"*.[265] Further still, the September 1983 Haemofact leaflet stated:

> *"Our message remains unchanged. The advantages of treatment far outweigh any possible risk. Balance the risks for yourselves but we would state again that the risk of AIDS is tiny compared to the risks from untreated bleeding episodes. By refusing treatment or not following your centre director's advice you are probably exposing yourself to even greater risk."* [266]

111. Mr Watters accepted in evidence that this was a very strong message to members that they should continue using factor concentrates.[267] It is apparent that this statement was based on information provided by **Professor Bloom**. [268]

112. The response of the Haemophilia Society, and those to whom they turned, was also influenced by stigma. This impeded recognition at an early stage of the risks associated with AIDS and blood products. Thus, **Mr Watters** described in evidence having difficulties persuading trustees that AIDS was going to become a problem in the UK. He referred in his statement to it being *"imagined that the United Kingdom was different to the United States"* and provided an example in his oral evidence of trustees saying that they did not have bath houses in the UK like they did in the US[269]. He said that the 1983 Mail of Sunday article's reference to a *"gay plague"* was upsetting to people with haemophilia and that people regretted that *"everybody was*

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[262] Professor Christine Lee [T/21.10.20/35/19-22].
[263] At the Royal Free Hospital and Chairman of the Haemophilia Working Party of the NETR Association of Haematologists and co-director with Professor Tuddenham. Professor Edward Tuddenham [T/22.10.20/2/18-21].
[264] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/101/18-21].
[265] Presentation from Counsel to the Inquiry on knowledge of risk [T/23.9.20/103/19].
[266] Mr David Watters [T/10.2.21/62/3 – 13].
[267] Mr David Watters [T/10.2.21/62/16 – 21].
[268] Mr David Watters [T/10.2.21/41/7-25 - 42/1-21 and 62/22-25 - 63/1-4].
[269] Mr David Watters [WITN3429001/36/83]; and Mr David Watters [T/9.2.21/92/19-25].

being tarred with the same brush".[270] He was further shown an edition of Haemofact from December 1984 which stated that they had *"made a major effort to provide the media with the facts about AIDS"*.[271] He stated that he would have been referring to AIDS as it related to haemophilia and gave the following explanation:

> *"It was kind of time to bash everybody, whether they were gay, whether they were drug abusers, whether they had haemophilia, and so on and so forth, and we were very keen to get away from this heavily tainted and biased approach of the media, although having said that, there were people with haemophilia and HIV who were also gay and there were people with haemophilia and AIDS who were also drug abusers. But the vast majority fell into neither of those categories and were simply the victims of the products that the UK Government destined them to receive."*[272]

[270] Mr David Watters [T/10.2.21/22/3-9].
[271] Mr David Watters [T/11.2.21/31/3-4].
[272] Mr David Watters [T/11.2.21/31/16-25 – 32/1-2].

Part 3(ii): Patient involvement

Introduction

113. The infection of people with haemophilia with HCV and AIDS during the 1970s and 1980s largely occurred without those people with haemophilia or their parents and carers having been warned about the risks or provided with information about the risks associated with the transmission of blood products, including any enhanced risk attributable to the use of particular products. Instead, people with haemophilia were largely marginalised from their own care, with the approach of clinicians epitomised by a *"doctor knows best"*, *"my children*[273]*"* and patrician response. Misinformation was widespread (some is dealt with in Part 3(i)). This misinformation included the (deceptive or reckless) minimising of the extent of the risk posed by Factor VIII products, the conflating of incidence with risk (most notably the notorious 1 in 1000 assessment provided by **Professor Lee** and **Dr Kernoff**), among other matters.

114. It also occurred without consent in its meaningful sense; that is comprising *agency, autonomy and liberty*: that is, capacity,[274] informed[275] and without coercion.[276]

115. While by the 1970s the risks associated with NANB could not be entirely alleviated, they could have been mitigated. Though it has been suggested otherwise at points,[277] it was not *necessary* to administer blood products that were

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[273] Robert James Statement No2, [WITN1004002] [15/8].
[274]Medical Ethics Expert Group, [T26.1.21/113/22 – 114/5].
[275] Medical Ethics Expert Group, [T26.1.21/113/ 9-13].
[276]Medical Ethics Expert Group, [T26.1.21/ 114/ 6-10].
[277] See for example, Professor Preston [T2.11,20/ 74/8-13]: On the subject of changing treatment after the emergence of AIDS, he could not recall the specifics of Reference Centre Directors meetings at the time, but stated: *'I don't think anybody disagreed with the concept of continuing with treatment, with the concentrates. Because if patients were not treated with concentrates, they would be severely incapacitated or even die. So treatment had to continue with concentrates'*. See too, Professor Ian Franklin, [T27.10.20/116/14-117/10].

or ought to have been known to carry the enhanced risk of infection with an unknown, but known of, contaminant. However, even if excruciating pain and/or death would have resulted from the use of less risky, or no, blood products, adult patients were entitled to know of the risks and exercise a judgment for themselves, with the expectation that they would be provided with clear advice, guidance, and risk assessment. Further, for some people with haemophilia treatment carrying the risk of a fatal disease was not on any basis essential: the balance most firmly lay in not administering life threatening therapies. This is especially so in the case of children to whom the State has enhanced obligations and who found themselves in their teenage years or young adulthood discovering that they had, what were then thought to be, terminal and heavily stigmatised illnesses. All of this occurred, generally, without the planning, support and counselling that would have helped mitigate the additional ill-health (mental ill-health, including apparently post-traumatic stress disorders ("PTSD")), experienced by so many.

116. Crucial risk assessments were made about the treatment of people with haemophilia without the involvement of patients. Critical measures and practices were not in place to protect and ensure the well-being of people with haemophilia and empower them to make informed choices. The rights of people with haemophilia to information about their health status was not respected.

117. As mentioned above, all of this occurred without patients' consent, in its meaningful sense: that is, without comprising *agency, autonomy and liberty*; that is, with capacity,[278] informed[279] and without coercion.

118. The response to the identification of risk arising from HCV and HIV and Factor VIII, and the experiences of those infected by HCV and HIV, were both affected by stigma. Thus, clinicians and policy makers were resistant to the notion that "*innocent*" people with haemophilia could be affected and people with haemophilia who were infected faced stigma and marginalisation. As **Robert** said

[278] Medical Ethics Expert Group, 26 January 2020, [T26.1.2021/113/22 – 114/1]
[279] Medical Ethics Expert Group, 26 January 2020, [T26.1.21/29/3 – 33/3]

in evidence, the association with homosexual men, sex workers and drug users *"made it very much a disease… nobody wanted to be near"*. He described a high level of paranoia and "*bombardment of tabloid stories… it was always being presented as the worst disease in the world and it was being associated with 'bad people'… those of us with haemophilia were endlessly called 'innocent victims', I hated that term, and I hate the fact that that blamed people"*.[280]

119. The institutionalised nature of the bigotry accompanying a diagnosis was (and is) reflected in the now notorious words of James Anderton, Chief Constable of Manchester, who described people with HIV as "*swirling in a cesspit of their own making"*.[281] The *"innocent vs. guilty"* narrative, that regrettably some in the haemophilia sector engendered too, resulted in the polarising of care, sometimes depriving people with haemophilia of the best care for their infections. This is because haemophilia clinicians were reticent about associating their patients with people from these stigmatised groups and so did not refer to specialist services and sometimes, no doubt, people with haemophilia did not want to access them because of the stigma associated with the groups using them (gay men, drug users). This was exacerbated by the fact that many patients with haemophilia would be young children, with some doctors seeing them as *"their children"*.[282]

120. There was as a result of these divisions a lack of expertise in the haemophilia sector and significant cultural differences. Specialist AIDS clinicians involved patients in their care. Haemophilia clinicians routinely did not: "*that whole approach of… the patient being in charge of their treatment, the patient deciding on risks, the patient deciding on what treatment they have, was just so extraordinarily different*".[283]

121. The stigma *"got in the way of [their] doctors"* reaction to what had happened to the Saunders CPs. As was made clear in evidence, all the Saunders CPs *"feel very strongly … that we have seen over the years since we were infected the stigma that gay*

[280] Robert James [T.8.6.21/19/9-20/8].
[281] Robert James [T8.6.21/19/4]
[282]Robert James [T8.6.21/19/20]
[283]Robert James [T8.6.21/34/16-19]

men, IV drug users and other people have had to put up with. We have shared it with them as well. And HIV, it was really, really difficult way back then and it's still difficult now and people who are seen as different are still discriminated against. And it's wrong. And when we look at haemophilia and HIV it should be no different, and hepatitis C, it should be no different as anybody else with HIV and hep C."[284] For the Saunders CPs, everyone with HIV and HCV is as deserving of respect, care and empathy wherever, whenever and however they were infected. Had this approach been adopted during the AIDS crisis, the likelihood is that people with haemophilia would have received better care and everyone would have been treated with dignity, empathy and with respect for their fundamental human rights.

122. One other matter by way of introduction, the Saunders CPs are getting older. They had not been expected to live this long and they are among a fairly small cohort of (ex-)co-infected people with haemophilia moving into old age. As they get older, there will be increased difficulties in accessing specialist holistic services from those who know how to treat the complex needs of people with haemophilia infected with HIV and having been infected in the past with HCV.[285] Those health bodies and Ministers receiving a copy of the Inquiry's report should know that urgent attention will need to be paid to this issue. It is hoped that they will be included in decisions concerning their own treatment and the need for holistic care.

(a) The Saunders CPs

123. All the Saunders CPs are infected with HCV and HIV. All of them experienced testing without consent, secrecy, stigma, harsh disclosure, an absence of support from mainstream services, lack of empathy from treating clinicians, misinformation, and for 3 of the CPs (adults at the time of discovery of their infections), support from organisations and clinicians supporting gay men and drug users.

[284] Mr AK [T11.10.2019/212/3-15]
[285] Mr AK [T11.10.2019/210/8-20].

124. All four were notified of the risk vCJD "register".

125. Some features of the Saunders CPs' experiences are described in summary below.

126. **Mr AK** received Factor VIII produced by most of the main manufacturers over many years, commencing in the late 1970s,.[286] These were prescribed by the Royal Free Hospital ("RFH") in the early to late 1980s, and from time to time by other NHS providers. **Mr AK** was also treated with whole blood, unnamed experimental blood products, plasma, viper venom, and cryoprecipitate prior to Factor VIII.

127. **Mr AK** was given no warnings or advice about any risks associated with Factor VIII [287] and nor was there any discussion about the choice of factor product that might be available. Indeed, he has no recollection of ever in the whole of his adult life being given a choice of blood clotting treatment.[288]

128. **Mr AK** was infected with HBV as a child (something he discovered later on and something his parents were not told). [289] He was later notified, in 1990, by the RFH that a frozen blood sample taken on 12 August 1980 showed positive for HCV.[290] He was notified of this in essentially what looks to be an impersonal circular containing little by way of detail.[291]

129. **Mr AK** last tested negative for HIV on 3 August 1982. His positive HIV result was dated 18 September 1984 and so he was infected at some point

[286] **Mr AK** [WITN1005001][1/3]; [T11.10.2019/152/21-153/5
[287] **Mr AK** [WITN1005001] [3/11b]. At some point he became aware that he was: *"probably injecting myself over and over again with HIV but advice was to carry on with (probably still infected) product until the new heat treated product came along";* Mr AK [T11.10.21/153/6-10]
[288]Mr AK T11.10.21/153/10-19
[289] **Mr AK** [WITN1005001] [3/11b] ; Mr AK [T11.10.21/155/8-156/2
[290] **Mr AK** [WITN1005001] [3/11a]
[291] Mr AK [T11.10.21/167/12-170/5

during that 2-year period; that is, after the link between Factor VIII and HCV and HIV infection was known.

130. **Mr AK** was told that he was HIV positive most likely before 1985 (though his records suggest he was told at an appointment on 4 June 1987[292]). **Mr AK** had not been asked whether he wanted his blood tested for HIV and did not know he had been tested until he was told after the event at a hospital appointment.[293] At that appointment, he was asked if he wanted to know his *"status"* and responded affirmatively to which (after a check) the doctor replied, *"I'm afraid you are positive"*.[294]

131. **Mr AK** was told almost nothing about what the diagnosis meant, and he was not provided with counselling or information to help him manage and understand his infection.[295] The experience was a lonely one.[296]**Mr AK** had very little support outside the Haemophilia Centres,[297] and this was not a positive environment for someone in need of emotional mental health support. **Mr AK** had two positive experiences from the NHS in dealing with knowledge of his infections, both times from people outside the mainstream Haemophilia Centres services: a counsellor and a young doctor apparently on secondment.[298]

132. Otherwise, outside mainstream services, **Mr MK** sought support from Body Positive, the Terrence Higgins Trust and Mainliners - specialist organisations supporting gay men and drug users - and otherwise he has informed himself of the effects of, and managing his infections, himself.[299] It is apparent from **Mr AK's** experience as with that of others, that haemophilia

[292] **Mr AK** [WITN1005001] [3/11b
[293] Mr AK [T11.10.21/156/17-158/16]
[294] **Mr AK** [WITN1005001] [3/11b]; Mr AK [T11.10.21/157/7]
[295] **Mr AK** [WITN1005001] [3/11b]
[296] Mr AK [T11.10.21/161/23-162/2]
[297] **Mr AK** [WITN1005001] [3/11b]
[298] **Mr AK** [WITN1005001] [3/11b]
[299] Mr AK [T11.10.21/160/3-24;187/1-16]

doctors were simply not experts in HIV and unable to respond adequately to patients' needs.[300]

133. **Mr AK's** relationship with the Royal Free Haemophilia Centre was hostile, in particular his relationship with **Professor Lee**. The Inquiry now knows that she was taking samples and testing without consent. [301]Additionally, she attempted to prescribe **Mr AK** AZT (as then unlicensed and of course toxic) as part of a trial, something that may, had he accepted it, have hastened his death.[302] **Mr AK** did not accede to **Professor Lee's** efforts to have him take AZT, and when he challenged her, reflecting the lack of empathy manifested by other haemophilia clinicians, she said to him *"you're lucky you're living in the UK because your Healthcare is free, but you wouldn't get it free in America."* [303]

134. **Mr AK** experienced serious emotional and mental ill-health, attributable to his infections and additional to the physical impairments and pain. [304] He surmises that most people who have shared his experience have experienced Post Traumatic Stress Disorder. [305] The Inquiry may think that he is right about that.

