Friday, 3 February 2023

(10.00 am)

SIR BRIAN LANGSTAFF: Mr Stein.

Closing Statement by MR STEIN KC
On behalf of 23 individual Core Participants

MR STEIN: Good morning, sir. A number of people have indicated that they are looking forward to these closing submissions. All I can say is I pray I don't let you down.

Let me make three basic opening points. Treatment without consent was never acceptable. Treatment without consent is no excuse for substandard care. Those who treat without consent and cause harm should be hauled up before the criminal courts

Sir, as you are aware my name is Sam Stein KC and, with Ms Milligan, instructed by Milners Solicitors, I appear on behalf of 23 of my clients. All of them are either infected or affected and victims of this disaster.

We thank you, sir, and the Inquiry team for its care, the respect with which all parties have been dealt with, and the depth of this investigation. The hard work of the entire Inquiry team, its support services and structures have made this Inquiry as accessible as possible and as positive an experience as it could be in

evidence. This may feel a little like bereavement but

this community is used to that.

Next, for a moment I want to single out for praise the Inquiry legal team, led so ably by Ms Richards KC. We thank them for the four years of weeks away from home and the evenings and sometimes the nights worked through to get this right. We recognise that this has not been a marathon for the Inquiry legal team; instead, this has been a series of ultramarathons, run towards what must have seemed at first to be a very dim light at the end of a very long tunnel.

Now let me turn to my own small but mighty client group we have had the great pleasure of representing before this Inquiry. We, their legal team, have learnt everything from listening to you, learning about what was done to you and what you did as a result.

Our clients have been infected, affected and killed by the scandal. We remember in this regard the loss of Peter Mossman, aka Mossy, an infected haemophiliac and great campaigner who died after developing pneumonia and was buried a year ago today on February 3rd, 2022. His son Gareth has said to the press, "My father was consumed by his need to get justice and battle for this Inquiry for so long", and it makes me feel emotional to think that the Inquiry is coming to an end on the

the circumstances.

Sir, we also thank you and the Inquiry for the clear thinking and organisational skills which meant that we heard from the victims of the scandal first and returned to victims periodically throughout.

The evidence from the infected and affected -- and please understand, I understand myself how clumsy and objectifying those words "infected" and "affected" are -- the evidence from those people have given this Inquiry the bedrock of evidence that it needed in order to understand what happened as against the evidence from the clinicians, the bureaucrats and politicians.

It should be noted, sir, that the Penrose Inquiry only heard from a limited number of those infected and affected.

After Penrose, the infected and affected community were left devastated by the Penrose Report. The community thought that Penrose was the last shot at truth and meaningful reparations, and I know that some people wanted to give up. Mark Stewart, whom I represent, thought about taking his own life.

The evidence and the submissions in this, the Infected Blood Inquiry, finishes today. It will, I am sure, take time for everyone to cope with the loss of the constant engagement and consideration of the

anniversary of his funeral.

Gareth went on to say, "It is massively upsetting that he is not here to see it."

Our clients' lives have been devastated and derailed by their and their loved ones' exposure to infected blood products. They have truly lived through the worst of times: the stigma, the fear, the desperate day-to-day ill health, the pain, the bain frog -- the bain frog! -- the brain fog and continual sleep deprivation.

Those infected and their families have been told that they won't survive their infections many a time. Mark Ward told us doctors told him on a number of occasions that he is going to die, yet instead he survives and continues his astonishing campaign to spread the world about healthy blood products to the world.

Some of our clients are women who supported their partners through terminal illness, and of those, few gave any thought at any time -- and some were in turn infected themselves. One of our clients, the terrific Colette Wintle has had to achieve recognition of her very own identity as a female haemophiliac, ignored and assigned to a bin of heavy women's problems or dismissed as a carrier.

Some of our clients had been misdiagnosed as

haemophiliacs and then mistreated as such, cruelly infected through blood products which they never required. It would be wrong of me not to record that our misdiagnosed clients remain of the view that they have at times felt ignored by this Inquiry as it has not been about mistakes made in their treatment but of course how that treatment came to bear on those who received it

Sir, we have -- you may remember at the very beginning of the Inquiry my misdiagnosed clients wore a T-shirt. I have one here. Sir, whilst the Inquiry is, of course, welcome to have it, I note that it is probably more me sized, an XXL, than anyone else.

And, of course, many of our clients are campaigners, who have fought and fought and fought for justice and truth. If ignored, they knocked on another door. Like great fighters, if ever knocked down they got straight back up. They never stopped. And without them -- and this needs recognition -- this Inquiry would never have happened, and the government line would have prevailed.

All of our clients are passionate, unrelenting and angry, but this is a righteous anger, sir. This is the righteous anger of the ignored, the sidelined and the discriminated. We don't apologise for our clients' visceral anger. We don't apologise for their desire for

truth and for proper compensation for the damage done to them.

Instead, let me be pinpoint clear. They are right to be angry and they are right to demand compensation, right to demand change and right to demand restitution.

It has been a privilege to represent all of our clients, work with them and for them, and it is an honour to be trusted with the responsibility of -- although rather nervously -- with the responsibility of standing up here on their behalf.

I apologise sincerely to them for sometimes not always understanding at first or getting the point only slowly at times. But I hope we got there in the end.

I would also, of course, like to thank my juniors,
Alan Barker from Nexus Chambers for his hard work in the
early part of this Inquiry, and then more recently the
great Scarlett Milligan of my own wonderful chambers,
39 Essex. Myself and my brilliant but long-suffering
solicitor. I emphasise suffering, from me that is.
Mr Harrison -- who sits on my right, from the great
Leeds firm, Milners Solicitors -- and I have had many
a lively discussion over these last four years. He has
my enduring thanks.

Ben, we made it.

In making these submissions, let me describe the

structure of what we have to say. First of all, I will be dealing with the DHSC, Department of Health -- I will probably refer to it as Department of Health -- though that will be the first chapter; then I will move on to consent; risk; other medical choices; experimentation and, sir, at that juncture, with your permission, I will break. After the break then returning with licensing; what should have happened; campaigners, recommendations; and the way forward.

I have to say, sir, I am slightly conscious that I could have come up with some snappier chapter headings. Let me deal, first of all, with the Department of Health.

We, like others I am sure, awaited with interest the oral submissions to be made on behalf of the Department of Health by Ms Grey KC, to see after all of this time and after hearing all of this evidence how their apology would be shaped after their opening remarks on 28 September 2018.

When speaking on behalf of the Department of Health and Social Care in England and its predecessor, Ms Grey KC said things happened that should not have happened and that things went wrong. Now, sir, as you will be aware, in the Department of Health, the DHSC's written submissions, paragraph 1.7, they refer to their

unreserved apology saying, as they do there, nothing in those written submissions should be seen as changing this.

Unfortunately, what will we got from Ms Grey on 18 January was "It's uniquely your role to make those findings", referring to you, sir. Ms Grey went on to say this "and we might have remained silent and made no submissions but instead we have gathered together the perspectives of those involved at the time".

Really? Was it really a choice for the Department of Health that they thought that they might have remained silent and made no submissions? After hearing the submissions from Ms Grey, I reached for the dictionary to look up the word "candour", just wanting to check my own often inadequate understanding of common words and, sir, as you no doubt know, it means of quality of being honest and straightforward in attitude and speech.

May I compliment Ms Grey as an advocate for the high standard of her delivery of her clients', the Department of Health's, submissions but sadly deprecate her clients' instructions to her.

Those instructions seem to be that it is the Department of Health's view that it is somehow acceptable that they can hide behind the curtain as they

feel they cannot be compelled to state a case, let alone provide a meaningful apology, which references the facts established and now known to us in this Inquiry.

Well, sir, you put it to Ms Grey, what exactly can you -- was it at that time -- referring to their opening submissions -- "As a matter of history, as opposed to now, what was it that the Department had in mind that you are apologising for?" We suggest that the Department of Health's responses have shown an absolute lack of candour and a failure by those currently in the Department of Health to realise that apologies must mean something.

Restorative justice requires not just the form of an apology but the sense to those who are being apologised to that the apology giver accepts wrongdoing. We have a proposal for the Department of Health which we hope helps. The very long fight for truth and justice was never about the credible evidence that already existed, that the long-standing campaigners discovered and discussed and preserved, but it was about the supreme effort that went into the Government denials, lies, blocking and cancelling out of campaigners and infected and affected voices.

It was always about the refusal to look at and address what was plain on the documents. So we make

told that time has dimmed their recollections.

Our clients and this community has not forgotten about what the doctors told them or didn't tell them. They have not forgotten about the fact of their infection, or the way they learnt of their infection or multiple infections, or being told that they will not survive, or the hammer blow of letters in relation to vCJD, or the deaths.

We suggest that the community has not forgotten those points to the Department of Health. Let me be clear, this response from the Department of Health is simply a demonstration of the latest Government line used to fob off the survivors of this tragedy. But in taking the latest version of the Government line, the apology at the beginning of this Inquiry now appears contrived and the lack of true acceptance of fault is disrespectful to everyone and to Lord Morris's comment about blood products, that this is the worst treatment disaster in the 75-year history of the NHS.

If nothing else, this perpetuation of harm should be considered an aggravating factor in the compensation decisions and deliberation.

No doubt my PI lawyer friends will tell me after my speech how far that is actually possible.

I turn now to consent. We have witnessed in this

an offer to the Department of Health: if you the Government, Department of Health, are struggling to work out what you need to apologise for, then we have the people, we have the community, we have the survivors, we will be happy to meet with you any time, any place to have that discussion.

But, in the light of the empty apology, we suggest and agree with my learned friend, Mr Dawson KC's submissions that any reading of the Department of Health's closing written submissions shows this in fact it leans towards an attempt to provide a defence for the Department of Health. Let me look at a couple of points.

Firstly, the Department of Health suggests that the years have taken their toll on recollections, suggesting, paragraph 1.16, Department of Health written closing, that of the effect of time on memory that:

"Such limitations affect the memories of all those heard in this Inquiry whether former ministers, officials, doctors or patients. Secondly, that again due to the passage of time the documentary record will be incomplete."

You will find that, sir, at paragraph 1.17. Well, sir, I doubt whether any single patient who suffered the long consequences of their infections appreciates being

Inquiry the evidence given by all of the haemophiliacs and family members and all of the witnesses about their treatment with infected blood products.

We hope and believe that the Inquiry is likely to accept the overwhelming preponderance of evidence from the patients and their families which shows that haemophiliacs were not properly informed and were not provided with sufficient information to make an informed choice as to whether they -- and "they" is the important word, isn't it -- as to whether they, the patient, was prepared to take a risk.

Consent, sir, is about and always has been about the ownership of risk. On 17 January this year, we heard the careful submissions from Mr Bragg, an individual who had been infected with hepatitis as a result of a blood transfusion. Mr Bragg, because of his work, referred to the employment of risk analysis within the regulatory world and, in truth, that is what both regulation and medical treatment is all about.

Risk is one of, if not the main issue, to be considered, monitored and reconsidered with regularity as part of a doctor's or indeed regulator's function.

The questions are always what is the risk, what is the degree of risk, changes in risk and what could be done to ameliorate risk or avoid it entirely?

So how should risk analysis have been addressed for haemophiliacs when considering the treatment using blood concentrates? First of all, there needs to be consideration of the severity of the condition of the patient who will suffer the consequences and side effects of any treatment, and for haemophiliacs we have broad and rather crude labels for the severity of haemophilia. Those are mild, moderate and severe.

Those labels are an attempt to describe the effect on an individual of the condition, mild haemophilia 6 to 50 per cent factor level, may only have minor bleeding problems. Moderate haemophilia 1 to 5 per cent factor level, may bleed one time per month. Severe haemophilia, less than 1 per cent factor level, may bleed one or two times per week.

Now, myself and Ms Milligan and Mr Harrison have learnt that using these labels to describe the individuals' lived experience of haemophilia is a mistake. Some haemophiliacs with so-called mild haemophilia experience a much more severe response to bleeds than might be expected from that label "mild haemophilia". So it is always about the experience of the individual, rather than any broad or brush stroke attempt to provide a label.

So as ever with risk, the analysis should be based

that the patients had discussions with their haematologists about the use of blood products, commercial products, blood pools and the growth of medical understanding? We think back, very little if any at all.

Now we listened on 19 January this year to submissions from Mr Kennedy KC, on behalf of the UKHCDO and he included the point that patients are much more prepared to ask questions than they were in the '70s, when there was a more paternalistic approach, and that you can also take account sir, he said, and I paraphrase, of the patient protections from organisations such as NICE.

So we suggest that this is and remains a submission that could only be made by a doctors group. Not all patients are able to ask questions. Not all patients are confident enough to ask questions and not all patients know what questions should be asked. It also misses the point. In this scandal, the patients, if told anything, were not told the truth.

The British Medical Association publication *Professional Standards*, a statement prepared by a special panel appointed by the Board of Science and Education of the British Medical Association -- sir, I will give on occasions Relativity references, I don't upon risk of treatment through the use of blood concentrates or indeed any blood product for any recipient, and then analysed for that recipient.

In short, should this treatment be provided for this patient? The decision about treatment should therefore be: what treatments are available for this patient? What are the benefits of each of the available treatments for this patient? What are the harms which may be the result of any specific treatment? Is there a treatment which may be less effective but less risky? Overall, do the benefits outweigh the harm? And, of course, the big question, what is the decision of the patient or the patient's guardian when properly informed of these questions?

Now, the decision by doctors as to their view regarding treatment and the decisions made by patients may change over time; as knowledge changes and as products change, options change or may become more limited. Sometimes it is useful to think about not only the evidence we have heard but the absence of evidence.

What evidence have we seen that reflects upon discussions with patients about the relative severity of their haemophilia and how that affects treatment options or of medical advice?

What evidence have we seen or heard which shows us

expect them to come up on screen, I have some points to go on the screen, and Lawrence knows them, as we go through -- the reference for that is BMAL0000082, page 9.

So this document from the BMA, *Professional Standards* document, in the early '70s, discussed the need for patients:

"... to maintain good communication and exchanging information to patients and, of course, maintaining patient confidentiality."

So have we found within this evidence over these years any real explanation of why obtaining consent for treatment was ignored? There are, we suggest, some pointers. WITN3437002, page 24, Dr Winter says this:

"Relevant to this is that the nature of haematology training changed in the mid-'70s. Prior to this, haematologists had been trained in laboratories. But under the new system haematology training required postgraduate experience of general medicine and the passing of the Royal College of Physicians exam. When viral contamination issues emerged [he went on to say], some centres were managed by doctors with very limited experience in breaking bad news."

In his evidence to the Archer Inquiry, Dr Winter made a similar point at page 90 of the transcript. He

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said this:

"Haemophilia was really a branch of pathology prior to that and the senior haemophilia doctors had worked in laboratories. They were gifted academics, they were scientists, they were not experienced in, for instance, dealing with very sick people."

In her interview for the Royal College of Physicians Oral History Project, Professor Lee said of researchers -- she spoke in this way about researchers:

"You would be wasted on medicine", she said.

