THE TRIBUNAL RESUMED ON THE 11TH OF JULY, 2001, AT 2:00 P.M. AS FOLLOWS:

THE CHAIRPERSON: Good afternoon.

Mr. Finlay?

MR. FINLAY: Madam Chairperson, before Dr. Jones commences his evidence, I think I should first of all apologise to everybody for the delay in starting Dr. Jones's evidence. I'm anxious to explain a little bit; importantly first of all to make clear that it's in no way Dr. Jones's fault. He's been here since yesterday and was in a position to give evidence at half past ten this morning. Secondly, the reason for the delay was that there were some discussions between the lawyers for the Tribunal and the legal team for the Irish Haemophilia Society, who are proposing Dr. Jones as an expert witness to the Tribunal. And it has been agreed that Dr. Jones, in giving his evidence, will deal essentially with two things. His statements of evidence comes in two parts: The first part deals with a report on the response of the staff at the Newcastle Haemophilia Centre in order to help people with HIV infection. And Dr. Jones will deal with that in full. His second statement of proposed evidence deals with the Armour dry heat-treated product, the product heated at 60 degrees for 30 hours. And it has been agreed that Dr. Jones will give evidence of his state of knowledge about that product in 1985 and 1986, and the contributions which he made to the general state of knowledge about that product at that time. Now, it has also been agreed that the question of whether Dr. Jones would give evidence in relation to matters referred to in his statement of proposed evidence in relation to that Armour product, which would have come to his knowledge since 1986, the question of whether Dr. Jones would give that evidence will be left to another day. So Dr. Jones, please.

DR. PETER JONES, HAVING BEEN SWORN, WAS EXAMINED AS FOLLOWS BY MR. FINLAY:

A. My name is Peter Mercer Jones.

Q. Good afternoon, Dr. Jones. I think are you a medical doctor?
A. I am a medical doctor.

Q. And when did you qualify as a doctor?
A. I qualified in 1962.

Q. Yes. And I think in your postgraduate work, did you become a consultant paediatrician?
A. I did.

Q. And when were you appointed a consultant paediatrician?
A. In 1972.

Q. And I think was that in Newcastle?
A. That was in Newcastle-upon-Tyne.

Q. And did you hold the post of consultant paediatrician in Newcastle from 1972 until the year 2000?

A. I did.

Q. And when did you retire?
A. I retired in April of 2000.

Q. Yes. Now, did you have a particular interest in your work as a consultant paediatrician?
A. Yes. My main interest was with haemophilia in all ages.

Q. Yes. And how did you pursue that interest, if I might put it that way?
A. When I was appointed, I was appointed as a consultant paediatrician with a special interest in haemophilia, and was given the remit to help organise haemophilia services in the north of England.

Q. And I think did you become, in fact, the Director of the Newcastle Haemophilia Centre?
A. I did.

Q. And was that in 1972?
A. That was in 19 -- that was a little later because there was a director when I was appointed.

Q. I see. But shortly after that?
A. Shortly afterwards, yes.

Q. And from that time until your retirement in the year 2000, did you hold the position of director of the Newcastle Haemophilia Centre?
A. Yes, I did.

Q. Yes. Now, I think, Dr. Jones, you have provided the Tribunal with a statement reporting on the response of the staff of the Newcastle Haemophilia Centre in order to help people with HIV infection, isn't that correct?
A. Yes, I have.

Q. And at the commencement of your statement, I think you deal with the historical background in terms of the provisions for treatment for persons with haemophilia --
A. Yes.

Q. -- isn't that correct? And I think you identify something there that perhaps the Tribunal would already be familiar with; that it wasn't until the mid-1960s that cryoprecipitate became available as an option and a possible treatment?
A. That's correct.

Q. And before that the treatment available was distinctly limited?
A. The treatment was very limited and it was really a fresh frozen plasma for both sorts of haemophilia.

Q. Yes. And I think then in the early 1970s, was there a development in terms of treatment, Dr. Jones?

A. Well, we knew already that we could concentrate Factor VIII and Factor IX both in animal plasma and human plasma, but there was a great shortage. And in the United Kingdom in 1973, the shortage was recognised as being detrimental to people with haemophilia and, for the first time, the government licensed products for importation for the treatment of haemophilia.