135. **Paul** was originally treated with cryoprecipitate in the late 1960s but developed inhibitors. By the early 1970s his doctors decided not to use any treatment other than bed rest, ice packs and analgesics.[306] This was designed to allow Paul's inhibiter levels to decrease in case he had a life threatening or severe bleed. After a three-year period of no treatment, Paul was referred to Oxford as **Dr Rizza** was researching the use of high dose prophylactic Factor VIII concentrates on patients with inhibitors. **Paul** then started on NHS

[300]Mr AK [T11.10.21/164/21 -165/22]
[301] Professor Christine Lee [21.10.2020/63/23-67/5]
[302]Mr AK [T11.10.21/166/4-7]
[303]Mr AK [T11.10.21/166/14-19]
[304] **Mr AK** [WITN1005001] [3/11b]
[305] **Mr AK** [WITN1005001] [3/11b]. See too **Mr AH** [WITN1006001] [4/19]
[306] Paul [WITN1003001] [1/3]

products in mid-1976 to try and control bleeds in his knees and elbow. Neither he nor his parents were given any information as to risk. By November he was given U.S. commercial Factor VIII. By April 1977 he had developed acute HBV as a result of infection. **Paul** was not given

136. At first **Paul** was injected with NHS products. He was then moved on to commercial products in November 1976 and by April 1977, he had become infected with HBV as a result. **Paul** was only treated on demand after that.

137. **Paul** and his family were told he had been *"unlucky"* when he contracted HBV.[307] It seems clear, however, that **Dr Rizza** knew very well of the enhanced risk associated with commercial products because **Paul's** notes record **Dr Rizza** writing to **Paul's** doctor *"it would be wise to try, as far as possible, to treat him with the NHS concentrates. As a last resort, I think it might be justified to put him onto one of the commercial Factor VIII concentrates.* **Paul's** treatment was simply part of a research project that was undertaken without **Paul's** or his parents' consent. **Paul's** parents were given no advice or warning as to risk:[308] he was a non-consenting PUP.

138. The first warning **Paul** heard of the risk of AIDS was in 1983/4 with the World in Action programme.[309] When he discussed this with his clinicians, he was told that it had been sensationalised and the risk was repeatedly played down. [310] Nor were **Paul's** family given any proper advice about the risks associated with Factor VIII and any risk was always minimised. **Paul's** parents had read the Haemophilia Society's 1 in 1000 advice and so were no doubt reassured. However, at around the very same time, **Paul** was unknowingly – and without his consent -being tested for AIDS.[311]

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[307] Paul [WITN1003001] [5/14]
[308] Paul [T10.10.2019/11/20-24].
[309] Paul [T10.10.2019/20/23-21/2].
[310] Paul [T10.10.2019/21/13-23].
[311]Paul [WITN1003001] [5/15] [6/17].

139. **Paul** was told of his infection with HIV on 24 June 1985 when he was invited to a *"short"* appointment to *"briefly discuss one or two …results"*.[312] There was no preparation for that appointment and no support afterwards. He was told that he would probably have only a couple of years before developing symptoms and a few years to live.[313] He was also told to keep his diagnosis a secret because of the stigma.[314] As **Paul** says in his statement, *"the stigma in the mid 1980s through to the mid 1990s was one of vile hatred and fear"* .[315] As with all of the Saunders CP's, the news for **Paul** was devastating.

140. He assumed that he had again been *"unlucky"*[316] since all he and his parents had to go on was the 1 in 1000 story (in the Haemofact leaflet authored by **Dr Lee** and **Dr Kernoff**)[317]. The impact for him was deeply traumatising.[318] It took some years for **Paul** to be able to access psychological support.[319] In the meantime, in around 1987, **Paul** was referred to an HIV clinic where his experience of health services improved. There too he met gay men and drug users and much of the advice he received thereafter came from organisations established primarily to support gay men and drug-users (Terrence Higgins Trust, Body Positive and later Mainliners, among others).[320] **Paul** was able too, to provide support to these groups of people in accessing medical treatment themselves because of the vast experience he acquired in doing so. As with **Mr MK**, **Paul** saw nothing that distinguished him from those people from other groups infected with HIV and HCV – none of them were more or less deserving of it.[321]

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[312]Paul [WITN1003001] [6/19].
[313]Paul [WITN1003001][7/20].
[314]Paul [WITN1003001][7/22].
[315]Paul [WITN1003001][19/52].
[316]Paul [WITN1003001][6/17]
[317]Paul [T.10.10.2019/37/15-38/4]
[318]Paul [WITN1003001][12/33]
[319]Paul [WITN1003001][13/35]
[320]Paul [T10.10.2019/41/1-4]
[321]Paul [T10.10.2019/41/10-12]

141. When **Paul** was told he had HCV in 1992, he was told not to worry about it because the HIV would kill him a long time before the HCV would cause him problems.[322]

142. **Robert James** began receiving concentrates in 1977.[323] His last U.S. blood product before his diagnosis of HIV infection was administered on 27 November 1981. Neither **Robert** nor his parents were told that there was an increased risk of HCV and HIV infection associated with the use of Factor VIII,[324] prior to his diagnoses. Further, **Robert** is not aware of having been asked at any point whether he wished to revert to cryoprecipitate or of his parents being offered that choice.[325]

143. **Robert** was made aware at some point, and was aware by his teenage years, that there was a risk of HBV associated with Factor VIII, though he was told that this was something that the body could generally manage.[326] Though **Robert** had had abnormal liver function results from tests performed in 1977 (or thereabouts), there was no follow up or diagnosis of NANB[327] and he was not diagnosed with HCV until sometime in the early 1990s.[328]

144. **Robert** was diagnosed with HIV in April 1985 when he was 18 years old. He was not informed in advance that he was being tested for HIV. **Robert** was told of his HIV diagnosis when he called to make a special appointment to see the haemophilia doctor quickly to deal with a matter. If **Robert** had not needed to see the doctor, he would not have been informed until his next routine appointment, a month or two later I would have found out. [329]

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[322]Paul [T10.10.2019/57/7-11]
[323] Robert James [WITN1004001] [25/52-53]
[324]Robert James [T8.6.2021./3/10-21]
[325] Robert James [WITN1004001] [31/67]
[326] Robert James [WITN1004001] [26/54]
[327] Robert James [WITN1004001 [27/56]
[328] Robert James [WITN1004001 [30/64] ; Robert James, [T8.6.2021/ 9/20 – 10/15]
[329]Robert James, [T8.6.2021/ 4/25 – 5/17]

145. As with **Mr AK** and **Paul**, **Robert** accessed support from organisations supporting gay men and drug users and became heavily involved with general HIV organisations.[330] The emphasis in those organisations was on rights and dignity,[331] and those have informed his own work as an activist in extensive campaigning, lobbying and peer supporting, as well as in collecting oral histories and *"memoralising"*. [332] As **Robert** said, there was a key distinction between organisations and health services generally supporting gay men and drug users: whereas haemophilia clinicians were patrician in nature, HIV clinicians were collaborative and warm.[333] [334]

146. **Mr AH** is the youngest of the Saunders CPs. He was 7 years old when his parents were informed that he was HIV positive (in the mid-1980s).[335] This infection was acquired as a result of the use of Factor VIII. **Mr AH** occasionally received NHS BPL Factor VIII but more commonly a variety of different commercial products (pretty much all of those available) during the period commencing 1978 through to the mid-1980s.[336] His parents were not warned of risk at any time. [337]

147. When **Mr AH's** parents were told of **MR AH's** HIV infection, they were told they should prepare for his death. [338] **Mr AH** was told of his infection when aged 12 by a play supervisor at the hospital. It is clear she did not have permission to do so and she caused **Mr AH** profound psychological distress.[339] **Mr AH** was

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[330]Robert James Second Witness statement [WITN1004002] [5/11].
[331]Robert James Second Witness statement [WITN1004002] [5/11].
[332]Robert James, [T8.6.2021/92/8-14]
[333]Robert James, [T8.6.2021/ 33/1 – 34/21]
[334] Dr Mark Winter gave evidence at [T.2.10.2020/18/11-19/23] . He observed that, as an HIV doctor, he believes his gay patients changed the way doctors related to patients: *'the gay patients with HIV changed the nature of practice in the sense that they, in many ways, were a new generation of patients who came along to doctors, quite rightly, and said, 'Hang on a minute. This is my life, my illness. I want all the facts and I want to do all the decisions', all of which is completely correct.'*
[335] Mr AH [WITN1006001][2/6]
[336] Mr AH[T/10.10.19/93/1-7].
[337] Mr AH [T/10.10.19/93/12-13].
[338]Mr AH [WITN1006001][2/6]
[339]Mr AH [WITN1006001][2/7-8]

informed that he had been diagnosed with HCV when he was 12 years old: he was told by a nurse when he was alone, as a child.[340] She conveyed to him, in what appears to have been a breezy manner, the impression that it would not *"become a problem …..[for some years] years so it's nothing much for you to worry about. Kind of, for me it was indicating that, you know, HIV/AIDS would kill first so it wouldn't matter"*. [341]

148. **Mr AH** was still a child, in his early teens, when he developed AIDS causing physical illnesses but also mental distress including suicidal thoughts. As with others, he and his family experienced the negative consequences of the stigma attached to AIDS.[342]

(b) Haemophilia clinicians

149. There is considerable evidence of haemophilia clinicians objectifying patients, treating them with a lack of empathy, and not securing their consent to treatment, testing or research.

150. Thus, for example, in a letter written by **Professor Ludlam** to **Dr Craske** on 28 April 1980, accepting, an invitation to serve on the Hepatitis Working Party of UKHCDO, he stated: *"I am very conscious of the almost unique group of haemophiliacs we have in Edinburgh because they have never received commercial concentrate. They are therefore, as you are aware, <u>useful material</u> for a variety of studies in relation to liver disease."* [343] He described this in evidence as *"perhaps not the best wording"*.[344] But it was apt to convey the sentiment being expressed: for him these patients were objects, *"material"*, to be put to use for research. The contents of the infamous letter from January 1983 from **Professor Bloom** and **Dr Rizza** discloses a similar sentiment:

[340]Mr AH [WITN1006001][3/9]
[341] Mr AH [T/10.10.19/99/14-18]
[342]Mr AH [WITN1006001][7/32-35]
[343] Emphasis added. Professor Christopher Ludlam, [T.1.12.2020/111/19 – 113/21]
[344] Professor Christopher Ludlam, T.1.12.2020/111/19 – 113/21]

> *"Although initial production batches may have been tested for infectivity by injecting them into chimpanzees it is unlikely that the manufacturers will be able to guarantee this form of quality control for 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 is being reduced. The most clear-cut way doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates."*[345]

(As **Paul's** evidence demonstrates, that research was undertaken without patients' consent and put them at considerable risk.)

151. Further, samples were taken from patients and then stored and tested, sometimes for research purposes, without consent.[346] There is also evidence of a failure to secure ethical approval for research for which such approval would have been required (see, for example, "*The Aids Study*").[347]

152. Research was undertaken that contemplated the risk of injury. The **Rizza** research is such an example. As is the example of **Professor Ludlam** continuing to use blood products that he knew were associated with risk to "*monitor the immune status of patients*"; that is, to determine whether they got AIDS.[348]

153. **Professor Lowe**, when asked by Sir Brian, where he felt the ethical position fell between his duty to his patients and his interest in publishing research, **Professor Lowe** disagreed that a duty to the patients should take

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[345] Professor Bloom and Cardiff Haemophilia Centre , Inquiry Presentation - [T.24.9.2020/135/17 – 136/24]

[346]Professor Ludlam, [T.2.12.2020/80/13 – 84/18]

[347] No doubt **Kernoff resesearch same: Professor Tuddenham** discussed why **Professor Kernoff** at the Royal Free stored samples of patients' blood. He recalled: '*Peter told me straight off from the start why he was doing it… it was to track the potential effects of transmissible agents given to our patients. Because he also stored a sample bottle from every batch of concentrate that we used'*. He did not know whether these samples were ever tested. Professor Edward Tuddenham, [T22.10.2020/121/7 – 22 and 135/8 – 136/5

[348] Professor Ludlam, [T4.12.2020/82/22-23]

precedence, stating: *"I think the first duty of all the Haemophilia Centre Directors in Britain who sent samples, stored or unstored, usually without permission from the patient, was doing a time-tested emergency procedure in public health… to establish the extent of a new infection and take appropriate action to turn off the tap, to stop any further patients being infected."*[349] Leaving aside the point that this overlooks the fact that infected patients could potentially transmit a disease so informing them would also be in the interests of public health,[350] it is contrary to a patient's right to autonomy over their own body.