"Well, tell me more about that", she was asked.

"I think that people who did pure science and particularly at that time biochemistry was pretty new science, regarded medicine as rather a simpler option really, a less scientific option."

Reference to that is MACK0002586.

So there may have been a tension in haematology between those of a more scientific background and those trained primarily as physicians. Part of this issue may be that haematologists came from a pathology background, meaning that they did not come from a patient treating background.

Such attention could and might explain some of the differences in treatments administered by haematologists. Dr Dormandy at the Royal Free as an

Now, I will refer a few times to Peter Jones. He is a name that's familiar to all. Didn't give evidence. There are reasons for that. But he was a significant person and a significant doctor, a significant individual within the UKHCDO:

"Dear Mr and Mrs Longstaff,

"I am sorry that you could not come to the last clinic and I enclose another appointment. You will have received a letter from Lord Mayor Treloar asking for your permission for Peter to participate in the special trial of regular factor VIII injections."

Referring to other individuals:

"... parents have also been asked for their permission. I saw the [redacted] last week and explained that I was in complete agreement with the trial and that it could do nothing but good for the boys and for other patients."

Then the sales job:

"It has been most carefully worked out, was discussed at the last meeting of the Haemophilia Directors in Oxford, and has the support of the Medical Research Council of the United Kingdom. I will of course be extremely happy to discuss any points that concern you about the trial when I see you, but wonder if you would feel able to sign the acceptance form for

example. Or the fact that some physicians -- Dr Winter is an example of this -- made early switches to heat-treated products based on their assessment of the evidence at the time, whereas others, I'm being generous, perhaps more rooted in scientific backgrounds, were slower to move away from what were the obvious and better treatment options.

It is possible differences in haematologists may have arisen because those trained as physicians were more focused on the condition of their patients, whereas those whose training was rooted in pure science might have been more inclined to wait until facts had been established to a scientific standard of proof.

Let's have a look at 1973. Bearing all those points in mind, let's have a look at 1973.

Lawrence, this is the first of the documents, please, on the screen, WITN1055172.

Sir, this is a letter from Dr Jones at the Newcastle Haemophilia Centre to Mr and Mrs Longstaff, the parents of Peter Longstaff, who grew up and married Carol Grayson.

A small point, but a point I will refer to later on in these submissions, top right-hand corner, obviously the heading, "Newcastle Haemophilia Centre", "Attic Laboratory". 12 April 1973 is the date.

Lord Mayor Treloar at this stage. I saw the doctors concerned in London yesterday and they are trying to get things organised for next term."

"Nothing but good". 1973. That's what's being explained.

I turn now to my chapter heading which is "Risk". Sir, a risk is a risk. You have been addressed in differing ways trying to discuss with you, sir, how to address the question of risk. Most if not all treatments carry a risk of harm. Any "only over-the-counter" medication will also carry a long explanation in the tiniest of writing detailing the known possible common and less common side effects. Those are risks.

With blood products there is no need for debate; it was always known that blood products bring with them the risk of hepatitis. I repeat, a risk is a risk is a risk. The words "possible risk" or its cousin "potential risk" add nothing to the debate.

Clinicians knew of the risk from blood products. Professor Tuddenham explained, WITN3435002, page 14:

"When I first began to treat people with haemophilia at Liverpool Royal Infirmary in 1969, my senior registrar told me the tragic story of a patient with severe haemophilia A who had resisted being treated with

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cryoprecipitate because of fear of hepatitis. He had come in with severe bleeding and my colleague convinced him to have cryoprecipitate infusions. They controlled the bleeding, but the patient developed hepatitis and dies. From that time, I was well aware of the potentially fatal consequences of treating haemophilia with blood products and that the risk increased with donor exposure."

Those risks could not have been more clearly expressed than by Richard Titmuss in his book *The Gift Relationship* in 1970. Chapter 8, page 142:

"To the recipient the use of human blood for medical purposes could be more lethal than many drugs. The ... use of ... certain blood products carries with it the risk of transmitting disease, particularly serum hepatitis ..."

He goes on to then refer to malaria, syphilis and brucellosis. He then says this:

"in the United States, Britain and other modern societies the most dangerous of these hazards is serum hepatitis. It is becoming a major public health problem throughout the world. No scientific means have yet been found to detect in the laboratory the causes agents ... in the blood before it is used for a transfusion or for conversion into ... blood products. The quantity of

'68, Professor Zuckerman's letter to the BMJ entitled the *Price of blood*, warning of the dangers of using paid donors and the greatly increased hepatitis risk. Reference LDOW0000210, page 2.

Mr Aldworth KC submitted in the morning of 27 January of this year that paternalistic attitudes may have been at least a partial basis in the clinicians believing that they should spare the patients the worry about the consequences of hepatitis.

And he argued -- I put it in my terms -- that it was only after the studies in the later '70s, which he suggests revealed the longer term effects of hepatitis, that doctors became generally more aware of the risks.

Now, there have been some other submissions made from this lecturn saying that it was only in the later '70s that there was this increased awareness of the risk within the profession.

Now, why is that submission being made?

Well, presumably, the point of making a submission which is that the awareness of risk grew in the later '70s, is that the blame and culpability should be considered as having a late starting point after the studies which related to biopsies concerned with liver damage, Preston and the like.

It seems that from those submissions, that, sir, the

infected blood that can transmit hepatitis may be as little as one-millionth of a millilitre."

The risk from contaminated blood and blood products leading to hepatitis were well known for years within the medical profession.

Another example, in '43 it is referred to, in fact, FACT000005 in 1943:

"Medical officers of the Ministry of Health published a memorandum on homologous serum jaundice, in which they stated: any doubt as to the reality of the association is removed by the frequency with which hepatitis has followed the injection of human blood products."

The danger was recognised to be particularly acute in pooled plasma products in journals in 1946, RLIT0000052, where it was recommended that "pooled plasma should not be used prophylactically" and "only small pools should be used for transfusion purposes".

The further article in 1947, RLIT0000054, physicians are advised that transfusion therapies should only be administered when the clinical indications are absolute.

In 1966, RLIT0001219, the British Medical Journal, BMJ, reported a high incidence of hepatitis transmitted to patients who had been given whole blood or blood products.

Inquiry is being pointed in the direction of a finding that with a growth of knowledge, or we presume at least the availability of knowledge of these facts, that it is from that stage the failings, which had been wrapped up in the warm comfort blanket of the paternalistic attitude designed to protect patients from the truth, really started to hit patients.

We reject those arguments. They fall away against the strong body of evidence that there was a general knowledge, set out in detail within the Inquiry presentations, within the material that has been long sought through the diligent work of campaigners and preserved, which demonstrates that blood and blood products were well known to be dangerous well before licensing and the common use of blood concentrates.

Clinicians did know that the risk from use of blood and blood products was real. They always knew that. They did know that the risk was serious. They did know that, from the get-go, that infection with hepatitis might mean death or serious illness. Blood and blood products have long been known to pose a risk of death: a killing risk.

We ask instead that the Inquiry, that you, sir, find that in those early days the medical risks to patients were known. Of course, there was a manifestation and

the use of the moniker "non-A, non-B" and later turning to hep C -- interestingly though Dr Wallace in Edinburgh in his book about blood transfusion was already referring to it as hepatitis C in, I think, 1975/76.

Now, what was going on, we suggest, was always an enormous experiment in treatment on haemophiliacs. Now, that doesn't absolve the doctors and clinicians from responsibility but instead emphasises the responsibility to inform the patient. In other words, the responsible treating physician at the time should have said — if they believed that blood concentrates was the right treatment, they should have said "We think that these products will treat your haemophilia but there are very real risks of infection with hepatitis which can sometimes be serious and which might kill you faster than non-treatment or treatment with other options".

The point has been raised in the Department of Health's submissions, and indeed by Mr Cory-Wright KC on behalf of the Blood Transfusion Service, that access to materials, research materials and the like, was more limited in the past.

Okay, now there is a limited point to be made here. It is right that perhaps obscure journals from remote parts of the world might not have been as accessible as

contributing to the pool, were discussed in the past, leading up to the '70s. The leading haemophilia doctors were aware of this and discussed it amongst themselves.

I turn to my next document to go on the screen, which, Lawrence, fingers crossed, should be NHBT0000055. As we see, this is a discussion about "Management of the Haemophiliacs, Second and Third Meetings of European Home Therapy Group Held in Newcastle upon Tyne (1976) and Madrid (1978), Edited by P Jones and J Martin-Villar", reference also to the *Scandinavian Journal of Haematology*, supplement numbering something.

Can I then please go -- I think you have the right page -- 62, on the screen. It is the bottom two paragraphs, if you can highlight those. The first paragraph helps us and this tells us what should have been discussed with patients, the whys and wherefores, what is useful to know.

Set out here is reference to -- I'm going to say his name very wrong, I'm sure -- Dr Panicucci:

"The widespread use of plasma fractions in the home and hospital treatment of haemophiliacs has brought not only advantages, but also a significant disadvantage. Factor VIII or IX activity is much greater in freeze-dried concentrate than in cryoprecipitate or plasma. They are also more stable and have a much more

they are now, using the power of the internet and the advent of digital libraries. But most of the literature that we have considered and has been considered by this Inquiry has been mainstream, and we are talking about specialists in the field, haematologists.

Three examples of the many well-known publications are hard to miss sources of information: prince, AM and others in 1974, his article *Long incubation*, post-transfusion hepatitis without serological evidence of exposure to hepatitis A virus in The Lancet; Craske, 1975, reporting a rise from 3 to 50 per cent of his patients among his group of patients with haemophilia, with 58 being infected and two deaths; an outbreak of hepatitis associated with intravenous injection of Factor VIII concentrate, reported clearly in The Lancet.

Wider information available to all. In 1975, the World in Action documentary travelled with hepatitis expert Arie Zuckerman to the US to look at the types of donors who were being used in what was described as "Skid Row", plasma donation clinics. Zuckerman noted that these were donors that the UK would have rejected straightaway due to safety issues, describing them as affront to human dignity.

Issues, such as the greater incidence of infection from the use of pool blood or the increase in numbers

predictable action. Concentrates do not produce the allergic reactions which sometimes occur with cryo or plasma. They have made home treatment practicable and major operations on haemophiliac much easier. These concentrates, however, which are prepared from pools of more than 1,000 units, may expose the patients to a high risk of contracting transfusion hepatitis. Random observations during routine examinations revealed a high incidence of elevated liver enzymes in patients with haemophilia.

"112 of our patients with severe haemophilia A or B and 24 with mild to moderate forms, were studied to determine the incidence of liver damage which may have resulted from blood product therapy. Physical and biochemical examinations were performed on all the patients at 3 and 6 month intervals. Most of them had been heavily exposed to commercial concentrates. Only 4 patients had never received concentrates, whereas 23 had received concentrate on more than 100 occasions. Acute hepatitis with jaundice was found in 23 patients: 12 children ..."

In a nutshell, this discussion embodies either the reason why blood concentrates should not have been used or what should have been explained to patients so that they can make their choice.

Now, I have considered with you, sir, the evidence of knowledge of risk and the dangers of infection with hepatitis but how well was the risk of hepatitis from blood products known more generally within the medical profession? In other words, is there a possibility that it could have been missed by some doctors, even though this was their special area of work?

Now, this is why we have had these submissions about the lack of internet access, limited availability of communications and the slowness of snail mail but they want a finding, sir, from the Inquiry that doctors had a limited knowledge of this matter. But the evidence tells us that the dangers of hepatitis being transmitted through blood or blood products was absolutely the stuff of common medical knowledge.

The notes of the meeting of the Hepatitis Advisory Group refer to their discussions on the 11 January 1971 at Alexander Fleming House, reference DHSC0000114. I quote:

"Professor Dogood observed that the hepatitis hazard was not only an anxiety for renal units, it was a matter for the whole hospital and others to concern themselves with. Communication was vital and material to be communicated. It therefore followed that records of tests and incidents should be kept assiduously. He

to his own transcript of that at PRSE0006080:

"I recall that routinely laboratory products and request forms from patients who had received blood products had yellow dangerous specimen labels applied."

Paragraph 27 of his statement, Dr Lowe said this:

"As a clinical medical student in 1970 to 1972, I was taught about hepatitis A and B. I recall one of our questions in the final examination in medicine in 1972 was write an essay on hepatitis. As a house officer in '72 to '74, I was taught the risks of transmission of hepatitis, including hepatitis B, from blood products."

It was Dr Lowe who referred in his statement at paragraph 23.1 and who recalled the reference to hepatitis in Colin Douglas' book, *The Houseman's Tale*, a copy of which I have here. That was first published in '75. The author Dr Douglas graduated in medicine at the University of Edinburgh in 1970. His book includes a reference to a clinician colleague who Dr Campbell, the main character in the book, visited. Page 198:

"Campbell hurried along to the isolation unit, a building on its own, beyond the coke dumps and the disused tennis courts."

He continues in his book, describing the building as having taken over by a specialist medical unit to

undertook to prepare a passage for the report in this sense."

The document also refers to a comment by Sir Michael Woodruff, who suggested that, as regards renal units, ideally he would like to have three areas in the unit, white, yellow or confirmed cases and grey for suspects, especially new cases, going on to say that the grey area might use peritoneal dialysis.

Within that document there is a question raised, if you care, sir, to look at it, about whether nurses that had been employed in renal units which were found to, in fact, have carried an infection should then be employed in units which were described as "maiden units", those that didn't have or haven't had an infection.

So there is clear knowledge within the wider medical profession of the dangers of hepatitis. Of course, you will recall the recollections that have been addressed earlier on, with other submissions, of Dr Winter. I now refer to Dr Tuddenham.

Sorry, you have already been referred to the recollections of Dr Winter and, indeed, I have referred to Dr Tuddenham. I now make reference to Dr Lowe's statement at paragraph 7.1, WITN3496013. Dr Lowe said this:

"As I stated at the Penrose Inquiry", and he refers

intensive care and barrier nursing facilities for dangerously infected patients. On arrival, the fictional character in the book, Dr Campbell put on "a disposable mask, overshoes, a gown, a white unfestive paper hat and a face mask". In the book it is Christmas time. The book continues and describes the patient:

"Mack was sitting up in his cubicle smiling and faintly jaundiced.

"Welcome to the pest house. They tell me I've got the yellow peril and it'll be six months off the booze.'

"Which of the yellow perils, is it?' Campbell asked, 'Plain or fancy?' There were two types of hepatitis, one of which killed people, serum hepatitis did, and was less common but more likely to occur among hospital staff. Mack said this:

"They are running a test now but from the way they are treating me I'd say that it is the real fancy, no messing about, nasty serum stuff. They are taking no chances. You know Ivor, the SHO here, he came at me for blood dressed like a deep sea diver, you know bootlets, gauntlets, a thing like a welder's mask on. It made me feel I wasn't nice to know."

Now, that's not the first time that transmission of hepatitis in blood-borne viruses was or had been referred to in a medical comedy. In M*A*S*H, the

31.