Q. Yes. And I think, in fact, did you use those products in your centre from 1973 onwards?
A. We did.

Q. Was there a known risk associated with those products?
A. Yes. There was a risk right from the beginning, indeed before those products were licensed, in that we knew that serum hepatitis, then later known as Hepatitis B, could be transmitted by blood. And it was more likely to be transmitted in pooled products, products from several donors.

Q. Yes. And what was the perception at that time in 1973 in relation to that risk?
A. The perception was that the risk was overcome by the need to treat the bleeding in haemophilia. If I can just underscore that by saying that the major cause of death in haemophilia in those days was exsanguination or bleeding into the head, at any age. And in the natural state, people with severe haemophilia could not expect to live beyond their 35th year, and the majority of them died in childhood or early teens, quite often after minor surgical procedures. So the thrust of treatment in those days was to afford patients treatment whenever symptoms occurred or even before symptoms occurred. And we could only do that by using these products. So the risk of hepatitis in comparison with the risks of bleeding in haemophilia was considered to be relatively small and worthwhile, if one can use that term, in those days.

Q. Yes. Now, I think in your statement, Dr. Jones, you then deal with the concept of comprehensive care?
A. Yes.

Q. And could you just summarise for us what was meant by that?A. Well, when one has a chronic disorder like haemophilia, and particularly severe haemophilia, the diagnosis colours every facet of one's life and the life of one's family and one's friends and one's colleagues. Comprehensive care is -- or was developed to answer all those needs for -- as a simple explanation: A child with severe haemophilia would not just be treated in the hospital for bleeding, but one had to take into account the fact that he had to go to school. So the schoolteachers needed to know about it; the family doctor needed to know about that; the family needed to know about it; the doctors, if that child went on holiday, needed to know about it. So it was really a way of looking at the life of somebody with haemophilia in totality and trying to answer the needs as they arose as that boy grew up.

Q. Yes. And I think in the United Kingdom was that organised through haemophilia treatment centres?
A. Yes.

Q. Provision of such care?
A. It was.

Q. And by 1974, I think was there a further organisation certainly of those haemophilia treatment centres into different grades of centres?
A. There was.

Q. And perhaps you can just explain that to us in general?
A. Yes. The government had recognised, through the Medical Research Council, earlier than that date, 1976, that there needed to be centres. Initially they were just for the diagnosis of haemophilia, but as treatment became more freely available and as comprehensive care developed, so government recognised that doctors, as a whole, should be aware that these centres existed and should refer people with haemophilia to them.

Q. Yes.
A. And so a health circular was issued in 1976 by the government.

Q. Yes. And perhaps, I think, if we look in the book of documents, at page 56 at the end of the book of documents. This is part of a circular about the organisation of haemophilia centres. And I think it dates from January of 1976, isn't that correct?
A. Yes, it is.

Q. And what I particularly want to refer to is at page 76, it deals with "reference centres."
A. Yes.

Q. And would I understand that these were centres of particular excellence for the provision of haemophilia treatment?
A. Yes. They had the expertise to treat haemophilia.

Q. And they were provided on a regional basis; the United Kingdom was divided up into a number of regions - England and Wales?
A. At that time not on a regional basis. The list that is on page 56 and at paragraph 7 shows that the -- some of the centres covered wide remits, wide geographical areas of the United Kingdom; at that stage it wasn't simply regional. It depended mainly on the expertise which had been built up in the hospitals listed on the left-hand side.

Q. I see. And amongst those - just quickly list them - was St. Thomas's Hospital; and the Royal Free Hospital; the Churchill Hospital in Oxford; The Royal Infirmary in Manchester; The Royal Infirmary and Children's Hospital, Sheffield; the Royal Victoria Infirmary, Newcastle, which I think would have been your own hospital --
A. Yes.

Q. -- and the University Hospital of Wales in Cardiff?
A. Yes.

Q. They were the reference centres?
A. They were the reference centres, yes.

Q. And the specifications - the functions of a reference centre were specified in this circular of 1976?

A. They were, and are, listed.

Q. And they're listed here at page 56. And perhaps if we could just go quickly through them: First of all, "to provide 24-hour telephone advisory service to haemophilia centres and associate haemophilia centres and to support them particularly during holiday periods." I think that speaks for itself. Apart from the reference centre, then, there would be smaller centres which were to receive that support from the reference centre?
A. Yes, and the difference between haemophilia centres and associate centres was really simply that the associate centres reflected, where there might be a doctor with one or two patients, perhaps, and he had been working with haemophilia but didn't have the overall expertise of his colleagues. So we were very anxious not to take away the possibility for care of haemophilia near patients' own homes, and really that's why associate centres were still listed.