154. When tests were taken without consent and proved positive, there was often delay in providing results,[351] creating risk for loved ones and others. As **Professor McClelland** said when asked the question whether it was imperative that patients were informed without delay, "*I think the answer has to be… 'yes', and that if he had been a patient he would "have been very, very disturbed not to know about it. And as you say, the question of the risks of transmitting it to another person would alone, I think, have been a strong reason for providing information as soon as possible".*[352]

155. A general pattern of absence of consent to treatment, testing and research, then, emerged from the evidence before this Inquiry.[353] Assertions from witnesses from time to time suggesting otherwise, lack credibility.[354]

156. Further, evidence from clinicians that consent was routinely obtained lack credibility and/or misunderstand the concept of consent. Where evidence exists otherwise much of it is unconvincing (**Dr Ludlam** on the HCV first and second -generation tests performed sometimes on stored samples in

[349] Professor Gordon Lowe, [T10.12.2020/73/4 – 76/25]
[350] Professor Gordon Lowe, [T10.12.2020/77/10 – 78/7
[351]Professor Ludlam, [T2.12.2020/80/13 – 84/18].
[352] Dr Brian McClelland, [T.28.1.2022/53/19 – 55/8]
[353] Counsel to the Inquiry made a similar point. Presentation about the Belfast Haemophilia Centre, [T31.3.2021/4/19 – 5/5]
[354] Presentation about the Belfast Haemophilia Centre, [T31.3.2021/4/19 – 5/5]. In her written statement, Dr Mayne of Belfast Haemophilia asserts that all patients were told of the risk of viral infections associated with all blood and blood products.

1989 and early 1990 is such an example.).[355] In Counsel to the Inquiry's presentation on Belfast Maemophilia Centre, there is reference to **Dr Mayne's** evidence that patients' blood was checked at every visit, they accepted the purposes for which blood was being taken, and *"seemed happy to consent to these arrangements"* – demonstrating a complete misunderstanding (deliberately or otherwise) of the concept of consent. [356]

157. Numerous examples exist in the evidence of clinicians' failures to obtain meaningful consent to testing or treatment. The evidence from the Saunders CPs illustrates this too.

158. In any event, many clinicians giving evidence to this Inquiry, sometimes unapologetically, admitted testing without consent. **Dr Colvin** told the Inquiry that he did not always seek consent to test. For him, telling patients in advance that he was testing for HIV was impractical, speculating that it would be difficult to discuss the test with his 80 or so patients then bring them back again to discuss results.[357] **Professor Lee**, too, accepted testing for HIV and (although more equivocally) HCV, without patients' consent, using stored samples, [358][359][360][361] as did **Professor Tuddenham**.[362]

159. As to treatment, while some witnesses recognised that patients should have been told about treatment risk and provided with the opportunity to explore alternatives, [363] the evidence indicates that it was unusual to do so in practice. Again, the Saunders CPs provide evidence of this. Further, by way of illustration only, **Professor Preston** of Sheffield told the Inquiry he did not

[355] Professor Christopher Ludlam, [T4.12.2020/50/13 – 54/15]
[356] Presentation about the Belfast Haemophilia Centre, [T31.3.2021/3/9 – 25]
[357] Dr Brian Colvin, [T.7.10.2020/ 68/21 – 71/16]
[358] Professor Christine Lee, [T21.10.2020/63/23 – 66/3]
[359] Professor Christine Lee, [T21.10.2020/75/25 – 76/24]
[360] Professor Christine Lee, [T21.10.2020/78/21 – 79/20]
[361] Professor Christine Lee, [T21.10.2020/80/13 – 82/13]
[362] Professor Tuddenham, [T22.10.2020/10/24-11/11]
[363] Professor Francis Eric Preston, [T2.11.2020/49/6-17]

think he told his patients that factor concentrates might be exposing them to the risk of chronic liver disease, but he was not certain. He stated he *"perhaps should have told them"*.[364]

160. For some clinicians, adopting a patrician approach was positively the right one. According to **Dr Colvin**, "*the process of paternalism wasn't always completely disadvantageous because it took the responsibility of what happened next away from the unfortunate patient.*"[365] **Professor Lee** echoed **Dr Colvin** to some extent, when she suggested that there was nothing improper in not telling patients by the late 1970s or early 1980s that the treatment they were being offered carried a risk of NANB, a serious condition with long-term effects. She said, *"I don't agree with that… there was… a great, great unknown…. I think all patients should be given information… But it's very difficult giving information when the information itself is being debated, and it is not entirely clear what is happening"*.[366]

161. There is also evidence of a widespread and shocking lack of empathy demonstrated to patients. The Saunders CPs give evidence of this but additional examples can be found, including the letter from Dr Mayne in 1985 informing a patient that they would *"be glad to know"* that they had *"became positive sometime between February 1983 and October 1983"*. [367] Dr Mayne has since explained the use of the word *"glad"* as being in response to the patient saying that he would be glad if she could find out exactly when he was infected.[368] This is barely an explanation and certainly not an excuse.

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[364] Professor Francis Eric Preston, [T2.11.2020/49/2 – 13]
[365] Dr Brian Colvin, [T7.10.2020/194/5 – 195/19]
[366] Professor Christine Lee, [T20.10.2020/138/20 - 139/19]
[367] Presentation about the Belfast Haemophilia Centre, [T.31.3.2021/91/4 – 93/16]
[368] Presentation about the Belfast Haemophilia Centre, [T.31.3.2021/91/4 – 93/16]. She states that this was a communication of seroconversion dates rather than the positive test result itself, although the Inquiry has received evidence to the contrary

Part 3(iii) Treatment, Care and Support

Treatment

162. In the early years after hepatitis was identified, people with haemophilia were routinely infected with jaundice and HBV or acquired jaundice through treatment that was considered necessary to treat their bleeds. When treatment evolved from cryoprecipitate to factor concentrates in the 1970s, there was a strong sense that infection was all but an inevitable feature of treating haemophilia.

163. Early concerns about NANB in the 1970s emerged at a time when Factor VIII was regarded as the new *"wonder drug,"* providing vast improvements in the lives of people with haemophilia. At the beginning of the 1980s, at the first sign of AIDS, the improvements from Factor VIII treatment had already begun to bed in and become part of what was considered normal. Clinicians regarded themselves as beneficent in securing this new treatment for *"their"* patients, and hubris, stigma and to a limited extent in limited places, supply, meant that they were highly resistant to withdrawing the treatment even in face of fatal risk.

164. This Part explores the broader context in which decisions were made about treatment in particular cases having regard to the absence of national guidance and the predominantly accepted notion of dominance of *"clinical freedom."* This granted discretion to clinicians to treat as they chose and resulted in inexplicable and unjustified and unfathomable inconsistencies in treatment. This made treatment for patients almost a lottery.

165. As already discussed, the commitment to *"clinical freedom"* and the absence of centralised guidance meant that there was no demand or framework for ensuring consistency in treatment across the U.K. and between haemophilia clinics. **Dr Mitchell** of Leicester Haemophilia Centre, for example, gave evidence that he was required to formulate his own treatment policy because of an absence of any regional or national guidance and he described himself as *"professionally isolated"*

since the nearest haemophilia centre was 30 miles away.[369] Many of the decisions made about treatment were, no doubt in consequence of this, unfathomable or simply irrational.

166. Thus, **Professor Ludlam** in Edinburgh said that in the 1980s, he used a decreasing amount of cryoprecipitate and increased the use of factor concentrates because he wanted to give patients the benefit of home treatment.[370] He used commercial concentrate in specific circumstances where more plasma was required or where PFC concentrate was not suitable, for example because there was a shortage.[371] It appears that he preferred commercial concentrates. On the other hand, **Dr Mayne**, in Belfast, seemingly preferred commercial concentrate (and **Professor Ludlam** the reverse) since she entered into an agreement with **Dr Ludlam** in 1983 for him to provide her with commercial concentrate in return for her NHS concentrate.[372] It is unclear what **Dr Mayne** would have gained from the arrangement because she was giving up NHS concentrate in favour of commercial concentrate (with greater risk as she will have known).[373] By 1985, **Dr Mayne** was using concentrates supplied by Scotland. This would have been heat-treated to remove HIV (this did not reduce the risk of NANB, and Scotland was around 18 months behind England in introducing a product which was thought to destroy HCV). However, there was a further proposal to swap Scottish NHS product for commercial concentrate in 1988 when **Dr Mayne** commented: *"we will run down our usage of NHS material and gradually change the home treatment over to Profilate. It would be interesting to see the reactions of the patients to this change over"*.[374]

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[369] Dr Vivian Mitchell [T/18.11.20/15/18-16/7 and 88/6-12].
[370] Professor Christopher Ludlam [T/01.12.20/66/3-69/13].
[371] Professor Christopher Ludlam [T/01.12.20/68/5–71/15].
[372] Presentation from Counsel to the Inquiry on the Belfast Haemophilia Centre [T/30.03.21/108/19–109/2].
[373] Presentation from Counsel to the Inquiry on the Belfast Haemophilia Centre [T/30.03.21/109/12–25].
[374] Presentation from Counsel to the Inquiry on the Belfast Haemophilia Centre [T/30.03.21/112/5-117/8] Sir Brian noted that this suggests that patients were not told in advance and described this as "using the patients to an extent as guinea pigs."

167. Leeds hospital, too, appeared to prefer commercial concentrate since it was the predominate product used there from 1978 with patients receiving more than one type of concentrate.[375] In 1981, approximately three times as much commercial product was used as NHS and this ratio further increased the following year.[376]

168. Similarly, Alder Hey Children's Hospital's annual returns showed a marked change in 1982 when by far the largest treatment was Armour factor concentrate and this continued into 1983.[377] There was greater balance between NHS and commercial concentrate in 1984 but no cryoprecipitate used at all. Over 90% of the patients with haemophilia treated at Alder Hey during the relevant years tested positive for HIV, which one child's mother has described as being like a: "*conveyor belt of children dying*."[378]

169. This can be contrasted with Sheffield Children's Hospital, a smaller haemophilia centre. **Dr Lilleyman** from the Hospital said in his statement that cryoprecipitate was the treatment of choice for all but the most serious bleeds or surgery, particularly as the transmission of NANB started to appear.[379] He said: *"We in Sheffield realised pretty early on that there was a potential problem of virus transfer in blood products used for haemophilia, since non-A, non-B hepatitis was already recognised as a problem following the observation that abnormal liver function tests were not an infrequent finding in both adults and young boys with severe haemophilia."* [380] He referred to a study from the Children's Hospital published in 1980 which he said reinforced the view at the Children's Hospital that cryoprecipitate was a safer

[375] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/128/19–130/1].
[376] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/130/15–131/6].
[377] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/53/6–21]
[378] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/90/15–91/9].
[379] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/105/18–22].
[380] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/114/20–115/1].

product than Factor VIII.[381] Although the UKHCDO does not record any positive cases of HIV from the hospital, it appears that there is a document which suggests that one patient did test positive.[382] However, as Sir Brian observed there was: *"a pretty clear distinction between Sheffield and the other centres we've been considering"*[383] and as between Alder Hey and Sheffield: *"They may be separated only by a few miles in the Pennines, but they're worlds apart… over 90% of children, some brothers from the same family, dying of infection with HIV in Liverpool, and probably one only being – seroconverting in Sheffield."*[384]

170. The annual returns for Bristol Haemophilia Centre, both Bristol Children's Hospital and Bristol Royal Infirmary, showed a range of different commercial concentrates being used from 1976, at the latest, with patients receiving more than one type of commercial concentrate.[385] Until 1982 around three times as much commercial concentrate was used as NHS, but from 1982 to 1984, NHS concentrate was used in greater quantities than commercial.[386] A letter sent by **Dr Scott** to a patient in October 1983 is instructive:

> *"As I am sure you know one of the patients attending the Bristol Haemophilia Centre has recently died of AIDS… There is reason to believe that the source of the infection in this case was imported Factor VIII concentrates but this is not proven and it cannot be said with certainty that these were the source of infection. I can understand that you are extremely worried that you have contracted a similar condition by using imported blood products. However, I would like to make it*

[381] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/115/2–13].
[382] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/119/21–25].
[383] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/16.06.21/121/3–5].
[384] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/102/24–104/2].
[385] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/170/5–13].
[386] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/178/1–15].

clear that the risk of this is extremely small… As far as possible we are avoiding the use of imported Factor VIII concentrates but there is not enough NHS produced Factor VIII available at the moment to meet our needs… In the meantime I think that the dangers of refusing treatment if only commercial concentrate is available is greater than the danger of contracting AIDS."[387]

171. **Dr Prentice** from Plymouth Haemophilia Centre, in his witness statement, suggested that they had to opt for what was available and as such did not have a choice of product and patients were not given a choice either. **Dr Prentice** stated that he wanted to avoid large pool products and recalls a difference in the risk of NHS and commercial concentrates. He tried to avoid blood products altogether when possible because he: "*was taught that a pint of blood is a potential biological time bomb"*[388]. As a result, he would use Factor VIII for patients with severe haemophilia, cryoprecipitate for those with moderate haemophilia unless it was a severe bleed, and DDAVP or cryoprecipitate for more mild haemophilia. [389]

172. Annexed to these submissions is an annex prepared from evidence collected by the Inquiry on smaller haemophilia centres. It shows that leading up to and at the start of the early 1980's, there was increased use of commercial concentrate with usage often peaking at or around 1982-1984. This coincides with the emergence of AIDS. There also appears to be a correlation between the increased use of factor concentrates and fatalities after infection with AIDS. The rare centre that used significant amounts of cryoprecipitate, namely Stoke on Trent Haemophilia Centre, seems to have had relatively few fatalities from AIDS infection. Use of predominantly NHS concentrates also seems to correlate with fewer AIDS infection and fatalities.