American series based in the Korean war, series 1, episode 11, titled "Germ Warfare", in which a transfusion of blood from Major Burns is suspected of having transmitted serum hepatitis to a patient, giving rise to comedic attempts to stop Major Burns associating with Major Houlihan or attempting to operate as a surgeon. The date of that broadcast, that episode, was 10 December 1972.

Submissions which attempt to say that the non-existence of the internet and digital library resources until much later in the 20th century hamper our understanding or that we must be wary of hindsight -- reference to the Department of Health's written submissions 1.23 onwards -- those submissions must, sir, we say, be reviewed with care.

First, that some of the earliest materials identifying the connection between jaundice and blood products came, in fact, from the Ministry of Health, as it then was, and not, as it seems that some of the closing submissions are attempting to say, from some type of obscure, hard to get at, unrecognisable source.

Second, doctors have expressed before this Inquiry their very own real understanding of risk from blood, which may cause a serious and potentially fatal hepatitis from the earliest days of their practice.

view describing and setting out what it is that they would want to say?

If we go, please, now to RLIT000041_0001. Sir, the book on the screen from Relativity is the first edition, 1974, of this book which I'm holding in my right-hand, which is the second edition, I think 1984.

If I can then go please very shortly to the sixth page, same reference, a very small point. We see first of all that the book is dated '74 and in reference to the letter to Peter Longstaff's parents we looked at earlier, you will see at the top right-hand corner of that, referring to the Attic Lab. This book was dedicated to those individuals and to the Attic Lab where it all began. Take us to page 0079, bottom right-hand corner. Chapter 5 is headed, "Treatment 1 -- Therapeutic Materials":

"Most of the materials used in the treatment of bleeding disorders are derived from human blood. This is provided by voluntary donors and is collected by a transfusion service which may be local or national; in the United Kingdom the donors receive no payment for their generosity.

"The blood is taken at special sessions arranged in localities suitable for the majority of donors in a particular area; these might be in factories,

Third, it was of such common knowledge that fictional sources, medical dramas, demonstrate that this was common knowledge both in the UK and the United States.

It was wrong to leave patients without an explanation about the possible consequences of infection. The fact that we know, as we have gone through, that hospitals themselves clearly viewed the risk of potential harm from hepatitis to be serious, and that they took steps themselves to warn each other of the dangers of blood that is just drawn from people with haemophilia demonstrates, we suggest, a clear double standard.

Patients need to be told. The fact that hepatitis was a risk to the patient and a risk of onwards transmission should have been discussed with that particular patient at that time to say, not only is this a risk to you, but there is a potential risk to your loved ones and others. We suggest that that was a clear duty that existed and always existed.

But having identified the risk of hepatitis, how was that translated into patient care? Well, we heard from the patients in their evidence about how they were not informed of the risks or that it was minimised. So what contemporary evidence exists from the clinician point of

universities, church halls or recreation centres.

Donors already enrolled in the area will often be notified of the session but new donors are always welcomed without prior arrangement. In order to give blood a donor must be an adult in good health and not known to carry a communicable disease ...

"After a session the labelled packs of blood are taken in a refrigerated van to the central laboratories of the transfusion service. Here they go through a series of stringent tests to exclude infection, including serum hepatitis, and to make sure that the blood groups on the labels are correct."

1984, jumping ahead, same book, same paragraph, "Treatment 1 -- Therapeutic Materials", page 81. This is not going to go on the screen:

"Most of the materials used in the treatment of bleeding disorders are still derived from human blood."

So 1984, same book/version:

"Most of the materials used in the treatment of bleeding disorders are still derived from human blood. This is provided by the voluntary or paid donors and is collected by a transfusion service which may be local or national. In several countries, including the United Kingdom, the donors receive no payment for their generosity. In other countries, most especially in the

United States, donors are paid a modest amounts for their blood plasma, which is then processed by one of the commercial companies."

A very similar paragraph we looked at in the 1974 version:

"After a session, the labelled packs of blood are taken in a refrigerated van to the central laboratories of the transfusion service. Here they go through a series of stringent tests to exclude infection, including serum hepatitis and to make sure that the blood groups on the labels are correct."

That's 1984.

We say this in our written submission, paragraph 334, page 112, we made reference at that stage in our written submission to the 1974 book but I suggest it applies equally to the '84 book.

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

treatment which falls below the standard of a reasonably competent medical practitioner.

That is not and cannotbe right. If somehow you choose to treat someone without their consent then that means the onus is on you to get it right, not just the treatment itself but the choice of treatment.

In taking choice and information away from a patient, in deciding to take their decision for them, you assume responsibility for the appropriateness of that treatment and for the consequences of getting that risk-benefit analysis wrong.

This was done, as we know, many, many times in the general treatment of haemophiliacs and the misdiagnosed, many of whom should never have been exposed to the risks posed by blood concentrates. We repeat, lack of consent is not an excuse for lack of care.

So, other medical choices. So what were the possible medical choices? Katharine Dormandy, Dr Dormandy ran an apparently successful home treatment programme from the Royal Free using cryoprecipitate until 1978.

In his statement, WITN3496013, Professor Gordon Lowe said:

"For treatment or prevention of a bleed in such patients, I said that the combination of desmopressin,

several hundred rather than several donations in size by the time of the publication.

Now, these books were written for the families of haemophiliacs, for haemophiliacs to understand about their treatment. They were deliberately designed for that purpose. So when you consider everyone's evidence against the contemporaneous materials published by an eminent and very well known haematologist, setting out the advice for patients in his published works, we suggest that doctors routinely failed to advise haemophiliacs as to the inherent dangers of this type of treatment, despite the fact that they and the rest of the medical profession knew of the risks.

I started with three particular points. May
I emphasise the second one. We suggest that the issue
of failure of consent needs to be considered for what it
is. If any doctor at any time or date proceeds to treat
without consent, that emphasises the burden on the
doctor to get it right, and get it right for that
patient, and get it right given the state of medical
knowledge. Not to get it wrong, not to muck it up.

What some have referred to as a paternalistic approach to consent appears at times to have been equated with doctors having a licence to give poor treatment or, as Ms Milligan would have me say,

and the response to injury (which also raises level of Factor VIII/von Willebrand factor), often allowed us to not have to give blood products."

In evidence to the Lindsay Tribunal, Dr Brian Colvin discussed how treatment with concentrates was more fashionable than using cryoprecipitate. He stood by this and repeatedly emphasised his view during his evidence to this Inquiry. In his evidence to the Lindsay Tribunal, Dr Colvin said this:

"It was certainly my policy to try to give children cryoprecipitate, because children are small and they can be treated with perhaps one or two or three donor units of cryoprecipitate. I think there was a feeling amongst some haemophilia treaters that the cryoprecipitate approach was rather old-fashioned, and indeed in many ways perhaps it was, but I think I was trying to use cryoprecipitate not to prevent HIV infection but to try to limit the amount of non-A, non-B infection in my children's community."

An example of what happened instead, of course, is that -- I use -- I made a reference to

Ms Colette Wintle, a teenager in 1976, supposed to be on cryoprecipitate, it was typed in her notes, a reference to cryoprecipitate struck through, instead replaced with a reference to Factor VIII.

Given after that point Hemofil, possibly one of the most dangerous of the products at that time.

Another example, Peter Longstaff, Ms Grayson's husband, a severe haemophiliac, was treated successfully throughout his early life with cryoprecipitate.

In this Inquiry we have all too often concentrated on the question of consent when in fact we should have been thinking in terms of patient choice. The evidence tells us that haemophiliacs believed that they were being treated by compassionate doctors who only had their best interests at heart. The Haemophilia Centres and their haemophiliac patients became part of each other's lives, and we heard evidence, didn't we, about social events and family events attended by haemophilia clinic staff members.

I suggest it must feel to the victims of this scandal, the haemophilia victims of this scandal and indeed others, that there cannot be a greater betrayal of trust, sir, because of what they perceived was the special relationship they had with their doctors. This closeness also attacks the patrician discussions that have been presented to you, as it might be thought that the very close relationship between these doctors and their patients should have demanded truth and clarity in medical advice.

my practice background. I come from a criminal defence practice background. So, for me, this has been a little like doing a case without looking at the murder weapon. Its very medical appearance is part of its seductive qualities. But for haematologists, the revolution that started with cryoprecipitate was complete. The lives, they thought, and the lifespan, of haemophiliacs had changed. This was referred to at some stages in the evidence as the "golden period", the theory being that no longer would haemophiliacs drop down dead from the near mythological brain bleed.

It seems likely that, so entranced with this new and seemingly great treatment, that they ignored the screamingly obvious: this treatment will -- not maybe, but will -- expose the patient to whatever disease was in the blood of the person who gave that blood. And when you start moving to pooled blood, you reach a stage where, the evidence tells us, there was essentially a certainty of infection.

Sir, I have a note from Mr Harrison saying this may be an appropriate time to have our break. The next section will take more than five minutes.

SIR BRIAN LANGSTAFF: This is "Other choices"?

MR STEIN: I'm moving on to "Experimentation", sir. I'm slightly behind.

This isn't the situation that we saw in the Carry On films of Dr Lancelot Spratt, wandering around his clinic doing his rounds, that distance between consultant and patient. These are the haemophilia consultants themselves engaging very closely with their patients, knowing that people had families, and indeed meeting their families. And they knew, therefore, that when treating an individual about the risks of haemophilia not only for the transmission to the individual, but the concern that was expressed across all medical literature as to the onward transmission to others.

Now, we accept that there is no actual evidence that haematologists had money paid into Swiss bank accounts, or that they sat down with a large brandy in hand and plotted the extermination of haemophiliacs. So what on earth were they thinking?

We believe they fell in love with blood concentrates. They were seduced by it. It was easy to use and it was, on the face of it, effective as a treatment.

Can we have on screen, please, the image of Factor VIII.jpg, please.

Here it is. Teeming with infectivity.

I'm not sure in this Inquiry that we have looked at a bottle of the Factor VIII before. And, sir, you know

SIR BRIAN LANGSTAFF: Let's take the break now then, shall
 we, and come back at 11.40 am.
 (11.11 am)
 (A short break)

5 (11.40 am)

MR STEIN: Sir, may I just make one small correction. I'm
 very grateful to Ms Milligan for bringing this to my
 attention.

I referred to a reference, which is FACT000005, to the 1943 Ministry of Health memorandum. She expressed to me, and she is right, that the reference should in fact be NHBT0000091_011.

Instead, sir, of patient choice, the shadow of experimentation looms large over this Inquiry. The evidence from victims tells us consent was not freely given, but the disturbing evidence that concerns experimentation and clinical studies is obvious and before us. The "only good" letter we examined earlier bears on this issue for obvious reason.

We have had examples of this. I'm going to be referring at the moment to the Royal Free.

The Royal Free's late adoption of concentrates gave rise, we suggest, to a greater responsibility on behalf of Drs Kernoff and Tuddenham to weigh the benefit versus risk of concentrates to each individual patient.

It was well known by 1978 that NANB was a particular risk in concentrates. It was not believed at that time, that was what was thought, to be so prolific a risk in cryoprecipitate. We suggest that there is a connection between Drs Kernoff and Tuddenham switching patients to concentrates and at the same time retaining a policy of obtaining blood samples from patients in order to study hepatitis.

The late adoption of concentrates at the Royal Free put the physicians there in a particularly advantageous position when in 1982 the risk of AIDS became apparent, because there had only been a relatively short interval since the use of cryoprecipitate had stopped.

We suggest that there was another choice available but not taken, that Drs Kernoff and Tuddenham failed to take advantage of at the Royal Free, which was to acknowledge the experience of cryoprecipitate treatment and revert to it, reducing the possible incidence of further infection with AIDS.

Professor Lee gave evidence to the Lindsay Tribunal concerning the organisation at the Royal Free, prior to '78. The reference is at LIND0000326_0005.

Well, at the Royal Free they went on using it probably for longer than other places, and this was because Katharine Dormandy had this pioneering

by Dr Goldman. As soon as Dr ... Kernoff arrived as my co-director in mid-1978, he took that over ... Dr Kernoff, with his research interest in blood transmitted hepatitis instituted a plasma/serum bank of stored frozen samples, taken regularly from patients attending for treatment."

Why was the Royal Free attractive to Professor Kernoff? Logically, given his interest in post-transfusion hepatitis, would it have not made more sense for him to look for a position in a centre with a higher incidence of post-transfusion hepatitis?

It is possible that Professor Kernoff's attraction to the Royal Free was the comparative number of patients who had not by '78 been exposed to large pool concentrates.

We suggest that the work of Professors Kernoff and Lee in their '85 paper entitled "High risk of non-A non-B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates" would constitute clinical research, in that Professor Kernoff altered the treatment of haemophilia patients with the intention of following them up and establishing the rate with which they became infected with post-transfusion hepatitis.

Now, in the early days of the use of blood

experience, I suppose, and was very enthusiastic about cryoprecipitate. She, Professor Lee went on to say, said, "I'm afraid our centres are full of disasters".

She in 1978, referring to Professor Dormandy, died, just at the point the new centre had been built, and two co-directors were put in, Dr Kernoff and Dr Tuddenham. They were young doctors and they came in '78 and very rapidly changed everybody to concentrate. There had been some people who had had concentrate before then but I think up until '78, the majority were still probably on cryoprecipitate.

Dr Tuddenham tells us that when he came to the Royal Free as the Haemophilia Centre Director in 1978, Katharine Dormandy was terminally ill and the service was then being run by Dr Eleanor Goldman, with the assistance of a senior nurse.

Dr Tuddenham goes on to tell us how arrangements changed once he and Professor Kernoff took their directorships. That is in reference WITN3435002_0009.

He says:

"To begin with obtaining supplies of treatment materials, cryoprecipitate, plasma, NHS concentrates of factor IX or factor VIII ..."

Sorry, I will change that in a moment:
"... and commercial factor concentrates was handled

concentrates as treatment, and essentially during the time whereby there's evidence before this Inquiry of experimentation, it wasn't in fact that long ago. In 1947 we had the drafting of the Nuremberg Code. The Nuremberg Code emphasises that voluntary consent of the human subject is essential when experimenting on them. And I quote:

"This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

In a moment I will turn to licensing and discuss its role in the facts that you have to consider, but before I do let me summarise what we say about consent, the timely provision of information, experimentation and harm and the consequences that may follow.

The criminal law is, in effect, the bottom line of regulation. Criminal law says that if people harm each other then there will be consequences. Doctors have no special immunity. A doctor treating a patient and

touching them for the purposes of a diagnosis and possible treatment does so with the consent of the patient who has come to the doctor for their medical expertise.

Well, so far so good.

Haemophiliacs suffer from an inherited disorder which means they require expert medical support throughout their lives. If a doctor invasively treats a patient without their consent and harm is caused, then they open themselves up to a prosecution.

Now, of course, the CPS in this country or relevant prosecution authorities in Northern Ireland and Scotland will have to consider whether it is in the public interest to prosecute any case, and some cases are clearer perhaps than others.