Q. Yes. And the other functions, I mean: "To provide a specialist consultant service for surgery, orthopaedic, dental, paediatric and social care." Again to the haemophilia centres and associate haemophilia centres?
A. Yes.

Q. And "to advise on and organised, when called upon, home therapy and prophylactic therapy for haemophilia patients"?
A. Yes. And that was very important at this stage because, in 1976, we're three years into the importation of concentrates. And the main thrust of that importation was to allow us to start teaching parents and patients to treat haemophilia at home.

Q. And that was done from the reference centres essentially?
A. Mostly from the reference centres, yes.

Q. Yes. And then: "To provide a reference laboratory service," to provide -- then the rest would seem to really be to -- in dealing with matters of providing education and training for doctors and other centres and coordination and liaison with the other centres, would that be correct?
A. Yes, I think that's so important, because the basis of this was a friendly teamwork.

Q. Yes.
A. The way it reads is perhaps more structured, but the whole basis of haemophilia care, even from those early days, was friendly and open teamwork.

Q. Yes. Yes. And then I think if we return to your statement, Dr. Jones, at page two of the statement you quote the specifications for a comprehensive care centre, which I think are contained in a 1984 document, is that correct?
A. Yes. That is correct.

Q. Yes. And again, it first of all provides to -- paragraph one: "To provide a clinical service provided by experienced staff for the treatment of patients with haemostatic disorders and their families at short notice any time of the day or night." So I suppose that would be a core function, to provide the actual necessary treatment for persons?

A. Absolutely essential.

Q. Yes. And then, secondly, a laboratory service, an appropriate laboratory service?
A. You can't treat haemophilia without that.

Q. And then, would it be fair to say that the remaining specifications would essentially be ancillary matters to those two fundamental functions?
A. Yes. I think that would be fair, except I think it's worthwhile underlining paragraphs five and eight.

Q. Yes, certainly.
A. The reason I say that, Mr. Finlay, is that it's so essential that you have audit, clinical audit, and you have some way of monitoring the standards in a laboratory.

Q. Yes.
A. And that is what's specified in five and eight.

Q. Yes. And is there any other particular paragraph, Dr. Jones, that you would attach particular importance to?
A. I think the counselling and privacy of patients and their relatives is paragraph 7.

Q. Yes.
A. And with anybody with a chronic disorder, which is also frightening - very, very frightening disorder, especially to parents of newly-diagnosed children, the privacy and the counselling is absolutely essential. And that's not a medical reason, it's a humane reason.

Q. Yes. Now, I think that you summarise the basic needs at the top of page four, Dr. Jones, is that correct?
A. Yes, bottom of page three, top of page four.

Q. Yes. And you summarise them I think to be -- the needs to be, for accurate diagnosis: A 24-hour cover, safe and effective treatment, regular follow-up, expert counselling and good communication between families and those with responsibility for their care?
A. Yes.

Q. If you were asked to condense the various functions, that would be how you'd do it, would that be right?
A. That is how I've done it right from the beginning.

Q. Yes. Yes. Now, if we come to practicalities, what was the accommodation in the Newcastle Centre when it commenced or became available I think in 1974?
A. The Newcastle Centre initially consisted of seeing patients onwards, but that was in the early 1970s. And we then procured rooms. And in 1980, the Haemophilia Society helped us to extend those rooms to include the provision for private counselling and for laboratory services and for treatment of patients.

Q. Yes. So where you mention in your statement that it consisted of a consulting room, a small waiting area, a coagulation laboratory, a treatment room and rooms for

the haemophilia nursing sister and a social worker, was that the initial level of accommodation?
A. That was the initial level of accommodation.

Q. And it was then expanded with the assistance of the Haemophilia Society?
A. Yes, and has since been expanded twice more.