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[387] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/17.06.21/187/16–188/18].
[388] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/7.10.21/102/8-10].
[389] Presentation from Counsel to the Inquiry on the smaller Haemophilia Centres [T/7.10.21/ 101/ 1 – 105/ 13].

173. **Professor Hay** of Royal Hallamshire noted that in 1996 it became the policy of UKHCDO to recommend recombinant for all patients, but he described the DHSS' reluctance to fund the treatment. When they did agree to provide funding, this was limited to patients under 18 to *"allay the concerns of parents"* rather than (purportedly) on grounds of safety. [390]

Haemophilia doctors

174. In addition to the broader institutional patterns, individual doctors took different views about the right approach and about the imperatives, impetuous or obstacles to using particular products. Below are some examples.

175. In his evidence to the Inquiry, **Dr Winter** of Kent Haemophilia Centre said that he regarded cryoprecipitate as essentially obsolete by May-June 1984 when he switched to heat-treated concentrates.[391] He agreed that cryoprecipitate was clinically efficacious with transient side effects, yet argued it was not considered a realistic option.[392] Regarding the relative viral infection risks of cryoprecipitate compared to concentrate, he stated: "*In theory because cryo might come from ten donors and the concentrates come from 20,000, there were these theoretical risks.*"[393]

176. **Dr Colvin**, of Royal London Hospital, accepted that the risk of being infected with HIV from cryoprecipitate was *"far, far"* smaller than from concentrates, but sought to marginalise that increased risk by suggesting that there was almost an inevitability of becoming infected with HCV with the use of cryoprecipitate[394] and further you may get a bigger dose from infected cryoprecipitate, as compared to concentrate, creating a greater risk of serious illness. [395] However, he accepted that

[390] Professor Charles Hay [T/04.11.20/130/2–132/12].
[391] Dr Mark Winter [T/01.10.20/143/3–18].
[392] Dr Mark Winter [T/01.10.20/94/22–96/23].
[393] Dr Mark Winter [T/01.10.20/31/15-17].
[394] Dr Brian Colvin [T/06.10.20/130/19–131/2 and 74/7-16].
[395] Dr Brian Colvin [T/06.10.20/131/3–16].

no risk analysis was undertaken comparing the risks and it did not occur to him to offer patients the option of cryoprecipitate on an individual basis.[396] Instead he said that it was not a *"realistic option"*.[397] Despite consensus by the end of 1984 that heat treated product was safer, **Dr Colvin** made clear his intention to continue using up existing unheated stock. This was explained on the basis of a lack of confidence that heat-treated concentrate would prevent HIV infection.[398]

177. The shift from cryoprecipitate to home therapy concentrates was explained by **Professor Tuddenham** in terms of practicality, convenience and efficacy. When asked what consideration was given to its relative safety, he acknowledged that they were aware by 1978 that donor pool size increased the chances of contracting blood borne hepatitis and: *"whatever transmissible agents they may be carrying"*.[399] However, he stated that: *"We had already encountered hepatitis in subjects who'd received hundreds by the time they'd been on cryoprecipitate regularly… so switching to a product which perhaps in the way, rather naive way, we considered it, oh well, they've already been exposed, this is not going to change that"*.[400]

178. When discussing the market value of Factor VIII and commercial incentives, **Professor Tuddenham** observed sharply: "*Did it overwhelm the safety issues? Well, when one looks at the sort of headlong rush to make more Factor VIII, getting the plasma from wherever or whoever, in those days of the late 70s, early 80s, I think it's fair to say that a commercial incentive did overwhelm the safety issues, yes*".[401]

179. **Professor Franklin** at Birmingham Haemophilia Centre diverged from other clinicians who have described a choice between life-saving treatment to prevent cerebral haemorrhage and the risk of treatments with concentrates. He instead framed this choice as involving *life-enhancing* rather than *life-saving treatment*: *"The long-term effect of even these bleeds in some of the survivors that we did have was pretty*

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[396] Dr Brian Colvin [T/06.10.20/132/4–19].
[397] Dr Brian Colvin [T/06.10.20/127/14–24].
[398] Dr Brian Colvin [T/07.10.20/ 209/4–210/7].
[399] Professor Edward Tuddenham [T/22.10.20/20/22–21/13].
[400] Professor Edward Tuddenham [T/22.10.20/21/16–24].
[401] Professor Edward Tuddenham [T/22.10.20/131/15–20].

devastating in terms of arthritis, employment prospects, personal relations, education. But I was always slightly suspicious about the idea that if we didn't carry on using concentrate -- and I did carry on using concentrate -- that if that was stopped then suddenly many, many, many, many people with haemophilia would have died…but, I have to confess, you know, I went with the -- I was at the meeting when Professor Bloom said you should carry on with concentrate and that's what I did." [402]

180. **Professor Preston** of Sheffield stated that even after his seminal article was published in 1978 which showed that NANB was a serious disorder, he did not consider different treatment or the reversion to cryoprecipitate because: *"it was impossible to achieve satisfactory levels of Factor VIII with cryoprecipitate for seriously affected patients"*.[403]

181. **Dr Aronstam**, Treloar's centre's director, received the letter sent by **Professor Bloom** in June 1983 recommending the policy that children who were mildly affected patients, or patients unexposed to imported concentrates, should be treated with NHS concentrates or cryoprecipitate. There does not to appear to have been any change in policy introduced, however. [404] An explanation for that may lie in the letter from **Dr Aronstam** in June 1983 in which he refers to "*the current hysteria about AIDS*" and "*the very small risk numerically of [the patient referred to] acquiring the disease.*"[405] In the same letter **Dr Aronstam** mentions a patient showing characteristics of AIDS. [406] Further, **Dr Aronstam** was noted in a meeting with Speywood in 1978 to say that his first requirement when choosing a product was convenience.[407] By 1980, the centre was using roughly nine times as much commercial concentrate as NHS concentrate, with patients still receiving multiple commercial concentrate

[402] Professor Ian Franklin [T/27.10.20/138/17–140/7].
[403] Professor Francis Eric Preston [T/02.11.20/48/6–49/1].
[404] Presentation from Counsel to the Inquiry about Treloar's [T/24.06.21/132/2–25].
[405] [TREL0000143_058]. See also Presentation from Counsel to the Inquiry about Treloar's [T/24.06.21/143/19–144/8].
[406] [TREL0000143_058]. See also Presentation from Counsel to the Inquiry about Treloar's [T/24.06.21/139/7–140/21].
[407] Presentation from Counsel to the Inquiry about Treloar's [T/23.06.21/126/16–128/17] .

brands.[408] In 1982 and 1983, there was no treatment with cryoprecipitate for patients with haemophilia at all and the vast majority of treatment was still with a variety of commercial concentrates.[409] Increased volumes of NHS product were used in 1984, but substantial volumes of commercial concentrates were still being used and a number of patients were receiving two, three or four types of commercial concentrate as well as the NHS concentrate. The annual returns also show a significantly larger volume being used on each patient in 1984, which reflects prophylaxis being a regular feature of treatment of the students.[410] **Dr Aronstam's** policy was also to treat bleeds "*vigorously*".[411] Thus (adopting the words of Sir Brian): "*in 1984, when the events were happening that you've described elsewhere, and other centres, some other centres, might have been adjusting their treatment policies, this Centre* was *very significantly increasing the amount of concentrate of one form or another given to its patients.*"[412]

182. The evidence indicates that a lack of capacity to produce or supply cryoprecipitates was commonly given as a reason for persisting with Factor VIII. **Professor Contreras** of North London Blood Transfusion Centre (NLRTC) confirmed that the NLRTC had the capacity to increase the production of cryoprecipitate in 1983/84 as an interim measure in response to the AIDS crisis, but they were not asked to do so. She could not recall discussing the possibility with the DHSS or with the Haemophilia Centre Directors.[413]

183. **Dr Hewitt** (also of NLRTC) confirmed that cryoprecipitate could be produced on demand and that there was no real limit on production. She further stated that if clinicians asked them to produce more, then they would have done so. In her oral evidence, she agreed that there was nothing to

[408] Presentation from Counsel to the Inquiry about Treloar's [T/21.06.21/62/19–64/4] .
[409] Presentation from Counsel to the Inquiry about Treloar's [T/21.06.21/69/9–77/14].
[410] Presentation from Counsel to the Inquiry about Treloar's [T/21.06.21/78/19–80/17]
[411] Presentation from Counsel to the Inquiry about Treloar's [T/23.06.21/141/1–19]
[412] Presentation from Counsel to the Inquiry about Treloar's [T/21.06.21/83/23–84/6]
[413] Professor Dame Carmen Marcela Contreras, [T/02.12.21/149/19–150/12]

prevent the processing of cryoprecipitate at the Centre and that there was no reason why she could not have just diverted plasma to cryoprecipitate.[414] This is in stark contrast to the evidence of **Dr Walford** that increasing cryoprecipitate production would take time.[415]

184. **Dr Wagstaff**, director of Sheffield Regional Blood Transfusion Centre,[416] agreed they would have been able to provide enough cryoprecipitate to meet demand by taking on extra staff and making changes such as shift work. When asked how quickly they could have made those changes, he responded: "*probably in terms of weeks rather than months we could have done a significant increase in the production*".[417] However, he stated that Haemophilia Centre Directors "*were quite clear in their own preferences*" and "*did not really want us to make any extra effort to make more cryoprecipitate*".[418] He thought that: "*both the Haemophilia Centre Directors and their patients felt that at the time, on the evidence that was available, the advantages of treatment with concentrate far outweighed their mainly theoretical disadvantages*".[419] **Dr Wagstaff** stated: *"We did use our best endeavours to try and persuade them that we could have been more comfortable with a greater use of cryoprecipitate or certainly a way of finding less use of American imports, but they just wanted to carry on pretty much as they were".*[420] Those endeavours were "*face to face discussions, presenting them with such figures as were available with regard to the more than theoretical possibility of transmission of not just the HIV virus but other viruses as well*", recognising that he viewed cryoprecipitate as a safer product.[421]

185. **Dr McClelland** stated that he had no recollection of any haemophilia directors or the Scottish Home and Health Department asking him to increase

[414] Dr Patricia Elizabeth Hewitt [T/09.12.21/44/18–46/3]
[415] Dr Diana Marion Walford [T/20.07.21/178/8–182/16]
[416] Director, Sheffield Regional Blood Transfusion Service (1974-95) and Director, Northern Zone of the National Blood Service (1995-98) and other roles.
[417] Dr Bill Wagstaff [T/25.01.22/47/14–48/15].
[418] Dr Bill Wagstaff [T/25.01.22/54/14–55/7].
[419] Dr Bill Wagstaff [T/25.01.22/55/8–20].
[420] Dr Bill Wagstaff [T/25.01.22/55/21–56/11].
[421] Dr Bill Wagstaff [T/25.01.22/56/17–57/11].

production for a short-term reversion to cryoprecipitate. **Dr McClelland** stated it would have been possible to scale up production and produce large quantities of cryoprecipitate and: "*if it had… felt sufficiently important to allocate an appropriate amount of finance, it could have been done very quickly*".[422]

186. In a 1976 BMJ article, **Professor Cash** expressed the view that: "*enough evidence shows that cryoprecipitate can be used successfully for home treatment.*[423] At a meeting of the Haemophilia and Blood Transfusion Working Group in March 1981, he is recorded as saying: "*the majority of home therapy patients had no problems when using cryoprecipitate*".[424] However, in a document prepared on 29 November 1990 for the HIV litigation, he stated that: "*Cryoprecipitate was very unpopular with some patients: for some of the reasons you have given but also the higher incidence of allergic reactions when compared to [Factor VIII].*"[425]

187. There was then no consistency as to the treatment provided to people with haemophilia. Despite the fact that, as was broadly accepted, Factor VIII was known to increase the risk of virus transmission (HIV and HCV in particular), there was no consistent effort to address this by a reversion to cryoprecipitate and no central guidance directing when cryoprecipitate should have been used and conversely when cryoprecipitate should not have been used. Treatment was a lottery and put people with haemophilia at considerable risk, just as occurred with the Saunders CPs.

188. The absence of any system for ensuring the safe delivery of treatment having regard to risk gives rise to issues that fall within the scope of Articles 2, 3, 8 and 14, ECHR, and the ICESCR to take appropriate action to secure the health of people with haemophilia, safeguard lives and protect against the risk

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[422] Dr David Brian McClelland [T/27.01.22/131/4–132/7].
[423] [PRSE0003425] See also Presentation from Counsel to the Inquiry on Professor John Cash (deceased) [T/10.11.21/127/4–129/15].
[424] [SBTS0000382_008] See also Presentation from Counsel to the Inquiry on Professor John Cash (deceased) [T/10.11.21/66/2–68/2].
[425] [SBTS0000053_055] See also Presentation from Counsel to the Inquiry on Professor John Cash (deceased) [T/10.11.21/46/23 - 47/5].

of degrading and inhuman treatment, loss of bodily autonomy and dignity, and the risk of discrimination.

189. The administering of products without consent that were known to carry unjustified risk or enhanced risk, including to the Saunders CPs, fell directly within the scope covered by Articles 2, 3, 8 and 14, ECHR and the ICSER.

Care and Support

190. The regime for care and support that followed the infection of thousands of people with haemophilia with HCV and HIV was wholly inadequate. As already described the immediate response to the discovery and disclosure of an infection in the case of an individual was generally harsh and unempathetic.

191. As to the broader systems for delivering care and support, these comprised almost exclusively financial assistance schemes. The introduction of these schemes by Government was largely motivated by the need to acknowledge public sympathy for those people infected, but at the same time to avoid any hint of an admission of legal liability and to keep the costs of any assistance package to the minimum. For these reasons, the schemes avoided the use of the word *"compensation"* which might imply some fault or blame.