I was discussing this the other day with Clive Smith, the Chair of The Haemophilia Society. He is an experienced criminal advocate as well. And his point, a good one, is that there may be real clarity in cases where patients were not told of their infected status and passed on their infection to their partners. That might mark a high point of criminality.

But all treatment without consent causing harm needs to be considered through that, as I call it, the bottom line of regulation, the criminal law.

the use of concentrates. You, sir, have heard and seen a great deal of evidence on the machinations of the licensing regime. This effectively operated as a chain. The Department of Health Medicines Division evaluated the licensing application and sent it to the most relevant specialist subcommittee of the Committee on Safety of Medicines, the CSM, which, in the case of blood products, went to the Biologicals Subcommittee. The Biologicals Subcommittee fed its recommendations to the CSM which, in turn, advised the Minister of the Department of Health, who is the Licensing Authority.

Against a backdrop of the decades of awareness of the risk posed by blood products that we have outlined and particularly the risks from larger pools, one of the central questions for this Inquiry to answer is how is it that this country's regulator came to license the use of large pool commercial concentrates in the early '70s? That was a decision which undeniably and irrevocably changed the landscape of risk.

The answer, perhaps, boils down to this, as with those administering blood products: the regulators failed if their duty to assess the risk by reference not only to the harm it might cause but also to the relative benefit to be gained.

Now, that was supposed to be the essence of the task

Now, it is now 2023, and in some cases it has been many decades, perhaps even 50 years since the individual was infected. Time itself is no barrier to prosecution of cases. You will have seen our discussion within our written submission, sir, of the difficulties of the operation of the old Year and a Day Rule that poses particular problems for allegations of a homicide.

Obtaining the interest and engagement of local police authorities is not going to be easy. It is always going to be difficult. They will regard these cases as complex cases. That doesn't mean that they should not consider them but we have to accept that there will be real difficulties in looking at that in the future

One of the factors that, sir, this Inquiry needs to consider, the compensation framework needs to consider in the future, is the lost opportunity for accountability through criminal law and criminal prosecution of individual doctors because of the passage of time and the prevarication by the state and the failure to own up or 'fess up to their own culpability.

Let me deal now and turn to licensing. In the creation of this scandal, the perils of a system where doctors decided to make their patients' choices for them went hand in hand with a failure to properly regulate

entrusted to them by section 19 of the Medicines Act 1968. They were asked to have particular regard to safety, efficacy and quality.

The first product licences issued in respect of concentrates were those for Hemofil and Kryobulin in February and March '73. As we have already discussed, at that time, it had been known for decades that blood products carried a risk of virus, transmission and, more importantly, that the risk increased as pool sizes themselves increased.

We know that. As an example, a memo produced in 1946 from the Ministry of Health, DHSC01000008_191, the Ministry's consultant adviser on blood transfusion wrote at that time:

"Whilst homologous serum jaundice follows the use of whole blood in very few of the recipients, the use of dried plasma is followed by the development of jaundice in about 10 per cent of those receiving it. This incidence is probably halved if plasma is used which is made from plasma pools derived from the blood of only ten donors instead of from large pools derived from the blood of greater numbers."

Can I emphasise plasma pools being referred to of ten donors. Anything in that Ministry of Health document above ten was a large pool.

That was 1946. Come '73, the time of the licence approvals, it was also known that imported blood products, particularly those obtained from the US, carried a higher degree of infection. In fact, that very same month, an expert group was convened by the Department of Health to create self-sufficiency targets.

The Inquiry's chronology quotes the Archer Report at page 28, which states:

"In '73 the Department of Health convened a group of experts to assess the likely future requirements of Factor VIII concentrate. It met on 20 March 1973 and quickly agreed that the UK shall become self-sufficient in the shortest possible time. It estimated that to achieve self-sufficiency would require 400,000 donations of blood annually of which 275,000 should be used for Factor VIII concentrates."

That effort was driven, at least in part, by the Department's knowledge that foreign blood products carried a greater risk of infection. That much was admitted in the 2007 Self-Sufficiency Report, since withdrawn as a result of the compelling critique in the dissertation of our client, Carol Grayson.

There can be no room for doubt that the specialists who constituted the Biologicals Subcommittee of the CSM, as well as the CSM itself, were alive to these issues.

short of recklessness. We know, sir, that this got worse, pooling and re-pooling. There was a well traversed path of apprehension towards larger pools of plasma and for good reason. On the other hand, there was a complete absence of evidence to justify increasing pool size or testing under control conditions, compliant with Nuremberg, those potential ways forward in relation to possible ways of trying to establish safety, thrown to the wind.

That reckless decision would prove to be a gateway to the infected blood scandal. Thereafter, pool sizes continued to sky rocket, climbing even to 50,000 donors and then 300,000 donors, with the advent of re-pooling. Infections, of course, sky rocketed.

These are not and were not complicated questions of medicine which are now being interpreted with the benefit of hindsight. This is a question of basic maths. If exposure to one donor's blood poses a percentage of risk, what happens when concentrate is made from the blood of two donors: the risk doubles. Children can do that sum. It should also be remembered that the initial decision to license was not a binary one. The Licensing Authority's choice was not merely between yes to allowing concentrates or no to banning concentrates. It had the power to work slowly and

For example, in its consideration of the product licence application for Hemofil, DHSC0105593_006, at paragraph 26, the CSM noted:

"The major disadvantage of currently available commercial preparation, such as Hemofil, is that they are prepared from very large plasma pools and carry the risk of transmitting hepatitis virus. Hyland screen all their donors for hepatitis associated antigen, which reduces but does not eliminate this risk."

We know that Hemofil at that time was prepared from pools of at least 1,000 donors. Kryobulin was manufactured from a plasma pool of at least 1,000 donors. See, in these terms, reference SHPL0000071_135.

A report from Dr Maycock in January 1973 noted that pool sizes for Kryobulin were smaller than those for Hemofil. That reference is MHRA00333322_057.

So we ask this question: how on Earth could the CSM approve a jump from ten donors to 1,000 donors?

A Ministry of Health document from '63, ten years prior, states that:

"All dried plasma or serum issued in the United Kingdom is prepared from pools made from not more than ten donors."

That is at JPAC0000162_021.

We submit that the leap in pool sizes was nothing

incrementally and to impose safety conditions or qualifications as a precaution.

Those conditions could have included, for example, restricting pool sizes; only permitting blood from certain sources; testing and batch release certificates which could be combined with a cautious product rollout; product warnings and guidance. All of those measures could have controlled or mitigated the risk. Instead, what happened? Everything was allowed in; caution thrown to the wind.

Our submission on this decision-making is simple. That expansion in donor exposure without controlled measures cannot be justified now and could not be justified then.

There was a failure by the Licensing Authority, the CSM and its Biologicals Subcommittee to treat patient safety with primacy. The CSM said in its consideration of the Hemofil application, DHSC0105593_6:

"It may be considered that the decision to use this material could be left to the individual clinician who can balance the potential hazard against the anticipated therapeutic benefit to the patient."

Similar risk benefit considerations were reported in the CSM's reflections, informally relayed -- this is from Norman Berry to Dr Eibl, and referred to in

SHPL000665_142 at item 2.7, and these were shared in relation to Immuno's 1973 application:

"The Committee see the justification of some risk of hepatitis in treating a haemophiliac who would otherwise die from haemorrhage."

Yet notwithstanding the CSM view or understanding that the risk should only be entertained for those for whom there might be grave consequences, that qualification or caution did not appear anywhere whether in licensing decisions or in requirements for product literature. It should have done and, as we know, clinicians did not take that approach, and they ought to have done.

Now, although licences did not always run back to back or for their entire period of five years, we suggest that it is instructive to look at what was going on and what was known every five years after those initial licences. We fast forward to '78 and using The Lancet alone as a source, although there are many others, in a study by Professor Alter with inoculated chimpanzees, it was concluded that NANB hepatitis seems to be due to a transmissible agent which can persist and remain infectious for long periods, PRSE0004515, and of course a study by Professor Preston and his contemporaries concluded that NANB hepatitis was more

serious and progressive than was generally thought to be the case, PRSE0003622.

We also know that around that time the yellow card system reporting to the CSM incidents of NANB hepatitis following treatment from various Factor VIII products and discussed in the recently served witness statement of Anne Ryan, exhibits a table and seven such reports from '79. The table, we have reference WITN7183007, another reference to it is at WITN7183006. It is unclear as to why they chose 1979 and what the records from the earlier year show.

But those references should have resulted in action. If one considers the 1989 affidavit of the CSM's chairman in a judicial review relating to anti-depressant licences, WITN6406024, Professor Asher says this. This is at page 9, paragraph 15.2, that the yellow card scheme distinguished between serious and minor reactions. Serious reactions were to be defined as those which were fatal, life threatening, disabling, incapacitating, which result in or prolong hospitalisation. Professor Asher said that blood disorders would always be considered serious. Yet the CSM and the Licensing Authority, the Ministry, were still approving licensing and licences with ever increasing pool sizes without adequate control

mechanisms.

Five years later in 1983, knowledge of the dangers of HIV and AIDS have become part of everyone's lives. What is more, at that stage, the CDC had published its reports which linked the transmission of HIV to blood products. The CDC notified directors of the Haemophilia Centres and advised that patients and parents should be aware of the potential risks. The reference to that is BAYP0000018_119. Why didn't that happen here? Why did the CSM and Licensing Authority not take similar measures? Why instead were licensing continually approved with increasing pool sizes and without adequately controlled mechanisms?

The CSM's push for the Licensing Authority to move towards heat-treated Factor VIII came very late in '84 and into '85.

I refer now to the minutes of the meeting of 22 November 1984, DHSC0003947_015.

Dr Joseph Smith informed the Committee that heat treatment of Factor VIII, which is used in the treatment of haemophiliacs, abolished detectable infectivity of AIDS virus added to the preparation, therefore companies should be encouraged to apply for the variation of licences to permit widespread use of heat-treated Factor VIII, so that the incidence of AIDS in

haemophiliacs might be reduced.

The Committee -- this is the final paragraph -- requested that the Licensing Authority proposed to the companies concerned that they make early applications for variations to use a dry heating process in the manufacture of their Factor VIII products. Even at that late stage, the Authorities' approach was not to mandate heat treatment, backed by a threat of pulling licences or indeed to pull licences, but instead made proposals to the manufacturers that they make early applications for variations.

We suggest that a closer look reveals that the Licensing Authority's approach to those variation applications were slipshod and we say that they were focused on external appearances rather than being genuinely motivated by patient safety. Consider, for example, in this regard, the internal Immuno communications, SHPL00008_026, in which it was reported.

"Subject to minor alterations in title and directions circular, we have been awarded a product licence modification. We have, however, been informed, both unofficially and officially, that the information submitted by us for this modification was most inadequate and, but for the panic situation which existed to get everywhere on heat treated material as

quickly as possible, we would have been turned down. They expected far better proof of inactivation with evidence obtained against six, seven or eight different viruses. They wanted greater evidence shown by clinical evaluation that the product remained equally effective and with no increase in side effects."

Make no mistake, sir -- make no mistake -- a regulator truly motivated by patient safety would have pulled the non-inactivated products and only allowed those with adequate evidence of viral inactivation.

We repeat the actions of the CSM and the Licensing Authority were reckless.

Although we have presented our analysis by reference to those five year intervals, it must be remembered that those intervals, representing theoretical product licence renewal applications, were not the only or isolated windows of opportunity. The Licensing Authority had the power to revoke, suspend or vary licences at any time if the concentrates could no longer be regarded as safe or efficacious.

Despite all of the information that was known to those authorities, as this Inquiry has shown, those powers were never exercised. They should have been.

Again, the only reasonable conclusion to be drawn from that action or inaction is that patient safety came

risks posed by the products and indeed of the developing science.

As we explain in our written submissions, the statutory regime only required the CSM's input were a licence to be refused. So the system was this: the statutory system was for an application to be made for licensing, that would go to the Medicines Division, and then if it were or might be rejected or refused it would then go to the CSM.

Although some of the evidence presented in this Inquiry has suggested that in fact the CSM's views were routinely sought, the evidence disclosed just two perhaps three days ago now shows that this was not always the case. And this was the second loophole.

The second witness statement of Dr Diana Walford, the Senior Medical Officer at the Department of Health -- the witness statement I refer to is this, WITN4461158, disclosed on Wednesday -- explained that in 1977 the CSM and the CSM Biological Subcommittee were not consulted on Immuno's variation application in respect of Kryobulin. That had included the fact that it sought to move from German and Austrian sources of plasma to those from the US.

What's more, it is also apparent from that statement that Immuno were able to conceal knowledge of the

second and firmly behind commercial continuity.

Finally, we highlight that the efficacy of any regulatory regime also has to be judged by its workarounds or loopholes. The Medicines Act 1968 created significant loopholes in the licensing regime which may have contributed to the erroneous decisions being made and to the extent of infections which were spread. Can we highlight two important points.

First, one of the most significant loopholes was the named patient basis exception. Now, that allowed medical professionals to go about purchasing and importing blood products which had not been granted a product licence at their whim, or perhaps because of the effective advertising by pharmaceutical companies.

There was no adequate regulatory oversight of the use of products on that basis until May '84.

Sir, as you are aware we say much more on that loophole in our written submissions. But for the purposes of today's submission, we say that that was the "doctor knows best" dogma, robbing a regulatory regime of any teeth and cutting it off at the knees.

Second, there is evidence that licensing decisions bypass the CSM and the CSM Biological Subcommittee and therefore evaded the scrutiny of those who might reasonably have expected to have been in the know on the

American plasmas' higher risk of hepatitis from the Licensing Authority.

Undoubtedly the loophole that was the lack of routine CSM input contributed to that situation, but, and this was something that the Inquiry's Rule 9 request also picked up on, the licensing regime also failed to impose any legal obligation on a manufacturer to disclose that information by way of reference in relation to applications.

Those are, we say, issues that arose because of the opt in and toothless nature of that regulatory regime.

New chapter heading. What should have happened? There was a history of research, sir, dating back to Pasteur which showed the efficacy of heat treatment and, in particular in relation to vaccines, its use in rendering safe plasma products.

The effects of heat treatment in rendering safe otherwise potentially harmful substances is well established and dates back to the work with bacteria in the mid-19th century. The discoveries that, first, there existed viruses as well as bacteria, and subsequently that these viruses could also be vulnerable to heat, predate the events giving rise to this Inquiry by decades. We have set out in our written closing submission how this knowledge progressed and how,

through the Second World War, albumin was rendered safe through pasteurisation.

Given that efforts by Behringwerke in Germany to virally inactivate concentrates had borne fruit by 1978, BPL, Blood Products Laboratory, were dilatory in their approach to developing virally inactivated concentrates. Once a concerted effort was made, from a standing start it took no longer than two years for fractionators to produce effectively heat-treated concentrates.

If untreated blood products had been prevented from use, the very market forces which drove their dissemination into this country and into the veins of this community would have meant that the companies supplying this material would have turned their minds and their money to the inactivation of viruses within their products.