Q. Yes. And when did those expansions occur, Dr. Jones?
A. In 1980 we made the expansions.

Q. Yes. And in summary, what did that expansion involve?
A. We had a larger treatment room which was now able to cope with people without haemophilia who needed transfusions; we had a consulting room which allowed the doctors concerned to examine patients both in privacy -- both lying on couches and walking around. Because, of course, gait in haemophilia, because of the arthritis, is one of the main -- arthritis is one of the main complications. And they allowed counselling of families and talking to families without tables in the way, as you or I are sitting now, but more intimate contact for long discussions and the answering of all the questions that arose. There was a social work room, again where the door could be shut and patients could be seen for as long as they wanted, for talking. The laboratory was actually at the building next door to the centre so that it was adjacent. And there was provision for storing blood products on-site, so the treatment was immediately available. And there was a room in which sister - a nursing sister could go and work quietly by herself. All to welcome families in again for this privacy of counselling.

Q. Yes. Now, I think you then deal with the question of staffing, Dr. Jones. The staffing; presumably are we talking about in the early 1980s?
A. Yes, this was the beginning of the AIDS epidemic; so early 1980s, this was the level of staff that we had.

Q. So 1984/1985/1986, that sort of time?
A. It was a little earlier than that, actually.

Q. I see. Very well. And the staff at that time, a director employed as a National Health Service consultant paediatrician with a special interest in haemophilia full-time, being yourself?
A. That was me full-time, yes.

Q. And then a co-director employed by the NHS as a consultant haematologist part-time?
A. Yes, he was part-time for haemophilia, the rest of his time is spent in general haematology.

Q. Yes. And then a sister employed at the haemophilia centre, but with a role in the outpatient care of haematology patients full-time?
A. Yes.

Q. So would the centre have treated haematology patients apart from haemophilia patients?

A. We had the skills and the nurses built up the skills of being able to give intravenous therapy. When we started it was illegal for nurses to give intravenous therapy, and the development of that was spearheaded in our case by our haemophilia sister. And so to use those skills on patients with, for instance, leukaemia, was an obvious progression. And that still exists within the centre now.

Q. I see. And then four nurses, three with grades equivalent to staff nurse; two social workers, one initially, the second being appointed to help cope with HIV infection. And I'm not quite following, "both maximum part-time."
A. Yes, when we stopped -- the haemophilia started before I became a consultant in terms of running a children's clinic. And as I've intimated, the social needs of patients, we tried to attend to those right from the beginning by appointing a social worker. And we had a social -- we still have the social worker. But when HIV infection came, the work was so enormous -- the counselling and the help at all levels was so enormous and so important that, without any difficulty, we got hold of a second social worker. And we still have two social workers.

Q. Yes. And would they have -- first of all, would they have been full-time, the social workers?
A. We had a full-time social worker to start with, yes, and then they juggled their work according to money available and resources and everything else that happens in a health service.

Q. Yes. So what does that mean? Does that mean that the two social workers would not have been full-time?
A. The two social workers during HIV, one was full-time and one was part-time at the beginning of the epidemic. Later, the full-time social worker left to take up an AIDS post in the city of Newcastle. And when I left, we had two social workers who worked maximum part-time, and that was last year.

Q. I see. Perhaps "maximum part-time" is a term of art, but I don't understand exactly what that means?
A. Well, I guess it means they don't work full-time, they're not working a five-day, eight-hour-a-day week. The maximum part-time, to my memory, was four days a week.

Q. I see. I see. And then you mention a physiotherapist who would have divided her time between the haemophilia centre and the infirmary?
A. Yes.

Q. But the haemophilia centre had first call on her services?
A. Most definitely, yes. And she was a senior grade.

Q. And then two secretaries?
A. Yes.

Q. Yes. And then in addition to that staff, the coagulation laboratory, which would have had its own staff --
A. Yes.

Q. -- isn't that correct? And then apart from that, the centre would have had access to specialist consultant services in various different disciplines, would that be correct?
A. Most certainly, yes.

Q. Particularly orthopedics, general and dental surgery, and then contacts with genetics, psychology and psychiatry, and with infectious disease and hepatology?
A. Yes.

Q. Where would all of those services have been physically located; would they have been --
A. Within Newcastle-upon-Tyne. When we started, there were two major hospitals: One was the equivalent of a district general hospital, and one was the Royal Victoria infirmary, which was primarily a teaching hospital.