192. The intuitive resistance of some of those operating within haemophilia services to compensation awards is best captured by the evidence of **Professor Lee** who described herself as "*irritated*" with patients making such demands:

> *"… What I don't like about like about the idea is the idea of compensation, because what compensation does, it suggests liability, and I truly believe that people at that time were doing what they thought was the best, and the side effects were really not at all clear, and certainly HIV was a tragedy that nobody could have foreseen… I think what I was irritated about was that I had not been able to explain*

or convince people that what we did was in good faith, if you like. For the knowledge at the time… the idea that we would, anyone who is a decent person, would give somebody some treatment that they knew would cause harm is frankly ridiculous. And it's actually quite hurtful for those people, those many people, who cared for patients."[426]

193. Just as intuition, hurt feelings and a belief in the ingratitude of patients informed the response of some clinicians to compensation, so some of those involved in administering the schemes operated on a gut instinct that the media would not welcome too much generosity. Thus, **Mr Stevens**, trustee of the Macfarlane Trust from 1988-1992[427], though critical of the Government in its approach to the schemes, considered that lump sums of £20,000 paid out of the first special payment trust should be taken into account if and when registrants made future requests for financial assistance. He justified this by applying what he called *"the Daily Mail test"*, stating *'how would it look to the readers of The Daily Mail if they discover that this group of people were being given £20,000 and were then also being given other money from the same source, the taxpayer, that did not take account of the £20,000?"*[428] .

194. Apart from providing a context for highlighting again the lack of empathy towards people infected and affected, by those from whom empathy might be properly expected, the schemes are important too for the Saunders CPs' submissions, for three reasons. Firstly, the institutional arrangements for the Trusts were such that they lacked independence from Government and thus the ability to make objective decisions. Secondly, the way in which trustees carried out their functions in relation to intended beneficiaries was often paternalistic, judgmental and affected by stigma. Thirdly, if the schemes had been adequate,

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[426] Professor Christine Lee [T/21.10.20/157/18–158/18 and 161/1-5].
[427] *Chair of the Macfarlane Trust from 2000-2007, Chair of the Eileen Trust from 1999-2017, Chair of the Skipton Fund from 2003-2017 and Chair of the Caxton Foundation 2011-2013.*
[428] Peter Stevens [T/23.2.21/32/6-10]. Although ultimately his view did not prevail: [T/23.2.21/32/19-22].

they might have met the State's obligations under Article 13, ECHR to provide an effective remedy for violations of the ECHR rights: they did not.

195. Firstly, much of the work of the Trusts, even when established as charitable, was acting upon, even if informally, Government's direction or at least influenced by what it thought the Government would favour or disfavour. Thus, **Ms Hithersay** gave evidence in her witness statement that:

> *"We simply administered the fund that the Department of Health had given to us. We had no independent existence as an organisation or a charity. In common parlance we were a quango, carrying out work on behalf of the Department of Health. As I have explained above, the Macfarlane Trust had been set up to administer a Government fund and nothing more."*[429]

196. **Ms Hithersay** (who, as with other trustees who gave evidence, self-evidently had no understanding of her duties as a trustee) explained that: "*having worked in charities for a large part of my life before that, this was a very different set-up… I certainly think that the Trustee Board when I joined very much felt that we were administering a fund that had been provided by Government through the Department of Health*".[430] There was, then, for example, no campaigning aspect to the work undertaken by the MacFarlane Trust: *"we were administering the fund on behalf of Government, and… no liability had ever been admitted by Government, and our role was very specifically to administer the funds for the benefit of the beneficiary group"*[431].

197. **Ms Barlow** gave evidence that while both Macfarlane and Caxton were independent of Government and the DHSS, *"you can't get away from the fact that the Department of Health was the sole funder for those organisations and, therefore, you know, the Department of Health could exert a certain influence by virtue of the amount of the*

[429] Ann Hithersay [WITN3206002] [50/138]
[430] Ann Hithersay [T/25.2.21/108/20-109/1].
[431] Ann Hithersay [T/25.2.21/145/25-146/4].

money that it allocated."[432] Further, while she stated that the DHSS did not have any involvement on a day-to-day basis in terms of decisions, *"the fact that there was a – you know, the Department controlled the funding and it controlled the number of staff, it effectively meant that, if you like, the subtext was that the funding we received was to be channelled to beneficiaries, not for some of the activities that you might see in an organisation which, if you like, had a different foundation."*[433] **Roger Evans** accepted that he may well have described the MacFarlane Trust as *"an arm of Government 'whether we like it or not'"*,[434] with the DHSS having some expectation of *"loyalty"*.[435]

198. Doing the Government's bidding in the way described is obviously contrary to trustees' obligations in charity law, but for the Saunders CPs' purposes it also demonstrates a dysfunctionality at the heart of the Trusts. They were not truly *there* for beneficiaries. They were *there* to meet the desire of Government to do something to meet public concerns about the circumstances of those people infected and affected, and, ultimately, cynically, to avoid litigation. And the Trusts very much saw themselves in that way.

199. The first special payment trust (MSPT1) that was established to award the sum of £20,000 to beneficiaries was *"an attempt to buy people off"*,[436] as **Mr Stevens** said in evidence. It was also *"ludicrous[ly]"* underfunded[437] but nevertheless it was administered by the MacFarlane trustees (albeit through a different vehicle): there does not appear to have been any resistance to doing so.

200. In relation to the second payment set up pursuant to the settlement agreement in the HIV litigation, MSPT2, **Mr Stevens** gave evidence that, as is known, nobody would receive a payment without signing a waiver (that is, *"of*

[432] Jan Barlow [T/2.3.21/17/3-7].
[433] Jan Barlow [T/2.3.21/24/19-25].
[434] Roger Evans [T/4.3.21/68/9-12].
[435] Roger Evans [T/4.3.21/79/23-80/1].
[436] Peter Stevens [T/23.2.21/23/11-12].
[437] Peter Stevens [T/23.2.21/25/5-6].

litigation rights"[438]) including in relation to hepatitis infection. As **Mr Stevens** said, "*there was not parity of knowledge*"[439] and accordingly beneficiaries *"did not know about the risk of hepatitis"*.[440] They were required to sign away their legal rights without being informed of the extent of the rights that they were signing away. When asked whether he had *"any qualms or concerns about the fairness or morality of the waiver requirement"*, he answered *"I don't recall protesting or observing to the Department officials, let alone the politicians, that there was something wrong here. We just did what we were told."*[441]

201. Secondly, the way in which the trustees carried out their functions in relation to intended beneficiaries was arbitrary, hostile and demeaning. Decisions were often made without any principled basis for determining outcome (*"I was simply, as it were, on my own, a free agent doing- giving- making such decisions, giving such judgement as seemed to be right really as an individual"*[442]). They generally operated remotely from those they were intended to serve. Thus, the MacFarlane Trust kept confidential its address (using a PO Box Number[443]). It is not clear why, but the most credible explanation was posited by **Mr Stevens** as a possible explanation, namely *"to keep away unwanted callers"*. [444] Potential beneficiaries were not granted access to documents they sought (the charitable deed and objects[445]). At Caxton, while **Mr Lister** said that the trustees wanted better communication with beneficiaries *"it kept going down the priority list."*[446] Beneficiaries were also treated as though they could not be trusted: that they would not have the same degree of professionalism and objectivity as a person appointed by the DHSS having worked in its blood policy unit (**Mr Lister**[447]).

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[438] Peter Stevens [T/23.2.21/33/16-22].
[439] Peter Stevens [T/23.2.21/35/19].
[440] Peter Stevens [T/23.2.21/35/18].
[441] Peter Stevens [T/23.2.21/35/20-36/1].
[442] Peter Stevens [T/23.2.21/7/18-21].
[443] Peter Stevens [T/23.2.21/18/6-8].
[444] Peter Stevens [T/23.2.21/18/13-15].
[445] Peter Stevens [T/23.2.21/19/23-20/4].
[446] Charles Lister [T/25.3.21/154/15-17].
[447] Charles Lister [T/25.3.21/137/1-139/24].

202. Applications were routinely required to be processed through local haemophilia centres resulting in *"an element of post code lottery"*[448] since some were better than others at providing support in approaching the Trusts. Awards were made following demeaning means testing about which there was widespread resentment.[449]

203. The trustees of the MacFarlane Trust, in particular, were derisory about, and disrespectful to, intended beneficiaries, reflecting the culture of the institution itself. Thus, correspondence between two trustees of the MacFarlane Trust (**Mr Clarke and Mr Stevens**) referred to beneficiaries as *"the great unwashed"*[450] - something, even now, **Mr Stevens**, one of those trustees, regards as only *"probably"* an *"inappropriate term."*[451] **Mr Stevens** himself used the word *"thick"* in describing a beneficiary who had written to him,[452] offering the explanation that the beneficiary had *"probably just tried [his] patience"*.[453] He referred to the Partnership Group as *"a monumental waste of time"* and the beneficiaries participating in it as *"that lot of moaners"*.[454] These were, as with other examples explored in evidence, grossly offensive and contemptuous remarks about beneficiaries.

204. Further, the way in which the Trusts managed funds and applications lacked generosity,[455] compassion and empathy,[456] and the trusts lacked a culture of kindness.[457]

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[448] Peter Stevens [T/23.2.21/17/16-17].
[449] See for example, Peter Stevens [23.2.21/19/3-8].
[450] Peter Stevens [T/24.2.21/29/12-13].
[451] Peter Stevens [T/24.2.21/30/11-12].
[452] Peter Stevens [T/24.2.21/33/2-7].
[453] Peter Stevens [T/24.2.21/37/2-9].
[454] Peter Stevens [T/24.2.21/37/10–25].
[455] Ann Hithersay [T/25.2.21/40/1-3].
[456] Susan Daniels [T/10.3.21/43/7-8].
[457] Susan Daniels [T/10.3.21/99/20-22].

205. Beneficiaries who were ill and applying for funds were made to *"go through hoops to get … a simple grant."*[458] This was not always due to a lack of actual, or potential (that is, if the trustees had asked Government for more), funds.[459] Trustees simply lacked on understanding of the lives of people infected and affected.[460]

206. Thus, **Paul** (one of the Saunders CPs) described in his witness statement that seeking assistance from the MacFarlane Trust was tantamount to a begging bowl.[461] He said that he had to justify any application: *"All funding was linked to rules and restrictions that didn't seem to fit my lifestyle. The money was there because of financial hardship: to have to jump through hoops to justify hardship and then be restricted by their regulations never sat well with me."*[462] **Mr AK** described the MacFarlane Trust at times as *"unfair and discriminatory"* and as "*underfunded and poorly run.*"[463] **Robert** generally avoided applying for one off grants, as he *"disliked the system so intensely"*.[464] These were those for whom these trusts were supposed to be assisting.

207. The stigma attaching to those people with haemophilia who were drug users affected the approach of the Trusts in determining whether to make an award. Thus, for the Skipton fund, evidence of intravenous drug use would result in an automatic refusal of an application. This was because, as it was expressed: *"Do you like your tax money being given to somebody developed Hep C through intravenous drug abuse?"*[465]

208. Thirdly, the sums awarded did not amount to an effective remedy. They simply did not account for loss (see Part 2: The Law).

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[458] Susan Daniels [T/10.3.21/48/19-20].
[459] Ann Hithersay [T/25.2.21/42/5-15]; Susan Daniels [T/10.3.21/43/8-11].
[460] Susan Daniels [T/10.3.21/26/7-19 and 45/8-10].
[461] Paul [WITN1003001] [23/63].
[462] Paul [WITN1003001] [23/63].
[463] Mr AK [WITN1005001] [12/52]
[464] Robert James [WITN1004001] [40/89]
[465] Peter Stevens [T/24.2.21/113/10-11].

Part 3(iv): Accountability

Introduction

209. Almost all the key actors involved in the matters explored by this Inquiry were employees or agents of the State. The State therefore bears responsibility for their acts. Where those acts violated the human rights of an individual (reflected in those rights conferred by an international or regional human rights instrument), then the State must be accountable as a matter of ordinary principle. The relevant human rights norms are found in the ICESCR, the CRPD and the ECHR (Part 2: The Law).

210. In the case of private actors, the State may bear responsibility for their acts where a positive obligation arises under international human rights law to take steps to safeguard the rights guaranteed. These matters are addressed in Part 2 (The Law).

211. In summary, this is an area where the State would be responsible for direct serious violations of Articles 2, 3, 8, 13 and 14. This is so also where (a) it failed to put in place proper apparatus or institutional arrangements regulating the activities of pharmaceutical companies and ensuring the safety of commercially produced Factor VIII (b) it failed to take steps to address the stigma and prejudice surrounding those with HIV, creating an environment that was hostile and resulting in harm to them.

212. Additionally, the Governments in place at material times bear political responsibility for the matters that have been the subject of this Inquiry and in a modern, liberal democracy that is an important responsibility. Thus, **Lord David Owen** acknowledged, as he was bound to do, that while the CMO was responsible for advising on clinical matters or safety, the Secretary of State retained political responsibility for decisions for the judgement exercised by

the CMO.[466] Again as he was bound to do, **Lord Owen** accepted that as *"a matter of principle"* it is *"one of the first duties of the State to look after the safety of its population"* and *"that would extend to the safety of patients receiving blood or blood products"*.[467] However, it is not clear that the impact of the political responsibility was always understood. He did not, for example, expressly address Parliament on the dangers of imported concentrates or the risk of viral transmission. When asked about this, he said:

> *"We were still carrying on buying this blood and we were putting it into people's veins and we were utilising it and we knew we were going to have to go on doing that for at least two to three years. Until self-sufficiency took place, we weren't going to be able to stop it being used… I didn't want secrecy but I didn't want to create fear in people who were having it. That's not my job… It is very, very difficult to determine how much you should say to people."*[468]

213. In other words, the desire to reassure – no doubt a compelling political imperative -took precedence over transparency. Any disclosure that had to be made, he regarded as one to be addressed at individual level though, as described below, no steps were taken to ensure that clinicians gave appropriate advice as to risk.