By the early '70s and the advent of factor concentrates, we find an odd paradox where it is well known amongst those in blood collection and transfusion medicine that the pooling of blood plasma without any viral inactivation technique will increase the risk of virus transmission to the recipient. Yet at the same time we have those with an interest in haemophilia care, whether they be doctors or pharmaceutical companies, racing to produce blood products which were to present

a significantly greater risk of transmitting viruses.

One might expect that, fixed with the knowledge that increasing plasma pool sizes increases risk, those developing and marketing the products might have taken some time and effort and expense first to attempt to virally inactivate the filth that they were producing to haemophiliacs as a wonder drug.

Now, there is some evidence, Dr Foster, I referred to now -- there's some evidence -- Dr Foster said that this wasn't so. He said that Factor VIII protein was considered so heat-labile that the concept of subjecting it to pasteurisation was inconceivable to him.

There are problems with that assertion. The first is that heat treatment and other viral inactivation techniques were clearly not considered unthinkable by all fractionators. The chronology of events dictates that at the time Dr Foster and some other witnesses to the Inquiry were still averring that the idea was unthinkable, Behringwerke scientists had clearly had the idea a number of years before and had some success in developing pasteurisation techniques.

The second problem is that Behringwerke were no alone in taking steps to virally inactivate products.

They were not mavericks at the vanguard of product safety, they just got further than some of their

American rivals.

There is an extract of the book *Blood on their Hands* by Eric Weinberg and Donna Shaw available on Relativity. We will supply the Relativity reference at a later stage. The book recounts the story of Mr Weinberg's investigation and subsequent conduct of the litigation in America taken by haemophiliacs infected with HIV against the pharmaceutical companies, of which, sir, as you are aware, our client group took part.

Chapter 9 of that book from page 94 onwards described Dr Weinberg's first contact and meeting with Dr Edward Shanbrom, the chief medical adviser at Hyland with a responsibility for the first development of concentrates in the United States. Dr Shanbrom is said to have raised concerns about the viral safety of concentrates in 1970 after noticing patients who were HBV antibody positive were nevertheless falling ill with a new kind of hepatitis. Dr Shanbrom is said to have been slowly let go by Hyland as a result of the expression of those concerns.

Dr Shanbrom would, of course, ultimately go on to develop a detergent washing system for virally inactivating concentrates which was licensed by the New York Red Cross.

Elsewhere, the Inquiry has seen evidence that

Travenol was investigating viral inactivation techniques in the '70s, including heat treatment, but that its research priority was slowly downgraded during the course of '78 from a grade A priority to a grade B priority.

It is expressly stated within Travenol memos that the research cannot proceed any further without more funding and dedicated research time. References to that are CGRA0000213, onwards 214, 5, 6 and 7.

Why wasn't time and resource given to this research? That's because the pharmaceutical companies didn't need to. They were able to peddle their contaminated product with the knowledge, consent and approval of US and UK regulators.

Travenol did, in '79, urgently upgrade their research into pasteurisation. But not through motives of trying to protect patients; that was for the commercial reasons. And for no other reason than to protect their market position in light of Behringwerke's development of a heat-treated product.

Reference to that is CGRA0000218.

I will tie these threads together. There is no scientific or technological discovery which takes place between 1970 and '84 which suddenly enables viral inactivation. It is old science and old technology

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which is utilised ultimately to successfully virally inactivate the products: heating a product in a stabilising solution, the same technique applied to albumin for decades. Intellectual curiosity may have been lacking, but the only thing really missing from unlocking a safer treatment was an incentive.

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It is important that had the UK licensing authority done its job properly and refused to grant licences to these lethal products, a clear and loud message would have been broadcast not just to the pharmaceuticals but to other regulators across Europe and North America. That message would have been that the risk/reward balance did not tilt in favour of reward and that these products were unacceptably dangerous.

That, in turn, would have provided the incentive that pharmaceutical companies would have needed to address viral threat properly and sooner. After all, when they are forced to put their minds to the task in light of AIDS, they managed to largely succeed in the space of little more than 18 months.

I now turn to AIDS. This is a very short section.

The damage had already been done by 1982. The domino effect of the failure to protect people from the dangers of infection with hepatitis meant that haemophiliacs were inevitably going to be infected with

at that time. Clearly, insufficient (sic) was done to withdraw those products. The answer should have been: get them off the shelves, don't use them, dispose of them.

I now turn to campaigners. Lawrence, if you would, please.

We are going to be looking at some images, photographs of haemophilia protesters, and they start -if you look to the right-hand side first of all.

For date purposes, this is in relation to a march to Downing Street on 3 April 2001. If we look, then, at the photograph that appears on the left. If you turn it right way up, thank you.

That's Ms Wintle and her husband, Steven. Sir, you can see all around them the signs, what is being said: "Hep C", "death sentence", "RIP", "Help the sick, suffering and bereaved".

Next page, please. Again, left-hand side, a photograph of Colette Wintle. She is holding in her hands bags of blood -- these weren't real -- symbols being used to demonstrate the nature of what had happened in the past.

If we move on to the next page, please.

We see here again Ms Wintle and Ms Grayson and, at the top page and the bottom, at the Downing Street part

whatever viruses were swimming in the vast pools of blood from paid donors in the United States.

Essentially, our submission in relation to the transmission of AIDS into the haemophilia community is that this is a domino effect, and what had happened is that the earlier failure to protect people from the use of blood products and the obvious dangers from the viruses contained in those products meant that so many people were already infected by the time the message came through in the early '80s.

Dr Franklin, at paragraphs 36 and 37 of his statement, WITN4032001, says:

"By 1982 there had been a few cases of transfusion associated AIDS in the USA and also a few men with haemophilia had the condition."

Going on to say, regarding awareness of an association between AIDS and the use of blood products:

"For transfusion associated AIDS, late 1982 in the USA. For plasma products in patients in the UK during 1983. I found out [about that connection, from his point of view] via medical journals, news items and word of mouth."

Sir, you have our submissions which set out in detail the chronology of events leading to the awareness of knowledge of the risk of AIDS within blood products

of the march.

Thank you, Lawrence.

The incredible campaigning work of Carol Grayson and her husband Pete Longstaff, a severe haemophiliac who died of his infections, should be recognised by us all. Carol and Pete did everything possible to bring this dark passage of history into the light.

Ms Wintle joined with Carol and, together, their campaigning became their jobs, unfunded. The basics of life and healthcare became subjugated to the campaign.

I recall standing with Ms Wintle in the area outside of the tearoom in now, I believe -- I am told by Mr Harrison -- the torn-down building that we used to inhabit for this Inquiry, I was with her, standing outside the tearoom there, and we spoke about her years of campaigning -- and this is not just a reference to her but all of the other campaigners -- the years of campaigning, the lack of ability to pursue a career, how it took over everything, family life, finances.

This will have happened to many campaigners. The life of campaigners, sir, is very different to the commercial lobbyist paid for by corporate interests who don't have to fund their own travel, paper, printing and telephone costs. Their and others' relentless campaigning kept the very issues we have examined for

four years in the public eye in the discussion.

Carol and Colette's work has been foundational.

Other campaigners and this Inquiry have followed in the path they worked so hard to forge.

They were not the only campaigners. But, as we have heard from the evidence, from politicians, they were prolific and constant. In the history of this scandal, Carol Grayson's name and Colette Wintle's name should be remembered, acknowledged and honoured.

Following the death of her husband, Ms Grayson started her research leading to a seminal dissertation, available on The Haemophilia Society's website, entitled "MA Gender, Culture and Development. Blood Flows Not Just Through Our Veins but Through Our Minds".

I read only part, chapter 6, the conclusion:

"I believe that my analysis with the SSR (the Self-Sufficiency Report) reveals that much more could have been done by the government and medical practitioners to protect haemophiliacs from the risk of contamination with HIV and hepatitis viruses at every stage. Once they became aware that haemophiliacs were infected, they disempowered patients by withholding information, denying them informed choice in relation to treatment, carrying out unethical research and, in some cases, failing to treat their medical conditions."

HIV clinics, where the ready assumption was always made that they had been infected through drug use or had been sex workers. At times the evidence has demonstrated that women have been relegated to the back row and excluded from the heart of discussion. You will recall Ms Pappenheim, at paragraph 11 of her statement, WITN45040001 referring to the launch of the women's project. She refers to it as being very important the charity was recognising — was seeking to engage with the women affected by the scandal.

But this is what happens, isn't it? If the Government pushes aways or refuses to consider its own culpability then, in turn, it avoids its own responsibility to sort out its mess, instead leaving the debris of victims and the avoidance of support for those infected both directly and indirectly.

During the course of the Inquiry, I was sent a message by Clair Walton, whom I represent. I read it:

"As an infected widow, I have been out on a limb and ignored in the community. Most of my adult life, since 23, has been consumed with dealing with the aftermath of my husband's HIV diagnosis. Caring for my dying husband, making sense of my own HIV infection, loss of family life, discrimination, stigma and near-death from AIDS defining illness, relentless 30-year battle with

We suggest we should all pay attention to what Ms Grayson was writing there, because she foreshadowed so many of the aspects that we have been considering in the evidence over these many years of this Inquiry.

The campaigning work by so many didn't just have to address government but also had to look at times to the work of the represented body, The Haemophilia Society.

Now, The Haemophilia Society we say without question has become more representative and is trying to work with the community. But that has not always been seamless. The letter from Chris Hodgson that was examined within the Inquiry time, WITN1055079, referring to the campaign now being more inclusive. Suggesting that it hadn't been so inclusive in past.

Women campaigners and women infected with hepatitis and/or HIV have always faced stigma and discrimination and had to fight tooth and nail for inclusion within campaigns and consideration by government. Clair Walton and anonymous witness WITN1388 were forced, through this lack of recognition, to start their own campaign for those women who were infected with HIV by their partners, who had of course been infected by blood products themselves.

Non-haemophiliac women with HIV were not catered for by the haemophiliac centres and instead were treated at

the MFT over the charge on my home, restricting my freedom to move away and get on with my life, attempting to maintain a career I love, pursue a semblance of normal life, the campaign for justice and recognition and understanding of the needs or the needs of women living with HIV."

Then she finished that by saying then we get the THT.

Now, the effects of the decades of the delayed acknowledgement of harm done by the state is that, instead of considering and dealing with the fallout from the NHS and Ministry of Health's failures to protect its vulnerable patients, what we have instead is a failure to consider how far that harm has extended. Decades of delays, not just in compensation but in rounded support for its victims or families.

Haemophiliacs who have been infected all face complicating features of their conditions and the combination of medications also give rise to adverse effects through treatment interaction. You will recall the evidence from the witness before the Archer Inquiry reference ARCH0000004_0010. The description which I recall, which stuck if my mind, is being a bit like being on chemotherapy for the rest of your life.

Long-term, an individual infected with HCV and those

co-infected with hep B and HIV may go on to develop various chronic infections. Some of the complications are costochondritis, fibromyalgia, early onset of menopause, deterioration of the spinal discs connected to the anti-viral chemotherapy used to treat chronic HIV.

We are also behind, as I recall, in speaking to an anonymous client I represent, also very much behind in our research as to the long-term effect upon an aging population of haemophiliacs with infections and co-infections.

The damage to the liver in an infected individual is well known, as is the increased possibility of developing cancer, but the liver damage can also affect blood platelets which, if they reach a low level can be life threatening.

The consequences and possible complications which arise from the infection via contaminated blood and the need for support for partners of haemophiliacs and deceased haemophiliacs can be identified and the needs of the limited community of people are known. The partners of deceased haemophiliacs are inadequately catered for within the NHS, as they get older they face continuing, often worsening issues with stress, depression and PTSD.

in some detail in our recommendation submissions.

I don't want to overly labour this point but I do want to say that the former MFT, Macfarlane Trust, registrants' objections to the THT are not based on any foundation of prejudice or any sense of "guilty" and "innocent" victims of HIV. Their objections are based solely on the fact that the interests pursued by the THT do not coincide with those of the former registrants and, in fact, conflict with them.

That point has been illustrated recently with the THT throwing itself behind a campaign to make every contact count, exceptionally advocating an opt out scheme whereby every time blood is taken in a clinical setting it ought to be tested for HIV, HCV and HBV. Recalling the vast amount of evidence you have heard over the last four years, sir, the idea that people ought to have their blood tested for these viruses without a proper pre-test counselling framework in place is the antithesis of what the former MFT registrants would want to see in its place.

At its most fundamental the residual Macfarlane Trust funds represent power, which is capable of being wielded over the former registrants. The former registrants of the MFT Trust, those we represent, want to see those funds surrendered by the THT, divided

I spoke with Amanda Beesley the other day. She spoke about the fact of the way it feels to her sometimes that she's teetering on the brink. She spoke about her well-rehearsed knitting of threads together which might unravel, as being her mental state.

The failure by Government to listen to the truth and acknowledge its own responsibility for these decades has multiplied the suffering. That needs to be stated, it needs to be recognised and it needs to be acknowledged by the state.

Sir, I now go on to deal with recommendations. So this final chapter in my submissions is "Recommendations and the way forward".

Sir, you will have read and seen our submissions on recommendations. They are at page 196 onwards. We see no benefit in repeating those submissions orally. Instead, I'm going to make some submissions about the Terrence Higgins Trust, the THT, Governmental change and then go on to suggest a proposal for you to consider as to the delivery of your report.

Terrence Higgins Trust. Without wishing to take away from the important and life changing work that the Terrence Higgins Trust has done over the last 40 years, their involvement with the former Macfarlane Trust registrants is simply inappropriate. We deal with this

amongst the four national haemophilia societies and employed for the purposes of creating monuments to the former registrants. This is the only way that the power residing in the residual funds can be eradicated and the only way in which the former registrants will be freed from the advocacy which has been forced unwantedly upon them

Now, I turn to Government. Regarding Government, we must stop the head banging. The head banging I refer to is the head banging of campaigners and survivors against the administrative and overly bureaucratic castle walls of state, in what has almost become an oft-used hackneyed phrase: speaking truth to power. That only works if power is prepared to listen. Instead, what we have seen and discussed in this Inquiry and other Inquiries is that power only listens randomly, capriciously and, frankly, when it is politically in the mood and has a moment.

It is hard to accept, sir, that Government lobbyists paid for by corporate funds who employ basically insider club members, many of them ex-politicians, ministers and even prime ministers, who automatically, it seems, have access when campaign groups have to increasingly get permission from the police to demonstrate outside the hallowed walls, it is not difficult to say that

something clearly is going wrong.

Disasters have happened in the past and disasters are going to happen again. Disasters of themselves are not unusual. So why do we find that there is no system to cope? Why do we find there is no system to cope with the victims? Campaigners should not be met with a blank wall of state and the words "the Government line". The Government line, phrase or anything similar, should be treated by current and future ministers with scepticism and questioning and not blind acceptance.

A simple improvement, we suggest, would be for all Government lines to be dated so that we know when they started and for ministers to ask, if that is not apparent, for how long has this line been held?

In addition to consideration of ours and others' proposed recommendations, you may wish in your report, sir, to comment on the need for an Inquiry recommendation oversight system. We have considered how that might be done.