(a) The Department of Health and Social Security (DHSS)

214. The DHSS bore institutional responsibility for the safe delivery of health care. Within the DHSS, the CMO and medical divisions in general had the responsibility of ensuring that patients were informed of risks concerning communicable diseases (a public health issue). However, according to **Dr**

[466] Lord David Owen [T/22.9.20/155/7-12]. See too the evidence of Dr Walford [T/21.7.21/193/22-25] She stated that the Secretary of State for Health had ultimate responsibility for ensuring safe delivery of NHS treatment in the late 1970s and early 1980s.
[467] Lord David Owen [T/22.9.20/170/6-12].
[468] Lord David Owen [T/22.9.20/61/4-22].

Walford[469] they *"did not issue specific clinical advice"*[470] and *"[providing information to patients] wouldn't have been at all for the Department but it would have been for the Haemophilia Centre Directors."*[471] Instead, *"the Department would sometimes put out press releases or put out warnings… on the question of AIDS and what Haemophilia Centre Directors and haemophilia treaters might have been saying to their patients… none of us knew the extent but we knew that there was a hazard there, and so Haemophilia Centre Directors were well aware of that."*[472] As **Dr Walford** put it: *"I think the Department took the view that these were -- this was clinical material which doctors ought to make themselves aware of through their own reading or their own studies or they should be made aware of them through their specialist societies... We would not have been describing this to patients -- to doctors directly."*[473]

215. As to imported concentrate, once the risk of an association between Factor VIII and NANB and then AIDS began to emerge, there was, then, it appears, no advice given by the CMO or by others in the DHSS suggesting, and less so directing, that clinicians not rely as heavily on imported concentrate, and should consider more widely the use of cryoprecipitate.[474] This was so though the risk was well understood early on, as has been explored in Part 3(i) of these Submissions. Thus, in a document authored by **Dr Walford** at the beginning of 1980, she stated that: *"the risk of obvious post-transfusion [hepatitis B virus] infection remains greater for certain pooled plasma derivatives than for single donations... Partly this high infectivity may be explained by the fact that these fractions are often prepared from paid-donor plasma... positivity is 10 times that in plasma from a non-commercial source."*[475] **Dr Walford** agreed in

[469] Principal Medical Officer (1979-1983) and a Senior Principal Medical Officer (1983-1986, 1987-1989) and other roles in the Department of Health and Social Security.
[470] Dr Diana Walford [T/19.7.21/50/18-19].
[471] Dr Diana Walford [T/21.7.21/65/20-22].
[472] Dr Diana Walford [T/19.7.21/52/12-53/10].
[473] Dr Diana Walford [T/19.7.21/118/25-119/8].
[474] Lord David Owen [T/22.9.20/42/7-13].
[475] Dr Diana Walford [T/19.7.21/99/13-25].

evidence that there was a general understanding that the larger the pool size, the greater the risk.[476]

216. In the case of AIDS, once there an identifiable risk, the DHSS (through the CMO) ought to have issued urgent warnings and taken immediate steps as the precautionary principle requires.[477] Instead, as with so many others, the DHSS downplayed the risk and took no steps to promptly address it. **Dr Walford** became aware in 1981 of reports of AIDS in homosexual men in the U.S. and recalled reading about the *San Francisco baby* case in late 1982 or early 1983. She described this as "*instrumental in [her] feeling that it was likely that AIDS was transmissible through blood, as well as through sex.*"[478] When asked whether she was aware in early 1983 of anyone within the Department voicing a markedly different view, she responded, "*I think there was a degree of not necessarily scepticism but reticence amongst UK Haemophilia Centre Directors that this was potentially transmissible, but actually in the Department I don't recall anybody saying 'no, no, it's absolutely obvious that it isn't.'*"[479] In fact, that "*reticence*" was shared by **Dr Walford**. A minute from January 1983 recorded that: "*Dr Walford has confirmed that the value to severe haemophiliacs of clotting factors 8 and 9 far outweigh the possible and as yet unproven hazards of the transmission of acquired immune deficiency syndrome.*"[480] When asked whether on reflection she should have expressed herself in such strong terms given the high mortality rate, she responded, "*I must have spoken in quite definite terms that actually this disease is awful and haemophilia, so is AIDS of course, but haemophilia is a dreadful disease and they desperately need their Factor VIII and Factor IX. I will obviously have said that. He is reporting it in his words not necessarily mine, but I don't resile from the sentiment at all.*"[481] **Dr Walford** further stated:

[476] Dr Diana Walford [T/19.7.21/108/2-5].
[477] Medical Ethics Expert Group [T/26.1.20/91/5-24].
[478] Dr Diana Walford [WITN4461002] [169-170/71.2].
[479] Dr Diana Walford [T/20.7.21/123/20-25].
[480] Dr Diana Walford [T/20.7.21/130/10-14].
[481] Dr Diana Walford [T/20.7.21/134/19-135/1].

> *"What I would have thought was we have no evidence -- this hasn't happened in the UK... There's significant controversy as to what's causing it and relatively of course few people with haemophilia in America had actually developed the disease… What I did know about severe haemophilia was that the main cause of death from haemophilia was still bleeding… so from the perspective of not having any cases in the UK, not understanding the genesis of the illness truly, a lot of controversy... And the notion that on the other hand severe haemophilia was a dreadful disease and basically they needed their Factor VIII… I still believe that, at that time, the hazards were unproven of transmission and basically what one knew was that the severe haemophiliacs desperately needed Factor VIII or Factor IX."*[482]

217. Much of the source of **Dr Walford's** information on risk came from UKHCDO or Reference Centre Directors[483] so it perhaps no surprise that she adopted this approach. In particular, she stated that **Professor Bloom** "*ought to have been able to represent to [the Department] the views, insofar as they were aggregable, of the UK Haemophilia Centre Directors*",[484] and it appears that it was this upon which they relied. When asked whether she or her medical colleagues in the DHSS ever considered challenging how haemophilia clinicians thought matters should be addressed, **Dr Walford** responded: "*in terms of clinical matters, it would not have been (a) appropriate, (b) nor did I have the expertise and nor did I, as far as I can remember, actually intervene.*"[485] In her statement, **Dr Walford** also referred to *clinical freedom* and, again, as with others, a disinclination to interfere with clinicians' autonomy, which she said was because "*We were certainly not equipped to do it. We were not experts… It was the role of the expert bodies, the Medical Royal Colleges, the specialist societies, to determine what was or was not good practice.*"[486] Indeed she positively discouraged institutional engagement. In **Dr Tedder's** evidence to the Penrose

[482] Dr Diana Walford [T/20.7.21/131/20-132/23]
[483] Dr Diana Walford [T/19.07.21/69/14-19]
[484] Dr Diana Walford [T/19.07.21/86/15-17]
[485] Dr Diana Walford [T/19.07.21/88/2-5]
[486] Dr Diana Walford [T/19.07.21/48/6-10]

Inquiry, he recalled meeting **Dr Walford** in Spring 1983 to ask what the Department's plans were in relation to AIDS and being told to "*go away and stop rocking the boat*"[487]. Further, she considered that the implicit suggestion as she saw it from **Dr Galbraith** that U.S. products should be withdrawn, she considered that this was "*a very, very draconian proposal on the basis of one case*"[488], namely the Cardiff case, and gave evidence that: "*we really didn't know how much of an issue this was going to be in the UK… the evidence was strong epidemiologically, but we had no other evidence to support that. We had no transmissible agent, for example, that we could actually identify at that time.*"[489]

218. **Dr Walford** accepted the danger of conflating incidence and risk, and indeed that happened, but nevertheless "*it was a total vacuum of information and the only information that we had was numbers*"[490]. Thus, for **Dr Walford**, in utter contradistinction to the precautionary principle, they would need "*firm microbiological or virological evidence*" rather than "*epidemiological association… [which] is not actually evidence of causation*" for it to have been considered that it was necessary to take the steps proposed by **Dr Galbraith**.[491] Not only was there no withdrawal of Factor VIII and in particular commercially produced Factor VIII, but nor was there any warning conveyed to clinicians or the blood transfusion services and nor were there steps taken to urgently address this by, for example, increasing the production of cryoprecipitate, postponing elective surgery and reducing the amount of treatment used. According to **Dr Walford**: "*I am not aware that there was any formal consideration of that. I think the issue, really, is if there's a problem then you need to address it pretty well straight away. That means that you turn the tap off straight away.*"[492] The tap was not turned off though, and further a more nuanced response was not formulated though it was not of necessity an "*all or*

[487] Professor Richard Tedder [T/13.10.22/47/2-3]
[488] Dr Diana Walford [T/20.07.21/174/16-17]
[489] Dr Diana Walford [T/20.7.21/173/23-25 and 174/22-25]
[490] Dr Diana Walford [T/21.07.21/88/24-25-89/1]
[491] Dr Diana Walford [T/20.07.21/199/21-200/5-8]
[492] Dr Diana Walford [T/20.07.21/181/6-10]

nothing question."[493] It appears that no one in the Department applied their mind to coming up with a more targeted programme than *"turning off the tap"*[494].

219. Instead, the response was one of general denial or not seeing. Following media reports, the suggestion of a risk of AIDS to haemophilia patients was treated with scepticism or a deliberate disregard for risk at the highest level in Government. Thus, a DHSS briefing paper prepared for the P.M. dated 3 May 1983, headed *"Acquired Immune Deficiency Syndrome (AIDS),"* includes a *"line to take"*, namely that there was *"no conclusive proof that AIDS has been transmitted from American blood products"*.[495] This reflected the theme seen permeate institutions and individuals at all levels.

220. Even after the Council of Europe Recommendation promulgated on 23 June 1983 (Recommendation No. R(83)8), no steps were taken to bring a halt to the use of large pool plasma products and plasma from risk populations and from paid donors in the U.S.; to avoid the importation, blood plasma and coagulations factor products from countries with risk populations and from paid donors and nor was anything done to inform physicians and selected recipients, such as people with haemophilia, of the potential health hazards of haemotherapy and the possibilities of minimising these risks, as the Recommendation recommended.

221. Instead in November 1983, having seen a memo (referring to an article) that a "*British haemophiliac who died from AIDS almost certainly caught the disease from contaminated supplies of blood clotting agent Factor VIII, imported from the US… This case provides further evidence for a link between blood products and AIDS*"[496], with a note "*Dr Walford have you seen? Is it okay for me to continue to*

[493] Dr Diana Walford [T/20.07.21/182/22]
[494] Dr Diana Walford [T/20.07.21/183/24]
[495] Presentation from Counsel to the Inquiry on Professor Bloom and Cardiff Haemophilia Centre [T/24.9.20/8/4-6]
[496] Dr Diana Walford [T/21.07.21/152/9-20]

say there is no conclusive proof that the disease has been transmitted by American blood products", she replied *"thanks yes, it is okay."*[497] No steps were taken to inform clinicians of the health hazards and to minimise risk, as the Recommendation required. [498] Dr Walford gave evidence that it "*was not the role of the Department*"[499] and that they "*knew the Haemophilia Centre Directors knew very well what was going on*"[500] as it was "*inconceivable to [her] that people treating patients with haemophilia would not have been aware by that stage that AIDS was an issue and was an issue for haemophiliacs."*[501] Responsibility was therefore relinquished. The DHSS, then, did not take steps to provide information to patients with haemophilia and nor did they seek to ascertain whether haemophilia clinicians were telling their patients.[502]

222. As to the possibility of a reversion to cryoprecipitate, **Dr Walford's** evidence was that it was "*considered to be old hat*"[503] by the time she was in the Department. In her statement, she wrote, "*whilst the introduction of cryoprecipitate in the 1960s had been highly beneficial for severe haemophiliacs and significantly improved their life expectancy, they still suffered a life constrained by pain, disability and the need for frequent hospital admissions and, in many cases, premature death. With the advent of Factor VIII concentrates both life expectancy and quality of life were greatly improved… that lack of information [about AIDS] needed to be set against the very well-known and severe harms that would be caused to haemophiliacs if American Factor VIII concentrates were withdrawn or curtailed without any realistic replacements."*[504]

223. **Dr Walford** was asked in evidence the suggestion that removing factor concentrates for a temporary period and using cryoprecipitate would lead to

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[497] Dr Diana Walford [T/21.07.2021/152/25-153/13]
[498] Dr Diana Walford [T/21.7.2021/132/22-25 and 134/10]
[499] Dr Diana Walford [T/21.07.2021/133/21-22]
[500] Dr Diana Walford [T/21.07.21/134/21-22]
[501] Dr Diana Walford [T/21.07.21/136/4-7]
[502] Dr Diana Walford [T/21.07.21/138/5-12]
[503] Dr Diana Walford [T/19.7.21/5/14].
[504] Dr Diana Walford [WITN4461001] [182/80.4 and 198/86.34]

multiple cases of disability and death was an overstatement. She did not directly answer this instead responded that relying on cryoprecipitate "*wasn't feasible at the time*"[505], stating:

> "*The problem was that we didn't have enough cryoprecipitate. If there had been copious supplies of cryoprecipitate readily available, then you would have reverted to the status quo ante before concentrates came into manufacture… there would have been huge concern and complaints from patients that their entire lives were going to be turned upside down. That was on the basis of the fact by May we had one patient who had developed AIDS in the UK... So you would have made a massive transfer of, as it were, risk of bleeds and so on however severe and actually one ought not to minimise the awful bleeding into joints, really painful, really sometimes irreversible… it was an awful conundrum to be faced with and I don't think there was any particular right answer.*"[506]

224. There was, of course, no information or warning provided to patients about this. Further, not all regions experienced a shortage of cryoprecipitate (see Part 3(ii) Treatment) and there was no suggesting of managing distribution in a way that ensured necessary coverage.

225. And in any event, this does not provide any justification for the failures by the State since had the State met its *"pledge"* [507] to achieve self-sufficiency, [508] there would have been adequate non-commercial U.S. product (or at least a greater amount). There was no real interest in acting upon this pledge. Thus, **Professor Contreras**[509] criticised the DHSS for a lack of interest in self-

[505] Dr Diana Walford [T/21.7.21/27/5]
[506] Dr Diana Walford [T/21.7.21/24/21-25, 25/23-26/2, 26/8-12 and 27/1-3].
[507] Lord David Owen [T/22.9.20/56/21]
[508] Lord David Owen [T/22.9.20/56/17]
[509] Deputy Director, North London Blood Transfusion Centre (1980-84) 84) and Chief Executive and Medical Director, North London Blood Transfusion Centre (1984-95) and Executive Director, London

sufficiency. She stated that it was "*always [her] perception*" that the DHSS lacked "*genuine interest*" in self-sufficiency.[510] According to **Professor Contreras**, there were: "*two issues… (a) The funding was not available; (b) BPL did not have capacity or technology to produce everything that was needed to achieve national self-sufficiency… If every centre had been funded like NLBTC we would have been flooded in plasma, with no problem in achieving self-sufficiency… the possibility of collecting sufficient plasma from safe blood donors was always there… but what was needed was the political will and funding from the government and the Department of Health to utilise the willing donor population to donate regularly by plasmapheresis*".[511] There was, according to **Dr Smith**[512] simply a shocking "*the lack of appetite for self-sufficiency at a national level*" and that "*an influential group of Haemophilia Centre Directors saw it as limiting a clinician's choice of the best product available for his patient.*" [513]

226. The impact of that lack of enthusiasm cannot be overstated. **Professor Tuddenham** said this (and adopted in evidence):

> "*Would be provision of home produced concentrate have reduced the number of HIV infected patients? The answer here must very clearly be 'yes' despite the over-cautious remarks of Professor Bloom in his Lancet editorial of 1984. He would himself now I am sure agree that we would have half or less of the antibody positive cases that we have now had UK Factor VIII sufficiency been reached in 1977 as promised by the Government of the day. This means that the bureaucratic discretion of the Government is responsible for at least half of our antibody positive cases.*"

& South East Zone of the National Blood Service (1995-99) and National Director of Diagnostics, Development and Research, National Blood Service (1999-2007)

[510] Professor Dame Marcela Contreras [T/2.12.21/147/3-148/2]

[511] Professor Dame Marcela Contreras [WITN5711001] [107/432-108/438]

[512] A member of a committee on self-sufficiency in blood products set up by Dr Gunson.

[513] Presentations by Counsel to the Inquiry about the work and evidence of James Smith (responsible for product development at the Plasma Fractionation Laboratory 1975-1992 and Blood Products Laboratory 1979-82 and formerly of the Protein Fractionation Centre, Edinburgh), [T/17.3.2022/129/8-10 and 128/24-129/2]

(b) Government Ministers – political responsibility

227. Ministers of State were at best ill-informed, and their responses dilatory.

228. Thus **Lord Glenarthur**[514] believed that the risk to people with haemophilia of withdrawing Factor VIII was significant, whilst the risk in relation to AIDS was very small, given what he was told by officials and that there was no suggestion that cryoprecipitate could replace Factor VIII for patients with haemophilia.[515] He agreed that he was left with a clear impression that there was no alternative to the use of imported Factor VIII concentrates.[516] Nor was the letter from **Dr Galbraith** of 9 May 1983 recommending the withdrawal of blood products from blood donated after 1978 and imported from the U.S., drawn to his attention when he took up his post four weeks later.[517] He commented: "*I do find it quite odd, looking back, that I wasn't given the stark detail that appears in Dr Galbraith's letter*".[518]

229. **Dr Galbraith's** letter was not drawn to attention of **Lord Clarke**[519] either and nor was it discussed in the Department. He said in evidence *"I'm surprised that it never got to me, yes… I mean this guy's opinion is certainly superior to that of mine or the press office or people like that… it is quite startling to read that somebody in the Department somewhere had got… unless, for some reason, they dismissed him and thought he was a strange outlier"*.[520] He noted too: "*we can now say was spot on. I mean, 110 per cent on. This is the kind of thing, if only we'd all known that in early 1983, we'd have saved thousands of lives. So I'm just amazed to read a document which is so perspicacious"*.[521] He appeared to to step back from the stridency of

[514] Parliamentary Under-Secretary of State for Health and Social Security (1983-1985)
[515] Lord Simon Glenarthur [WITN5282001][53/39.2]
[516] Lord Simon Glenarthur, [T/22.7.21/180/9-16]
[517] Lord Simon Glenarthur, [T/22.7.21/168/1-169/10]
[518] Lord Simon Glenarthur, [T/22.7.21/170/6-8]
[519] Minister of State for Health (1982-85), Secretary of State for Health (1988-90)
[520] Lord Kenneth Clark [T/27.2.21/152/1-12]
[521] Lord Kenneth Clark [T/27.2.21/151/11-23]

this evidence later on, when stating "*we do have to remember… once you stopped giving Factor VIII, you were killing some haemophiliacs… had the decision been taken to stop Factor VIII, we'd have faced rage and fury from the haemophiliac community, who would have known that their quality of life was being damaged, that they were being killed… some of the campaigners would have accused us of overacting and getting panicked to American rumours… Had it worked, we'd probably have continued to be cursed because no one -- you know, had we done it, then 2,800 people, whatever it is, would not have died. So we'd have continued to this day to be reviled for condemning haemophiliacs to going back to the kind of life they'd enjoyed before this wonder treatment was devised*".[522] However, it is not clear how he formed this somewhat cynical view, particularly given his expressed deference to the expert view of **Dr Galbraith.**

230. **Lord John Patten**[523] confirmed that in 1983, he understood that haemophiliacs were one of the high-risk groups for AIDS, and that haemophiliacs in the U.K. were being impacted. However, he could not recall that there were any particular steps taken at the time to reduce or address the risk to haemophiliacs – saying: *"I think that my suspicion at the time would be – 'This is going to spread and we must be prepared', but I have got no document that says that, or no instruction to ministers that says that*". When asked whether proactive steps were taken by him or **Lord Glenarthur** in relation to the risk of AIDS, **Lord Patten** stated: "*I suppose it causes at least a raised eyebrow, now you ask me that question -- and I hadn't asked myself that question -- that maybe people should have been putting up advice to ministers to -- saying we should do something about it… But I accept responsibility for anything that wasn't done*"[524].

231. **Lord Fowler's**[525] attention was drawn to a minute dated 3 May 1983, copying in his private office, which identified evidence suggesting that AIDS

[522] Lord Kenneth Clark [T/27.2.21/154/4-155/1]
[523] Parliamentary Under-Secretary, Department of Health and Social Security (1983-1985).
[524] Lord John Patten [T/20.5.22/35/19-36/16]
[525] Secretary of State for Health and Social Security (1981-87).

is transmitted by blood, with patients with haemophiliac identified as being at an increased risk. He accepted that overall, it was not "*ringing alarm bells… as loudly as it could have been*" within the Department. When asked why he got involved in the issue of AIDS in June 1985, Lord Fowler responded, "*unless a Cabinet Minister like myself took charge, we weren't going to make much progress… You needed someone with… some weight in Cabinet, to be able to make the case... Unless you had that, you weren't going to make any progress. It wasn't something that could be done at a minister of state level, it could only be done at a Cabinet level… because they were the people that you needed, basically, on your side if you were going to change policy.*"[526] But gave no good explanation for not becoming involved earlier.

232. It was clear from **Lord Fowler's** evidence that there was, at times, a complete lack of engagement on the part of the **Prime Minister**, Margaret Thatcher, on the issue of AIDS and that she was difficult to work with. Homophobia and stigma clearly played a part, as illustrated by the following comment by **Lord Fowler**: "*her own concern on this was actually a rather odd concern. It was that if young people read the warnings, they would be introduced to things that they had never heard about -- which might well have been the case -- but the implication was that if they heard about it, if they'd be introduced to them, they would race away and do them*"[527].

(c) Pharmaceutical Companies and Licensing

233. The blood product industry is worth billions (see Part 3(ii): Treatment). The safety of the products emerging from industry ought, if safety were to be secured, to have subject to a robust regulatory regime. Instead, the licensing regime was weak and the relationship between doctors and pharmaceutical companies unhealthily close, and even corrupt.

[526] Lord Norman Fowler [T/22.9.21/59/12-22].
[527] Lord Norman Fowler [T/22.9.21/108/6-12].

234. **Professor Sir Michael Rawlins**[528], a member of the Committee of Medicines ("CSM") at material times, had no recollection of any discussion at the CSM after he joined in the late 1970s of either the source of blood donations for factor concentrates, such as whether it was collected from prisons, or from high-risk areas in the U.S., or any discussion about pool sizes and their significance.[529] He acknowledged that the power to attach conditions to a license was a wide ranging one, and so in principle it would have been possible to require a manufacturer to provide information about pool sizes or only to use pool sizes of a certain magnitude, or even to restrict the sources of blood donations used, for example not permitting products that had been sourced from prisoners.[530] **Sir Rawlins** was asked whether he was able to offer any insight into how it was that products made from large plasma pools were licensed in the 1970s notwithstanding the fact that it was known that they transmitted hepatitis which could have fatal consequences; he was unable to assist.[531] As to the discussions in the CSM in 1983 on the risk posed by blood products, which suggested the CSM viewed them as lifesaving and that the risk of contracting AIDS was small, he said that the view that the products were lifesaving came from the understanding that people with haemophilia could suffer with catastrophic haemorrhages and so required blood products to save lives.[532] There was, then, no appreciation of the extent of the risk though this was the body responsible for making judgements on whether a product should be licensed.

235. As to licensing and the relationship between doctors and pharmaceutical companies, **Sir Rawlins** was asked about a concern he was

[528] Professor of Clinical Pharmacology at the University of Newcastle (1973-2006) and Committee on the Safety of Medicines Member (1980-1986), Vice-Chair (1987-1992) and Chair (1993-1998) and Chair, National Institute for Clinical Excellence (1999-2013) and Chair, Medicines and Healthcare products Regulatory Agency (2015-2020)
[529] Professor Sir Rawlins [T/7.6.22/90/3-9].
[530] Professor Sir Rawlins [T/7.6.22/90/12-20 and 96/22-97/9].
[531] Professor Sir Rawlins [T/7.6.22/97/12-19].
[532] Professor Sir Rawlins [T/7.6.22/103/13-104/1-5].

reported to have raised during his time in the CSM about a degree of *"covert bribery"* between doctors and pharmaceutical companies, with practices of pharmaceutical companies providing excessive hospitality or sponsoring doctors to go overseas. He confirmed that he saw this as a serious problem.[533] Further, he gave evidence in answer to the question whether it was common for treating clinicians to appear before the CSM or its subcommittees to advocate on behalf of a commercial company, he stated *"Um, it did happen. I can't tell you how often it happened but it did happen, yes"*.[534] This is gives certainly an appearance if not evidence as a matter of fact, that there was, at least on occasions (we cannot know how many), a corrupt relationship between doctors and pharmaceutical companies.

236. Certainly the treatment of **Immuno** suggests a certain laxity in the arrangements for licensing. Thus, by November 1984, the DHSS were writing to pharmaceutical companies to *"encourage"* them to use a dry heat treatment in the production of Factor VIII to protect against HIV transmission.[535] In December 1984, Immuno applied to change its Factor VIII license to introduce a heat -treatment step *"to reduce the risk of transmission of viral diseases"*[536] That was approved in February 1985[537]. However, it appears licenses for non-heat treated products were approved in 1984 and 1989.[538] This means that **Immuno** was at least giving itself the opportunity to sell such products and the U.K. was permitting their use, notwithstanding that they knew of the risk.

Stigma

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[533] Professor Sir Rawlins [T/7.6.22/85/18-86/17].
[534] Professor Sir Rawlins [T/7.6.22/95/10-14].
[535] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/106/6-107/1-3]
[536] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/107/8-11].
[537] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.9.21/108/1-2].
[538] Presentation from Counsel to the Inquiry on the licensing of blood products and pharmaceutical companies involved in blood products: Hyland, Travenol and Immuno [T/23.09.21/141/10-142/23 and 144/10-16].

237. The U.K. Government did nothing to address the vile stigma that attached to AIDS and those who were HIV positive and, albeit to a lesser extent, HCV positive. Instead, their own institutions made decisions motivated, intentionally or unintentionally, by the stigma, so being reluctant to face the fact that patients with hemophilia might have AIDS or even be at risk of it. It created a polarized health service where those who contracted AIDS through sex or drug use were treated in one (usually better) part of the health service, while those people with hemophilia who were AIDS and HCV positive were treated in less well qualified, and often unempathetic, hemophilia centres.

238. This affected all aspects of the lives of people with haemophilia and AIDS and HCV, including their access to the best health care.

239. The State owed a duty to challenge that stigma and create a more positive environment. It did not do so.

Inquiry

240. Finally, the State has (until the establishment of this Inquiry) failed to undertake a full and prompt inquiry into the events that are the subject of this Inquiry. That itself would violate the investigative (adjectival) obligation under Articles 2 and 3 of the ECHR, for which the State would be accountable.