This could be by a dedicated select committee or the use of the standing departmental committees for the relevant ministry, with a duty to maintain a watch on inquiry and perhaps inquest recommendations. Select committees have the power to call for evidence and witnesses to come forward and publicly seek explanations

me "Finish the job" and I always took those to be wise words. Later on in my career, in moments of reflection, I have in odd moments whether she just meant to me, directly, "You finish the job". Nevertheless it stuck in my mind as a phrase and a touchstone for the work that I've done over many a year.

Peace in the way I have described it is very difficult to do within the powers of a statutory inquiry, because when you finish the last full stop on the last page of your report and your report is delivered to Government, your powers as an Inquiry Chair are extinguished. This has every potential to leave your report and its findings and recommendations at the whim of Government, and I think that we can establish one thing, Government is not trusted by our client group or indeed this community.

So what we ask is this, you consider issuing a final report, setting out your findings on the main evidential points and the conclusions that follow.

But deliver part of your report as an interim report, allowing time for Government to complete its internal discussions on the compensation scheme framework, incidentally allowing time for an answer from the Department of Health to your question about what it has apologised for.

for delays in implementation or reasons why individual recommendations are no longer required. This is never going to be a perfect system.

For example, we note that select committees have no power to call for evidence from Members of Parliament or ministers, although generally they do secure the co-operation of Government ministers.

I turn now to the delivery of your report, I do so gently and with trepidation because I, respectfully, am going to make submissions as to the shape of your report.

Can I suggest, sir, that in everything you do and consider, when looking at the evidence in this matter and looking and then thinking about your recommendations, that you aim as far as it is humanly possible at peace and finality.

After Penrose, Lindsay, Archer, let's make this the final report on the worst medical disaster in the history of the NHS. So what do I mean by "peace"? I think I mean that we must finish the job or, put it another way, leave no loose ends.

I remember now, sir, you may accept many years ago, working as a paralegal employed by a terrific East End solicitor, Ms Cherry McMillen, recently retired as a judge in the island of Guernsey. She always said to

The advantage of taking such a course, splitting essentially the report into a main report with its conclusions, findings and its main recommendations — the answer that would be provided would be the retention of your powers under the Act, so that you could then, if required and if necessary, call for evidence from whoever at that time might be the minister in charge or to recall Sir Robert to answer questions as to the viability and acceptability of the Government's response and proposals as regards compensation.

After all, sir, as we have seen very recently, not following report recommendations is hardly a new sport. We note the recent news and discussions about the Hillsborough report and the Home Secretary, Suella Braverman has recently reneged on the Government's commitments given in the light of the Windrush report recommendations.

Sir, we make these submissions and we find support for this way ahead in the terms of reference -- always useful -- treatment care and support, number 8 of the terms of reference. This Inquiry is bound to consider the nature and adequacy of the treatment care and support, including financial assistance provided to people who are infected and affected, including the bereaved.

Sir, to achieve finality and to achieve what I have discussed by way of the way forward, you may find that that paragraph would assist you in considering a split way of providing a report, to give Government the understanding of your findings, your consideration of evidence, while leaving open also the ability to consider the way the Government responds.

In our submission, this Inquiry will not have fulfilled its terms of reference, with the greatest of respect, until such time it has been established what the Government will do in terms of financial provision for the infected and affected going forwards. The Department of Health's evasive closing submissions lend, we suggest, special weight to the necessity to continue to apply scrutiny to the action of Government in this regard.

Before I set out my final and very short concluding remarks, let me use this platform to send a message to the Labour Party.

Wes Streeting MP is Labour's Shadow Health and Social Care Secretary and with, Sir Keir Starmer, we suggest that he and they must, as a matter of urgency, commit the next possible Government to the implementation of the Inquiry recommendations and the establishment of the compensation scheme.

We are, sir, all aware that the politics of the moment are even more unstable than usual, and that is saying something, but the victims and survivors of this disaster must not be left to wonder whether a possible future Labour government might hold up or stall the development of the compensation scheme.

My final concluding remarks. Sir, I have to accept that my request for peace is the hardest of goals. But many of those infected and affected simply want peace and the ability, as far as this can ever be achieved, to put this behind them and quietly get on with the remainder of their lives. We ask, sir, that you bear this goal in mind when finalising your report.

But, sir, at least for now, you get peace from me. Thank you for listening.

SIR BRIAN LANGSTAFF: Thank you very much, Mr Stein. You
 need not have worried, as you said at the start, whether
 you would do your duty by your clients, plainly you
 have.

I will have something to say perhaps this afternoon, which may touch upon the last matters that you are mentioning, but you will have to wait and hear that if you want to.

Before me, we will have Ms Richards but we won't have her now, we will have her at 1.50 pm. 1.50 pm.

(12.48 pm)

(The luncheon adjournment)

(1.50 pm)

Closing statement by MS RICHARDS KC

SIR BRIAN LANGSTAFF: Thank you. You really didn't have to stand up. Ms Richards does.

MS RICHARDS: I should perhaps explain that the Chair's new location is not because I'm about to start cross-examining him, sadly.

I want to start by saying something about the Inquiry's work over the last four and a half years. I'm then going to say something -- a little about the Inquiry's work after today because today is not the end. And finally I will make some observations about just a few of the issues that have emerged from the oral and written submissions that we have been considering over the last few weeks

The events which gave rise to this Inquiry have memorably been described as the worst treatment disaster in the history of the National Health Service. The scope of this Inquiry has been unprecedented in what I would suggest are four particular respects.

Firstly, as to the scale of the disaster. The number of those infected runs, as we now know, into tens of thousands, many of whom have died. And as we have

been powerfully reminded during the submissions, not least yesterday and this morning, people are continuing to die in consequence of their treatment with infected blood and infected blood products.

Secondly, the Inquiry's scope is unprecedented in terms of its geographical scope, covering all four nations within the UK, and giving rise, as you have heard this week, to considerations about the relationship between the UK government and Scotland Wales and Northern Ireland both pre and post-devolution.

Thirdly, the scope of the Inquiry is unprecedented in terms of its time frame, exploring over five decades of knowledge, of decision-making, of action and of inaction

Then the fourth respect is this, most Inquiries examine a catastrophic event and the circumstances, which may often be complex, which lead up to that event. This Inquiry's terms of reference have required it to consider the response of government, the NHS and others in the decades following the transmission of infection.

Mr Dawson KC yesterday talked about the way in which the harms caused by infection and treatment have been, and I quote from his submissions, "irrevocably and multiply compounded and increased by the way the state has reacted", and he described the compounding of the

harm as a unique and important element of the disaster which you, sir, will have to consider.

It is important that the wider public and the media understand that this is not simply an inquiry into matters of history. This is an inquiry into, as Mr Williams KC put it on Wednesday, the here and now. It is an inquiry with ongoing relevance and resonance to decision-making by government and the NHS today.

In the last ten days, three reports have been published.

On 24 January the Committee on Standards in Public Life published the report that its Chair,
Lord Jonathan Evans, told us about when he gave evidence to this Inquiry in November. That report is about the need for active work to ensure that the ethical values reflected in the Nolan Principles become the cultural norm for those in public life. The inference being that there is still more work to be done in that regard. And you may think one only has to read the news to believe that to be the case.

The second report published this week is the report from the College of Policing and the National Police Chiefs' Council, entitled *The National Police Response to the Hillsborough Disaster*. It is a response to Bishop Jones' report, about which you have heard a lot

to gather a vast amount of material. It has had to obtain, sift and analyse contemporaneous documentation from a wide variety of sources and then use that documentation to obtain statements from a large number of witnesses.

It is only right that I should acknowledge that the Inquiry has had extensive co-operation from Core Participants and their legal representatives and I should say that has included the Department of Health and Social Care. We are grateful for the amount of work that's been devoted by witnesses to the task of engaging with and responding to the Inquiry's requests for documents and statements.

A few facts and figures then about the Inquiry's work. The number of documents disclosed to Core Participants is, I am reliably informed, over 100,000, comprising over 0.75 million pages of material. We have received over 4,000 statements from those infected and affected. We have received well over 1,000 -- I think the precise figure, in fact, is 1,200 -- statements from other witnesses, from doctors, politicians, civil servants, those involved in the Alliance House Organisations, those working for pharmaceutical companies, and so on.

We have obtained material reports from seven

in recent weeks, his report entitled *The patronising* disposition of unaccountable power. And that police report accepts that those who lead must acknowledge when mistakes have been made and must not seek to defend the indefensible

The third report just published is a report from the Patient Safety Commissioner for England, Dr Henrietta Hughes. She's just reported on her first 100 days in post. It makes depressing reading. She says this:

"Over my first 100 days in the role I have heard a yearning desire for patient safety to be at the top of the agenda. It is clear from what they told me that the focus on the Health Service is on productivity, operational performance and financial control."

She said this, and this is a sentence which I think will resonate with all of you, "Medicine is industrialised when it needs to be humanised".

She said also this, worryingly:

"It is clear that the culture is getting worse and unless leaders set a strategic intention to listen and act we are heading straight back to the days of Mid Staffs and other health scandals, severe harm and death."

Turning then to the Inquiry's work. In order to fulfil its wide terms of reference the Inquiry has had

different expert groups and I will refer to some of those in the course of my address. The Inquiry has heard orally from 370 witnesses and has sat hearing evidence and submissions for 286 days, including today.

I hope you don't mind if I give you a quick recap of what we have covered in the oral hearings.

Following the preliminary hearings in September 2018 at Church House in Westminster, we heard the evidence of people who were infected and affected, starting in London at the end of April 2019, we then moved to Belfast, to Leeds, to Edinburgh and Cardiff and then again sat in London in October 2019.

In February 2020, the Inquiry heard from the intermediaries who were able to tell us about the experiences of those who had not felt able to give witness statements to the Inquiry but who wanted their story nevertheless to be heard. We heard from clinical experts in relation to hepatitis, HIV and on bleeding and blood disorders, and we heard from the psychosocial expert panel. Mr Dawson told you yesterday of the importance of that evidence from his clients' perspective.

That evidence helped all of us understand the multiple and profound ways in which lives have been impacted above and beyond the devastating direct

consequences of infection and treatment. I just want to read one short passage from the evidence of the psychosocial experts. It was on 24 February 2020 and it is page 150 of the transcript.

The question which I put was as follows:

"One particular feature from the evidence that the Inquiry has heard is that for many people their whole lives have become defined by the condition with which they were infected and treatment for it, for symptoms and so on. But the result is that they have had to live a life completely different from the life that they would otherwise have expected to and they have lost opportunities, been unable to fulfil a potential that would otherwise have been there. How does that bear upon their psychological experience?"

This was Professor Weinman's answer:

"Hugely, because [he said] going back to what I said earlier about one's sense of self, one's sense of self identity, I think some people have said, you know, if you think of illness as a sort of set of things and one's self as a set of things, for some people, you know, the sense of one's self can be completely obliterated because day to day this is what's happening to you. There is nothing else. So those multiple selves, one's future selves, all those really important

We also began the first of a series of presentations. We started looking at the work of Professor Arthur Bloom, the Cardiff Haemophilia Centre and the Oxford Haemophilia Centre. Such presentations are not a normal feature of the way in which public inquiries normally hold their hearings but it had seemed to us important where there was no living witness that the key facts and documents should be examined in a public domain for all to hear.

We heard the first of a number of haemophilia clinicians starting in October 2020 with the evidence of Dr Mark Winter. We heard from a number of other clinicians over the following months and, where we were not able to call key doctors, we continued to examine the contemporaneous documentation in the presentations.

We heard from the expert panel of medical ethicists in January 2021. I will come back to their evidence but, again, it is hugely important evidence from the Inquiry's perspective.

We heard from Mr Watters of The Haemophilia Society and evidence from those involved in the Alliance House Organisations through February and March 2021. In May 2021 we heard from Health Ministers in each of the four nations, together with those involved in the current financial support schemes.

dimensions become pretty well wiped out.

"That is from an experiential point of view but also in terms of people's aspirations absolutely devastating. The idea of having, you know, no obvious future or incredibly uncertain future which is completely dictated by this thing which now defines you is massively impactful."

Sir, I know the psychosocial evidence will be hugely valuable to you in your work of addressing part 4 of the terms of reference

Returning to the oral hearings, it had been the Inquiry's plan to start hearing from haemophilia clinicians in the summer of 2020 but as we all know events took a different course and the pandemic intervened. That led to those hearings being deferred to September 2020 but, since that time, the Inquiry has managed to continue to conduct its hearings, notwithstanding the constraints imposed by Covid-19.

The September 2020 hearings began with the evidence of Lord David Owen. His important evidence was then followed by an examination of medical and other literature, so as to analyse and importantly expose to public scrutiny what was actually known and what could or should have been known about the risks of viral transmission at the relevant times.

I am sure you will all recall Mr Matthew Hancock, then Secretary of State for Health, accepting moral responsibility on the Government to address the impact of what happened to you. He said this too:

"Should substantial compensation be the outcome of this Inquiry, then we [the Government] will provide it."

In June 2021, having heard further evidence about The Haemophilia Society, we heard evidence from campaigners and we examined and called evidence in relation to Treloar's. I do not think I am, in any sense, prejudging the conclusions you reached, sir, when I observed that the evidence that we examined and heard in relation to Treloar's was truly shocking.

In July 2021, we heard the first of our government witnesses, civil servants and politicians, Dr Diana Walford, Lord Glenarthur and, memorably, Lord Clarke. I am sure you will all understand when I say I am unlikely ever to forget the experience of questioning the latter

In September 2021 we heard the evidence of Lord Fowler, which you may think set a rather different tone. Then between September and November 2021, we examined the actions and roles of pharmaceutical companies, largely through presentations and analysis of the contemporaneous documentation but we heard also from

Christopher Bishop, an employee of Armour.

In November 2021 the Inquiry turned its forensic lens on the Blood Transfusion Services and that work continued into February 2022. As well as presentations on the organisational structures and history of the blood transfusion services, we examined the work of Dr Gunson and Professor Cash. We were able to hear from a number of surviving Regional Transfusion Directors, fortunately this was an area in which we were able to hear directly from those involved in Wales and Northern Ireland, which has not always been the case.

That phase culminated in the evidence of Dr Lloyd the Newcastle Regional Transfusion Director. You will recall no doubt that in 1991 he had been vilified for having the temerity to introduce hepatitis C screening ahead of other Regional Transfusion Directors.

In February 2022, we undertook the vitally important task of examining blood transfusion policies and practices through presentations and witnesses.

We moved in March 2022 to consideration of self-sufficiency, domestic production and viral inactivation, hearing from Drs Foster, Snape and Perry.

In May 2022 we returned to government decision making, mostly hearing from witnesses from England and Scotland, a range of civil servants and politicians,

have died and whose testimonies we have never been able to gather, those who have been infected but who have for perfectly understandable reasons not felt able to participate in the Inquiry, no doubt in part because of their experiences of stigma and trauma, and those who may have lived and died unaware of their infection as a result of blood transfusion.