Part 4: Conclusions

241. The Judge is respectfully invited to make findings of fact reflecting the submissions above. The Saunders CPs have experienced enormous harm. They want and are entitled to answers as to the events that occurred. But they also want this Inquiry to have closely in mind those considerations that Saunders CPs have at the forefront of their minds: human rights and stigma.

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PHILIP DAYLE

SAUNDERS LAW

Part 5: Recommendations

A. Learning

Recommendation 1:

Education and learning: An account of the circumstances in which men, women and children treated by the NHS were given infected blood and infected blood products, in particular since 1970, and this Inquiry's ultimate findings in respect of the same, should be embedded in the training of medical and health practitioners (including GPs, hospital doctor, nurses and specialist haemophilia clinicians).

B. Health Care

Recommendation 2

1. **Psychological support:** Arrangements should be made for the provision of psychological / counselling support for those infected and affected, without limit of time. The impact on those affected by these events has been profoundly distressing and, in some cases, has resulted in mental ill-health.

Recommendation 3

2. **Free access to health and social care for life and for all conditions, including for end- of-life care:** There should be access to health and social care for life in respect of all medical conditions, including end- of-life care, whether or not related to the infection/s. Further, those infected should qualify for free prescriptions and therapeutic aids, again whether related to the infection or not, and they should be added therefore to the list of persons who are currently entitled to free prescriptions whether or not the prescriptions relate to the qualifying condition.

Recommendation 4

3. **Priority treatment:** Some of the Saunders CPs seek a recommendation that those who have contracted HIV or HCV (or both) as a result of infected blood should be prioritised for medical treatment.

Recommendation 5

4. **Old age:** A review into the needs of those infected as they age, including the need for bespoke health care and the need for social care, should be undertaken.

C. **Systems**

Recommendation 6

5. **Risk Management:** An oversight body should be established (or the task should be allocated to an existing body) to record, review and act upon incidences of medical treatment and therapies where evidence is indicative of harm. This should operate as an "early warning system".

6. **Haemophilia Centres:** There should be a detailed review of the functioning and effectiveness of, and the development of a strategy for, haemophilia centres. The role of such centres is changing, and a review of what is presently being audited is required. This must ensure that that the auditing systems are adequate and cover, for example, the different needs of older people with haemophilia, current or historic viral infections and younger people without viral infections.

Recommendation 7

7. **Hepatitis treatment:** HCV testing should be promoted to ensure that those who are unaware that they have been infected with HCV (a problem identified during the course of the Inquiry so far) can access treatment quickly. The availability of testing should be widely publicised and made available for all those who request it.

Recommendation 8

8. **Pharmaceutical companies:** A rigorous review of the regulatory arrangements in place should take place. It must be ensured that products are not sourced from people with vulnerabilities (through poverty or otherwise) for commercial gain, in particular where that creates a risk of harm. This means having in place an effective regulatory system and enforceable standards.

D. Support

Recommendation 9

9. **Advocacy support:** An advocacy scheme should be introduced allowing for the provision of advocates for those infected. A theme running through this Inquiry is the extent to which information was denied to those infected and affected at each stage – infection, diagnosis, prognosis, cause of the infections and treatment. In part this has been because of the efforts of a number of bodies to obscure what actually happened.

Recommendation 10

10. **Insurance:** An insurance scheme should be introduced, underwritten by the Government. It should provide those infected with an entitlement to purchase (i) life insurance (ii) mortgage protection insurance and (iii) travel insurance, at the same cost as for any other member of the public of the same age.

E. Apology

Recommendation 11

11. **Apology and vindication:** An apology should be given by the Prime Minister, given the gravity of the wrong, the Secretary of Health for State and the United Kingdom Haemophilia Centre Doctors' Organisations, to those infected and affected. These apologies should include an acknowledgement of the failures of their predecessors.

F. Follow up

Recommendation 12

12. **Reflection and action:** All health care commissioning, regulatory and ancillary organisations, as well as health service providers, should consider the findings and recommendations in the Inquiry's ultimate report, and decide how to apply them to their own work.

13. **The recommendations:** The Government should commit itself to accepting and implementing the recommendations.

14. **Review and monitoring:** A review and reporting mechanism should be established to review and monitor implementation of the recommendations.

Part 6: Annex

Annex
Treatment patterns in smaller Haemophilia Centres

- **The Royal Liverpool** – Dr Boulton was director from 1975 to 1980, then Dr McVerry until 1985, and Professor Hay from 1987. The annual returns show a significant amount of commercial concentrate usage with four different types of concentrates from 1976 and commercial concentrates predominating from 1981 until 1984 when more NHS concentrate being used than commercial concentrates

- **Inverness** - The annual returns show the main treatment used to be consistently Scottish NHS concentrate and heat-treated products were supplied to the Centre in December 1984.

- **Dundee** – The annual returns show that predominant treatment between 1977 and 1984 was cryoprecipitate and then NHS concentrate with only a very small amount of commercial concentrate used in 1982. No patients appear to have been infected with HIV.

- **Greater Ormond Street Hospital** - There was a reduction in the use of cryoprecipitate, an increase in NHS concentrate and a majority use of commercial concentrates in the late 1970s.

- **Charing Cross Hospital** - Towards the early 1980s, only NHS concentrates and Armour were in use.

- **St Mary's Paddington** - In 1983, more NHS concentrate was used than commercial concentrate. Data from UKHCDO suggests that three patients tested positive for HIV at the centre: one patient in 1984, which may indicate early testing, and two patients in 1985.

- **Hammersmith Hospital** – Between 1976 and 1985, there were between 28 and 36 patients treated for haemophilia A. Cryoprecipitate was used extensively up until 1980, with smaller usage of NHS factor, Koate, Hemofil and Factorate. Armour usage increased significantly in the 1980s and became the most used product. Counsel to Inquiry pointed out that data shows that a significant number of patients were shown as receiving both Armour and Immuno products which suggested there was no obvious attempt to keep patients to one type of commercial concentrate

- **Middlesex Hospital** – Between 1976 and 1985, the centre had between eight and 22 patients with haemophilia A. Regarding product usage, in 1976 the main treatment was cryoprecipitate with some use of the commercial concentrate Hemofil and Kryobulin. Throughout the 1970s, the main treatment was cryoprecipitate with small amounts of NHS factor, Hemofil and Factorate.

- **Northwick Park** – Northwick Park was a small centre which only five patients with haemophilia A in a year between 1976 and 1986. Regarding product usage, most years show cryoprecipitate and NHS factor concentrates were used but annual returns between 1978 and 1982 show a small amount of Armour.

- **Edgware hospital** – Edgware hospital was a small centre and only cryoprecipitate was used between 1976 and 1977. From 1978, NHS Factor VIII and Hemofil were added. In the 1980s, cryoprecipitate, NHS product, Hemofil and Kryobulin were used. No patients were infected with HIV and there is no information on hepatitis C

- **Hillingdon hospital** - In 1984, cryoprecipitate and NHS concentrates were used, however no commercial concentrates were used. No patients tested positive for HIV.

- **Guy's hospital** - Cryoprecipitate was used along with NHS concentrate up until 1980. Commercial concentrates were barely used at all up until 1982 then they started being used to the greatest extent.

- **Lewisham Hospital** – On the 1972 questionnaire, Dr Holman wrote that he would prefer to use freeze-dried concentrate, not cryoprecipitate. However, cryoprecipitate levels were remarkably high from 1976 to 1984, with a large quantity being used for home treatment. NHS and a range of commercial concentrates were used from 1976. Patients at the centre state they were not informed of risks of commercial concentrate. The evidence suggests 28 patients tested positive for HIV between 1984 and 1987.

- **King's Haemophilia Centre** – Professor Davidson wrote on the 1972 questionnaire that he preferred freeze-dried concentrates, but in reality he used a mixture of cryoprecipitate and concentrates. A small amount of cryoprecipitate was consistently used over the period 1976 to 1984. A range of commercial concentrates were used early on. The dominant type of concentrate, NHS or commercial, varied year to year

- **Southampton haemophilia centre** - HS concentrates were in greatest use, followed by a range of commercial concentrates. There is no discrete figure for the number of patients infected. Records suggest un-heat treated concentrates were still be used in 1985, leading to at least one patient seroconverting that year.

- **Truro Haemophilia Centre** - Cryoprecipitate was used, but from 1980 onward only in small amounts in hospital. NHS and commercial concentrates were used consistently from 1977.

- **Bournemouth haemophilia centre** - Commercial concentrates were generally used more than NHS concentrates, even in 1983 and 1984.

- **Exeter haemophilia centre** - Between 1976 and 1984, NHS and commercial concentrates were the dominant products.

- **Taunton and Yeovil Haemophilia Centre** –Cryoprecipitate was the only product used in 1976. In 1977, cryoprecipitate was in greatest use, followed by NHS concentrate and one type of commercial concentrate. From 1979, use of cryoprecipitate reduced, either being used only in small amounts in hospital or not at all. Commercial and NHS concentrates were used from 1977, with commercial concentrates dominating in 1979 and 1980 and NHS concentrate the dominant product (though with a range of commercial concentrates also being used) from 1981 to 1984.

- **Bath haemophilia centre** - In the late 1970s the use of cryoprecipitate dropped and commercial concentrate started being used. From 1981 to 1983, NHS concentrate was used the most, with Kryobulin also being used to a considerable extent. The records show that three patients were infected with HIV.

- **Salisbury Haemophilia Centre** – The Centre had between four and eleven patients from 1976 to 1984. Cryoprecipitate was used exclusively in 1976 and 1977, and then usage reduced in 1979 and 1980, until it stopped being used altogether. The first commercial concentrate was used in 1979 and then three commercial concentrates were used from 1980 as well as NHS concentrates. Salisbury was affected by the contaminated Wessex batch.

- **Winchester Haemophilia Centre** – The Inquiry have little documentation regarding Winchester Haemophilia Centre. There's only one annual return, from 1982, which shows that cryoprecipitate and NHS concentrates were being used in nearly equal amounts. The evidence shows that in 1985, three patients receiving regular Factor VIII were being given the heat-treated product. The Centre was affected by the

contaminated Wessex batch. Ten contaminated vials had been sent out and nine vials were returned.

- **Cambridge haemophilia centre** - Cryoprecipitate was used to a substantial extent including for home treatment between 1976 to 1979, but from 1980 it was used in hospital only. NHS concentrate and a range of commercial concentrates were used throughout the period 1976 to 1984, but the use of commercial concentrates reduced in 1982. 18 tested positive for HIV

- **Norfolk and Norwich Haemophilia Centre** – This was the second major East Anglian centre and was confirmed as an associate haemophilia centre in the 1970s. Cryoprecipitate was used in 1976 and 1977 but usage reduced from 1978 until it was not used at all from around 1981 onwards. A large volume of commercial concentrates were used from 1976. NHS concentrates were used from 1977 when it became and remained the product in greatest use.

- **Caernarvonshire and Anglesey Hospital in Bangor** - Commercial concentrates became the products in greatest use from 1980 to 1983. In 1984, a small amount of cryoprecipitate and commercial concentrate was used, with NHS being the main product.

- **Derby Haemophilia Centre** - Cryoprecipitate was used to a significant extent from 1976 to 1984. Its usage reduced in 1982 and 1983 but increased in 1984. NHS concentrate and a variety of commercial concentrates were used in 1976, with commercial concentrates being used more than NHS in the late 1970s and for a couple of years in the early 1980s. NHS concentrate was used more than commercial concentrate in 1984.

- **York haemophilia centre** - A small amount of commercial concentrate was used in 1976, and this increased over the years. NHS concentrate was used in 1977 onwards.

From 1982 to 1984 it was the main product used, though substantial amounts of commercial concentrates were also used during that time. Five infected with HIV

- **Coventry haemophilia centre** - Cryoprecipitate was the main product used in 1976, but this reduced over the years, until 1984 when it increased slightly. NHS and commercial concentrates were used to a substantial extent between 1976 to 1984, with NHS becoming the main product used in 1983 and 1984. Dr Strevens said in his witness statement that blood products were avoided if possible, with cryoprecipitate and DDAVP used in preference to concentrates. However, this is not reflected in the returns.

- **Wolverhampton haemophilia centre** - NHS and commercial concentrates were used as early as 1976, with commercial concentrates generally the main product used. The records suggest that three patients tested positive for HIV.

- **Stoke on Trent haemophilia Centre** - Cryoprecipitate was used to a significant extent throughout the period. Dr Ibbotson stated that he thought of commercial concentrates as being riskier than NHS concentrates, and it was apparent to him that all blood products carried a risk of non-A non-B hepatitis. He also stated that "*during various meetings it became apparent that there was an association between blood products and HIV in approximately 1983*". He had unlimited supplies of cryoprecipitate. Six patients associated with the Centre tested positive for HIV.

- **Shrewsbury haemophilia centre** - Commercial concentrates were used from 1977 and NHS concentrates from 1979. A significant amount of Armour continued to be used (as well as NHS concentrate) in 1983 and 1984. Seven patients tested positive for HIV.

- **Hereford haemophilia Centre** - Commercial concentrate was first used in 1980 in very small amounts. Prior to that cryoprecipitate and NHS Factor VIII were used.

NHS Factor VIII was the only product used in 1982 to 1984. It appears no patients were infected with HIV at the Centre

- **Worcester haemophilia centre** - NHS concentrate was not used until 1981. Before then, commercial concentrates and small amounts of cryoprecipitate were used. In 1982 and 1983, NHS product was the main product used, but there was still a substantial amount of commercial concentrates in use.