Thirdly, in relation to the oral hearings, there are key individuals from government, from the medical profession, from pharmaceutical companies and elsewhere, from whom the Inquiry has not been able to obtain statements either because they are dead or because of impairments of health and age. Bloom, Gunson, Cash, Lane, Forbes, Willoughby, Galbraith, Acheson; those are some of the names that came to mind.

Had this Inquiry been heard in the 1990s most -- not all but most -- of those would have been able to give evidence. However, notwithstanding that disadvantage, we have, we think, been able to gather and shine a forensic light on sufficient of the contemporaneous documentation to enable you, sir, to answer the terms of reference comprehensively.

If I turn briefly to the Inquiry's ongoing work.

The oral hearings come to an end today but the work of the Inquiry continues. That burden will fall largely on

predominantly Health Ministers but also a former Prime Minister, John Major.

That took us to the end of July 2022 but of course, also in the course of July 2022, we heard the evidence of Sir Robert Francis, nearly seven months ago now.

Following further government evidence in September 2022, the Inquiry hearings moved into their last phases. Between September and October we returned to the vitally important exercise of hearing from those infected and affected directly.

We heard expert evidence from the public health and administration group, evidence from Professor Richard Tedder and then, in November, we moved into two weeks of evidence relevant to recommendations, covering a wide range of issues and culminating with the evidence of Professor Sir Jonathan Van-Tam.

Three short observations about the oral hearings. First, I must emphasise that whilst the Inquiry has heard orally from a significant number of the infected and affected community, there are many more who did not give oral evidence but who have provided written statements to the Inquiry. Their evidence is just as important — and I know you, sir, have faithfully read those statements.

Secondly, we must not and do not forget those who

you, sir, and I know you will shortly provide some further information in that regard. I won't try to steal your thunder.

There are some witness statements still being received, and hence there will be some continuing disclosure of documents and statements to Core Participants, as well as a process of publication of a large amount of material on the Inquiry's website.

It is very much now an exercise of crossing t's and dotting i's, filling in very small pieces of the jigsaw, and we do not expect the material that we are continuing to receive to be likely to alter any of the submissions that have been made.

If, however, there are any particular significant statements, I undertake to flag that up to recognised legal representatives, and if they wish to add to their written submissions, they can, where the Chair considers it would be helpful, be facilitated.

I want to turn then to some observations relating to issues that have arisen in the course of the submissions hearings. But I'm going to preface them with a general observation

Section 2.1 of the Inquiries Act precludes the Chair from ruling on or determining any person's criminal or civil liability. But section 2.2 provides that the

Chair is not inhibited in the discharge of his functions by any likelihood of liability being averred from the facts he determines or the recommendations he makes.

What that means, sir, is you are free to criticise. You are free to say that wrong was done and to particularise, if this is where the evidence leads you, the respects in which you consider wrong was done.

You are free to say that governments or clinicians or NHS bodies or pharmaceutical companies acted unreasonably, or unethically, or unconscionably or failed to act when they should.

With that in mind, can I then address three points that have arisen out of these submissions. The first is the nature of the obligation owed by the state or the government to its citizens.

Although the Chair is not empowered to determine questions of legal liability, as I have said, he is entitled to consider the nature and extent of the state's obligations and responsibilities to its citizens, and that may provide a useful backdrop to an analysis of what happened and why.

Core Participants in their submissions have identified three sources of obligations and responsibilities. The first are international and human rights conventions and instruments. They are

Inquiry's work.

One other source of responsibilities and duties identified by Core Participants in their submissions are domestic, legal duties. Mr Snowden's submissions take you, sir, to the National Health Service Act of 1946, 1977 and 2006. I don't propose to rehearse those. But you will no doubt need also to consider the position in relation to Scotland and Northern Ireland because those Acts cover England and Wales.

But the third source of state responsibility is what might be characterised the moral duty. Lord David Owen when he gave evidence from his perspective as a Health Minister in the 1970s -- and his evidence was given on 22 September 2020 -- was asked this by you, sir:

"As a matter of principle, do you see it as one of the first duties of the state to look after the safety of its population?

"Answer: Yes.

"Question: So that would extend to the safety of patients receiving blood or blood products?

"Answer: Yes."

Exactly one year later, on the second day of his oral evidence, Lord Fowler was asked a similar question by the Chair:

"Question: Would your standpoint have been that 103

discussed in some detail in Mr Snowden's written submissions and in Ms Monaghan's written and oral submissions, and I don't propose to repeat them.

There is only one additional matter which I flag up. Ms Monaghan, in paragraphs 30 to 31 of her written submissions, described one particular protective obligation under Article 2 of the European Convention, that's the obligation to protect life.

The obligation she described arose from a decision of the European Court of Human Rights in a case called Osman. It is an obligation often referred to as the operational obligation.

But there is a separate and additional obligation under Article 2 that you, sir, may wish to consider. It is referred to in the case law of the European Court of Human Rights as a systemic obligation. It is a duty to make regulations compelling hospitals to adopt appropriate measures for the protection of patients' lives, a duty to have effective administrative and regulatory systems in place, and a duty which encompasses necessary measures to ensure the effective functioning of the regulatory framework, including by way of superficial and enforcement.

You may think that those formulations of the state's duty to protect life have a particular resonance to this 102

keeping the public safe is one of the first if not the first duty of government?

"Answer: I think it is the fist duty of government and so I would take public health as being the first.

"Question: And therefore everything ought to depend first of all upon does this protect or help protect the safety of the public?

"Answer: Exactly."

Then Andy Burnham, who gave evidence in July 2022, was asked about his own words in a document called *Glaziers and window breakers*. The reference for the transcript, it doesn't need to go up, is RLIT0001140. It is a document that gathers together the reflections of a number of former Secretaries of State. Mr Burnham in that document had said this, about the job of being Secretary of State for Health:

"The job, as I see it, is to get the best possible health care, the safest, highest quality health care for the people of England and to protect them from health risks."

In his oral evidence to this Inquiry he said he would absolutely stand by that.

Moving then to a second issue emerging from the submissions that have been made by Core Participants. You have heard about hindsight and you have heard

warnings about the risk of hindsight bias. It has been suggested that the decisions and actions should be assessed, at least in the first instance, by the standards and norms of behaviour or conduct at the time.

That's a suggestion not limited to the Department of Health and Social Care but you will see it also in the submissions of SNBTS the Belfast Health and Social Care Trust and others.

There are two points I would like to make in relation to that. Firstly, something may be done in accordance with the standards and norms of the time and yet be wrong. A stark historical example but one that was referred to by the medical ethicists during their evidence is slavery. You, sir, are not limited to assessing decisions by reference to the standards or norms at the time. You are entitled to say that what was done was wrong, if that is where the evidence takes you.

You are entitled to said indeed that the standards and norms themselves were wrong. The medical ethicists said this in their oral evidence:

"And in medicine as in many other spheres of life we can see examples of practices and behaviours that at one particular point were deemed acceptable but subsequently with further thinking sometimes, and it is just with

and judged in this Inquiry: clinicians, civil servants and politicians.

In relations to clinicians, the medical ethicists told us about fundamental moral principles or values that were stable and consistent across time. They told us by reference to a 1979 publication, Principles of Biomedical Ethics about four principles, autonomy; justice; beneficence, in other words the imperative to do good; and non-maleficence, do no harm.

The ethicists agree that a basic and fundamental principle of clinical practice is that an adult with capacity should not be subject to medical intervention unless they had given a valid and informed consent. Their evidence explained that the philosophical basis for the idea of informed consent is patient autonomy. That is not a new idea. There was a discussion in the ethicist's evidence about the 18th century philosopher, Immanuel Kant, and Professor Savulescu said this in his evidence on 26 January 2021, referring to Kant's categorical imperatives of autonomy and rationality. He said this:

"Because human beings have autonomy and they have rationality, you should always treat human beings as an end and never merely as a means, and how you treat somebody as an end is essentially if you get their

further thinking, it becomes clear that those are just not acceptable and were actually never acceptable."

You may recall, sir, that I suggested to the ethicists that context and history might help us understand why something happened, why a practice took place but wouldn't necessarily provide a justification or excuse of that practice having taken place.

Professor Savulescu said:

"That's exactly right. There is a distinction between two kinds of reasons, explanatory reasons and justificatory or normative reasons."

So, for example a culture of paternalism or a dearth of guidance from the Chief Medical Officer or the General Medical Council might be an explanatory reason, it might help explain why something was done the way it was, but that doesn't mean that it is necessarily a justificatory or normative one.

The second point in relation to this issue about hindsight and standards and norms of behaviour at the time -- and this was alluded to by Mr Dawson yesterday -- there is evidence before you, sir, that some of the ideas, principles or ethical norms that are most relevant to this Inquiry have, in fact, been incredibly stable across time. I want to take three categories of people whose actions fall to be assessed

informed consent, in a nutshell. So when they understand what you are proposing and freely agree to it, you are treating them as an end. When you don't do that, you are treating them as a means. That's what's so important about obtaining informed consent, is that you are then treating the patient as an end in themselves and not merely as a means to something else."

The ethicists also told us about the importance of a series of lectures given by Professor Sir Ian Kennedy in 1980, the Reith Lectures, *Unmasking Medicine*. It is just one of those lectures I want to put up on screen.

RLIT0000620, "Reith Lectures 1980: Unmasking Medicine. Ian Kennedy Lecture 4: If I were you, Mrs B". Professor Kennedy said this:

"It would normally be accepted that ethical principles, the principles by reference to which we organise our lives and decide what we ought or ought not to do, are not the preserve of any one group. But the doctor may reply that, yes, he does make ethical decisions, but these are medical ethics things and so they are properly for doctors alone. This would suggest that there is a realm of ethics unique to medicine and within the unique competence of doctors to determine and apply. My response is that medical ethics are not separate from but part of the general moral and ethical

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order by which we live. Decisions as to what the doctor ought to do must therefore be tested against the ethical principles of the society. He has no special dispensation to depart from our moral and ethical order. It must be wrong that a doctor, by describing a decision as medical, can claim unique competence to make such an decision, even if it touches the basic values by which we live our lives."

Then we can go, please, to page 3, Lawrence, second and third paragraphs.

Professor Kennedy said this:

"Another rationalisation resorted to is the so-called therapeutic privilege. This suggests that, as a matter of good medical practice, circumstances exist in which the doctor may withhold information from his patient, if in the exercise of his discretion and judgment it wouldn't be in the best interests of the patient's health to know. This is clearly a device created by doctors to do what is in the best interests of doctors. It may be justified on some occasions but there is no effort to specify these occasions. Everything proceeds on the basis of the particular doctor's judgment. It all boils down to the doctor being good, gentle and kind. It would be nice if all our doctors were like this. But, just in case, can't we

"For, it is a basic moral principle of our society that we should tell the truth."

Those then are some of the standards and norms of the time relevant to an assessment of the actions of clinicians.

Turning more briefly to civil servants, the Public Health & Administration Group told us that the Civil Service attributes of integrity, honesty, objectivity and impartiality form the bedrock upon which the Civil Service was built. And that whilst those values were not enshrined in statute until 2010, the Civil Service had been firmly based on them for at least the last 160 years.

So no need for hindsight in order to understand the values and norms which should guide the behaviour of civil servants.

Likewise, in relation to politicians, the same
Public Health & Administration Expert Group enabled us
to explore the Nolan Principles, the seven principles of
public life. You will recall they are: selflessness,
integrity, objectivity, accountability, openness,
honesty and leadership. And although those were first
formally published as such in May 1995, the experts told
us that they were the principles that had long
underpinned the spirit of public service in this

have some more certain guarantees that our interests, as defined by us, may be allowed to prevail? The device of the therapeutic privilege pays lip-service to the principles of truth-telling and self-determination, while it creates a discretionary exception which is quite capable of swallowing these principles when the doctor decides the occasion requires it.

"If we look beneath these rationalisations we see an ethical principle which is certainly not part of received tradition in analysing the doctor-patient relationship. The traditional view is that the doctor-patient relationship rests on trust or at least on agreement. But what we see is an operational principle defined by the doctor and accepted by us by default, which allows the doctor to suspend the trust or rewrite the agreement when in his view this is appropriate. Of course, if the patient breaks his trust or violates the agreement, there may be dire consequences for him, even to the extent of his forfeiting further care. Not so the doctor. He remains arbiter of the relationship, even to the extent of claiming the privilege of resort to an operational principle which is the precise opposite of traditional ethics "

Then this last sentence:

country.

So, put shortly, the civil servants and politicians whose decisions and actions you, sir, will need to consider were always expected to act with objectivity, with integrity and with honesty.

The third issue that I want to say something about relates to the submissions that have been made about the position adopted by some of the public body Core Participants, most notably but not uniquely the Department of Health and Social Care.

Much has already been said by, amongst others, Ms Gollop KC, Ms Jones, Mr Williams KC and Mr Stein KC. You have heard in the submissions of Mr Bowie for the Scottish National Blood Transfusion Service and the Scottish Territorial Health Boards that it is indeed possible for a public body to engage even at this late stage in a valuable process of critical self analysis.

As to the Department of Health not having a position or a case, Ms Grey was of course right when she said there is no compulsion on a Core Participant to formulate a case before a public inquiry. There is nothing in the Inquiries Act or Inquiry Rules that compel that. But one may ask the question: if a public Inquiry is not the place for candour, what is?

For years, of course, the Department of Health and

government and indeed the Devolved Administrations have promulgated positions and views. We have examined some of them. The phrases are familiar to you all: no conclusive proof, best available treatment, no fault, inadvertence.

You, sir, may wish to consider the fact that the Department of Health and government have felt able to take a position to advance a case previously on the basis of what might be said to be a limited understanding of the underlying facts, but now, when so much more is known, it has not done so. But that is, of course, ultimately a matter for you.

I have already referenced Mr Williams' observation that this is an Inquiry looking into the here and now. The position adopted by any public body, and a disinclination, for example, therefore, to answer the questions posed of the Department by Mr Snowden on the first day of those submissions, is itself a matter that you would be entitled to consider if you wish, sir, as part of your assessment of the response of government under the Inquiry's terms of reference.

The other point to bear in mind about the situation of public bodies not engaging in the process of critical self analysis is a point that was made powerfully by Mr Dawson yesterday. He referred to the psychosocial

that would have prevented it. I've already said, had we taken the step we now know would have saved lives we'd have been treated with outrage by the Haemophilia Society and most haemophiliacs by denying them their Factor VIII. There just wasn't the evidence to suggest that.

"I don't think the Department did anything wrong, I don't think there was anything the Department could have done that it didn't do. It's the current way of the life now. It's part of the current political scene, that somebody has got to be summonsed, to use the old saying. Someone has got to be found to be blamed for this, and it's all the fault of the Government, really. Or sometimes it's all the fault of the Tory party; it depends who is in power at the time. I don't think we did anything really wrong."

Sir, you wanted the evidence which this Inquiry has heard to begin and end with the accounts of those infected and affected. I am going to end by reminding everyone about a particular piece of evidence that was heard during the course of the Inquiry hearing on 8 May 2019. The reason why I am going to do so I will explain after I have summarised the evidence.

On that day an anonymous witness, Mrs C, gave evidence about her son S. It was the first time she had

evidence and the evidence that a lack of apology, a lack of explanation can itself cause further harm.

The psychosocial group told us how that can lead to health care becoming compromised because patients avoid going back into the health care system. They told us people can become stuck with anger, that they can't move on with their lives because nobody has acknowledged or taken responsibility for what has happened to them.

So one further question you, sir, will be entitled to consider as part of your analysis if you choose, in terms of analysing the response of government, is whether the stance of public bodies on an ongoing basis has compounded or continues to compound that harm.

In that respect, it may be instructive to note that whilst the Department might not wish to take a position, some of the witnesses who they have supported to give evidence have done so. Some of course have accepted where things went wrong. Mr Burnham gave evidence in very powerful terms in that respect.

By contrast, however, we have the view of Lord Clarke in his evidence on 27 July 2021, if I may be forgiven for quoting:

"I don't think the Department did anything wrong. I've never heard anybody suggest anything that in the real world a minister or a civil servant might have done

ever spoken about these events beyond her immediate family. S was born in 1978. He had haemophilia A. He would go to hospital quite regularly to receive cryoprecipitate. He didn't like it, Mrs C said it was quite difficult, but there was no suggestion from her evidence that treatment with cryoprecipitate was ineffective.

In 1983 S's treatment changed to Factor VIII concentrates and he started home treatment -- in 1983. The significance of that date in relation to the events which the Inquiry has been examining needs no further explanation.

S was five years old when he began to be treated with Factor VIII concentrates. I asked Mrs C if she had ever been given any warning about the products that her son was being treated with. Her answer shortly was none. She was just told it was an amazing thing and, indeed, it seemed that way to her because it was quicker and it was more convenient than cryoprecipitate.

I asked her if there was ever any discussion with her about the particular concentrates being used or any differences between different kinds of concentrates, the answer was no. We don't know what particular concentrates S was treated with but the annual returns for the hospital in question for 1983 and 1984 show the

centre using both NHS Factor VIII concentrates and Armour Factorate for home treatment.

A year or two after S started being treated with Factor VIII concentrates he developed a tooth problem. Mrs C took him to the hospital where they called a dentist to come down and examine him and when the dentist appeared, she was wearing what Mrs C could only describe as a "space suit". The dentist didn't want to come too close to this little boy. He was six going on seven and it was as if the dentist didn't want to touch him. Mrs C didn't understand. So she turned to the doctor and asked what was going on and the doctor took her into another room, gave her a blue plastic bottle and plastic gloves and told Mrs C that her boys -- she had another son with haemophilia as well as S -- had been tested for HIV, had tested positive and, in future, when she administered Factor VIII to them she would need to wear the gloves and use the blue plastic bottle to put them in. Then the doctor sent them home and "That's how it was", said Mrs C.

The doctor didn't tell Mrs C anything about HIV or the connection with AIDS or the longer term prognosis for S and his brother. Mrs C asked about the risks at home; she had a baby at home. The only answer she got was that the doctor didn't know. Mrs C hadn't known

was not told anything about the side effects or the risks or disadvantages of AZT and it had devastating implications and effects on S's health. She felt he was used as a guinea pig by the hospital.

In early 1994 S became very ill. I'm not going to recount the details of his last weeks, it's in her written and oral evidence, but suffice it to say that he was very frightened and he was in a lot of pain.

Mrs C told us about a book that S wrote in, a kind of diary, it was entitled "My feelings and my life" and he wrote on the first page "Started 8 February 1994" and he wrote "Finish when all the pages run out". S didn't get to finish the pages. That month, February 1994, was the month he died. He was 15 years old.

There was no reference to HIV or AIDS on his death certificate. Haemophilia was on there but not HIV, not AIDS, and that wasn't at Mrs C's request.

Because of stigma, Mrs C kept S's diagnosis from her other children. She told them he had had a rare form of cancer but some time later one of her children was told by a doctor treating him at the hospital that his brother S had had HIV and AIDS and died from it. That was done without Mrs C's knowledge and consent, and her daughter was given the same information by their GP. The family was never offered any support or counselling.

that her sons were going to be tested for HIV and she never received anything in writing from the hospital about the tests and the results.

About a week later, the GP turned up at the door with someone else, someone to do with education, she thought, and they said they had to go to the boy's school and tell them about the HIV results.

There came a time when a newspaper reported that there were brothers carrying the AIDS virus in a London hospital. Their ages and the name of the hospital was given but not their names, but Mrs C knew that this was a reference to her boys. That information had, as she understood it, been leaked by someone at the hospital to the press.

The Inquiry was able to track down one of the articles before Mrs C gave her evidence. It was said in the article that haemophiliacs had a higher than average chance of the virus developing into AIDS. Mrs C told us the hospital hadn't told her that.

The article said that parents knew of the risks to their children; she said that wasn't correct. The article quoted a spokesman for the Regional Health Authority saying the family was being counselled by senior doctors; they were not.

When S was about 11 he was prescribed AZT. Mrs C 118

S received some money from the Macfarlane Trust during his short lifetime. The last Mrs C ever heard from the Macfarlane Trust was a letter with some money to help with funeral costs very shortly after he died. She learned that S had been tested for hepatitis C and been infected with hepatitis C only years later when a letter came out of the blue from the Skipton Fund.

I just want to read two short sentences from Mrs C's evidence. She said this:

"S did exist. He had every right to be here now.

That was taken away from him. I think people should know what happened to him because it shouldn't have.

Nobody's ever told me how this happened, why it happened or just said to me 'We are sorry'."

Mrs C's evidence was about S, was unique to S and was deeply personal. But I have recounted it today for two reasons. Firstly, because captured in that one account is so much of what you have all told this Inquiry over the years.

So much of what you have told us you and your loved ones experienced, whether infected through blood products or through transfusion, whether infected with HIV or hepatitis B or hepatitis C or all three. The failure to provide information about the risks of treatment to the individual being treated or, in the

case of a child, to the parent or parents. False reassurance expressly or implicitly through the use of phrases such as "wonder drug", about the safety of the treatment.

The absence of informed consent to treatment. The absence of discussions about alternatives to treatment with blood or blood products. Testing for HIV or hepatitis C without consent. Failures, gross appalling failures in the communication of diagnoses. The experience of stigma, including at the hands of the National Health Service.

The terrible effects of the treatments, particularly the early treatments, whether as in S's case and in other accounts that we have heard, treatment with AZT or, as so many of you have told us, treatment with interferon or ribavirin for those infected with hepatitis C.

The unimaginable pain and suffering endured by those infected and witnessed by their families. Deep abiding grief, whether for a life lost or a life whose course has been irrecovably altered. The lack of support, psychological and practical, and the lack of explanation, accountability and apology.

All that is in Mrs C's account of what happened to S and all that is in the accounts that you have given the

Was S's treatment the best available treatment in light of the medical knowledge at the time? That's a question, sir, for you to consider.

Very finally, in the course of closing submissions thanks have been expressed to the Inquiry and those working for it or on its behalf. Those are greatly appreciated and I can say on behalf, not only of the team I lead but I think on behalf of all those who worked for the Inquiry, that it has been an honour and a privilege and a truly humbling experience.

But the true thanks are owed by us and by every Government Department, every Government Minister, past and present, every civil servant, every doctor, every NHS organisation and every other organisation or an individual with an interest in these matters to you: to every man, woman and child who was infected and who suffered. To every family member whose loved ones had died. Every family member who has had to witness and may still be witnessing their loved ones suffering in the most difficult circumstances imaginable.

To those who have, with great courage, given oral testimony that has moved us to tears. To those who also with great courage have provided written statements to the Inquiry which have revealed their most personal experiences and suffering. To those without whose

Inquiry over the years.

The other reason why I wanted to recount Mrs C's testimony is because I want to remind you of three lines to take that we have heard about and suggest that it may be instructive to view those lines when you reach whatever conclusions you decide to reach, sir, about them through the prism of Mrs C's evidence and the evidence of you all.

The UK Government line, and this is a quote:

"The Government does not accept that any wrongful practices were employed."

The Scottish Executive line, and this is also a quote:

"... no reason to believe anyone acted wrongly in the light of the facts that were available to them at the time."

And, of course, the line that we have seen repeated so often and it is certainly articulated by the then Prime Minister, Mrs Thatcher, in a meeting on 22 November 1989, and the reference -- I'm not going to put it up -- is DHSC0002536_031, that line was then followed in the Northern Ireland Office and the Welsh Office:

"All patients received the best treatment available in the light of the medical knowledge at the time."

campaigning, tenacity and determination there would be no Inquiry.

You have laid bare the most personal and distressing parts of your lives in pursuit of truth and justice and in the hope that lessons can be learned for the future for the benefit of others and so, with the greatest of admiration and respect to you all, I say thank you.

SIR BRIAN LANGSTAFF: Well, I say thank you too. I have to say a personal note here, I could not have asked for a better counsel to the Inquiry.

What she has said has shown once again the importance of this Inquiry and the way in which there has been a response to that importance by the collaborative efforts, the collective efforts of all of you. Thank you.

This is no all probability the last time we shall meet here at Aldwych House. The last time that those of you who have followed proceedings more remotely can log on to hear evidence, see presentations or hear submissions.

It may well be some time before we meet again.

There's something perhaps -- I'm going off script a bit here -- but there is something almost like an end of term feeling about today and forgive me then for being just the headmaster I have occasionally been and

reminding you, please, particularly since there are so many of you here, you may want to take photographs -- you know what's coming -- please be careful when you do, if you do, to make sure there is no one in the photograph who does not wish to be photographed for obvious reasons, some of which you have just heard expressed.

But you being here or there throughout four and a half years, through Covid, through lockdowns, through the challenges of ill health, through strikes, despite, in many cases, bereavement.

Many of you have contributed through your statements, your evidence, your provision of documents but let me stress that your being here or watching online in such numbers as you have has also been important.

Let me tell you why I think it is so important. Nothing concentrates the mind of a speaker than seeing and knowing that they are talking to a large number of people. True, a few played to the gallery -- no names -- but, for most, the knowledge that so many are so interested after so long a time tends to make them realise the importance of what they are addressing and the need to tell it as best they can.

It also fully justifies the decision, even if

given everything that we have heard? But it will be as short as I can make it whilst doing justice to the evidence and the submissions which I have heard and read and to the breadth of the terms of reference. And it will be as quick to produce as I can.

Now, where there is a particular topic that interests you, I intend that you should be able to go to the relevant chapter to find the answers you are looking for, and I hope that it will be an engaging read.

There will, of course, be an overview so that you can quickly get a summary of my findings and recommendations, and so that members of the press can explain what we have collectively learned to the rest of the country.

Beyond the writing of the report itself there is a further part of the process which is required by statute, the Inquiry Rules require it, but I would in any event have considered it necessary in fairness. It is that where there is to be explicit or significant criticism in the report -- and there will be criticism -- that the person due to be criticised is told of what I intend to say and of the factual basis underpinning it so that they can respond if they wish.

Now, the process is not only fair, but it also reduces the possibility of challenge to the report.

belated, to hold a public inquiry, by definition one in which the public has an interest. Your sheer numbers reinforces the point that the public think this is important and it must help to bring that home to those who will in due course consider my report.

Your simply being here has made a real contribution.

Representatives of NHS bodies, the devolved administrations, politicians, civil servants, lawyers, clinicians, interested experts, Scottish, Northern Irish, Welsh, have also all contributed in their own way -- I suppose I should add the English -- to what I had asked should be a collective endeavour and, in my judgement, it has broadly been that, even with the odd wrinkle. I would like to thank you all of you for that.

As you know, as Ms Richards has kept reminding me over the last half hour, I must now turn to writing the full report. Now, I can't tell you at this stage precisely when the report will be published. I wish I could. But I tell you what I do know, and it is this, the process of writing the report will inevitably take some time. Time to weigh the submissions with the evidence, time to resolve issues where the evidence is not clear cut, and time to make the report as readable as I can.

The report will not be short. How could it be,

From the start we have designed the Inquiry's processes to avoid unnecessary delay at this stage. We have seen Ms Richards and her team put areas of potential criticism to witnesses, both for them to answer in their written statements and in hearings. I don't anticipate that many witnesses or organisations will be surprised by the terms in which they are criticised if they are. But I do have to allow a reasonable time for them to consider, in confidence, the criticisms which I propose to make and for me to consider any responses received.

As we know, some of our witnesses are old, some are not in good health, and so I must make due allowance for that, particularly if there is more than one criticism to be made. But I can assure you that I will allow no more time than is reasonable.

I know that many of you will want to make plans outside the Inquiry and so I can say this, that the report will not be published before the autumn.

Ms Richards has persuaded me that July is likely to be too ambitious, and I think she's right, and that later in the year will be more realistic.

It won't be August, since Parliament will not be sitting then, so in short, the best estimate I can give you is autumn.

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It has always been my intention to be as quick as reasonable thoroughness permits. Time is not a luxury I can squander. I assure you that I will be writing the report as fast as I can and that Ms Richards and her team will be handling the warning letter process for me with their usual efficiency.

I can also promise that we will give you plenty of notice about when the report will be published so that those of you who wish to come together and attend in person on that day are able to do so.

Let me turn from the autumn to these last three weeks.

First, I should say that the written submissions and these three weeks of oral submissions, mainly but not only from those who are representing institutions or groups of Core Participants, they have all been of great value to me. They have helped to highlight what has been most important to each of you. The written submissions have expressed it, the oral submissions have summarised it.

I should add that if you had asked me at the start of these three weeks whether each speaker would be able to contain what they had to say within their allotted time slots, you might imagine what I would have said.

It is often much more difficult to condense, to

Finally, I want to come back to what I said when I started with these few words. I would like to thank you for the spirit in which you have followed the Inquiry proceedings, in whatever way you have, here in person, online, through the Inquiry emails and wider media. I thank you with sincere appreciation for making this a collective endeavour, for the warmth with which you support one another, and for your kind words about the Inquiry team and its process.

Thank you all, individually and collectively. Thank you and goodbye, for now.

(2.57 pm)

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precis what you think and why you think it, it is something of an art. I'm not sure I would have had it as an advocate. But I'm glad to say I would have, in this case, been proved wrong. I would like to thank each and all of those who made submissions orally for respecting almost to the minute the timetable.

It was drawn up to ensure that the time available was shared fairly between everyone who wanted to speak and, by keeping within your slots, no one took unfair advantage. So thank you.

Many of the submissions in writing or orally asked me to make another interim report about compensation. You heard that general point touched upon by Mr Stein this morning. I will need to reflect on the submissions, especially those that point out that as little time as possible should be lost before finalising arrangements for compensation.

I want to tell you that I have written to the Paymaster General to inform him of my intention to make a further interim report about the framework for compensation. I anticipate that I will be in a position to do so before Easter if not earlier, will aim to tell you a week before publication when more precisely it is coming. The report will be shared with our contact list and published on the Inquiry website.

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