Q. Yes?
A. Now, there are three major hospitals in Newcastle, and by the way, these things evolve; some of them had specialist services which the others didn't. For instance, orthopaedic surgery was centered within one hospital, so patients had to be ferried between two hospitals. What we did with haemophilia was to invite specific colleagues who were interested to come and see patients with haemophilia within the centre when that was possible.

Q. Yes.
A. When it wasn't - for instance, if somebody had a cerebral bleed - they would be taken up to the neurosurgery unit, which was in a separate hospital from the haemophilia centre, but the staff of the haemophilia centre would look after their haemophilia.

Q. Yes.
A. So in other words, I would go up and go to theatre with somebody who was having a neurosurgical operation and all the treatment of that patient would be seconded from the haemophilia centre, ferried up to the other hospital, and the patient would be looked after until discharge by the haemophilia team in association - this was so important - with the people who were skilled in the other discipline.

Q. Yes. So in other words, sometimes if it was possible, specialists would come into the haemophilia centre; and if that wasn't possible, there would be a continuing input from the centre if a patient was referred to another hospital for specialised treatment?
A. Yes.

Q. Would that be it?
A. Yes.

Q. Thank you. Now, the association -- the aspect of your work, Dr. Jones, of providing a regional service, can you explain what that involved?
A. Yes. Our region is approximately 140 miles by 140 miles, from east coast to west coast, and from the -- all the way from the border of Scotland down to West Yorkshire. And we're dealing with a population of the equivalent of the Republic of Ireland. And right from the beginning, it was evident that we needed to address needs

near patients' own homes, and, of course, it was also evident that there were other people who were interested in caring for people with haemophilia. So one of the first jobs that I had, as director of the haemophilia centre, was to ask colleagues around the region if they would help with haemophilia care, and it was remarkably straightforward. And we set up haemophilia centres; that initially there were two haemophilia centres: There was Newcastle and Carlisle covering the west, and later we set up other centres so that each part of the region was covered by a haemophilia centre. And we call that a regional haemophilia service.

Q. Yes. And would those haemophilia centres, would they have involved consultant haematologists?
A. Yes.

Q. Yes. And in terms of home therapy and prophylaxis, how was that organised?
A. Well, by consent, we decided to centralise home therapy and prophylaxis, and the reason was two-fold: Firstly, we were dealing with very expensive treatment, and we thought that by centralising the control of home therapy and prophylaxis, it would be far easier to audit that treatment. And the second main reason was, because of what we knew already about hepatitis, we wanted to ensure that we were doing no harm to patients, and that meant very fundamental follow-up which was regular and understood by everybody and properly audited.

Q. Yes.
A. So we thought that by centralising home therapy, keeping the records properly, and following regular -- regularly all the patients within the Newcastle Centre, that would be the sensible thing to do.

Q. Yes. And so is that what was done; was the home therapy organised from your centre?
A. That was, yeah.

Q. Yes. And in terms of selection of product, Dr. Jones, I think you deal with that at page five of your statement?
A. Yes.

Q. And you say that "There was an annual exercise during which companies able to supply products that met the existing criteria for safety and clinical efficacy were invited to submit bids by blind tender."
A. Yes.

Q. And "The final choice was made by members of the administrative and pharmacology staff meeting with the centre director and the haemophilia sister --"
A. Yes.

Q. -- "one of whose roles was to ensure that patient preference was taken into account"?
A. Yes. Most certainly.

Q. Would that have continued up to your retirement in the year 2000, that system?

A. Yes. It was superceded a little by the European law and all the requirements of tendering under European law, of which I'm no expert.

Q. Yes.
A. But, in essence, yes, that continued.

Q. And the views of the persons with haemophilia were made known in this process through the mechanism of the haemophilia sister?
A. Yes.

Q. Was there any formal consultation with the Haemophilia Society?
A. Oh, yes. We -- at its extreme we had an annual meeting, a residential meeting at which people -- patients and their families were invited and they were allowed and encouraged to talk about and raise anything about treatment that they wanted. And in the informal way in which treatment was given within the haemophilia centre, sister and the nurses took stock of patient comments about the treatment within the centre and the efficacy and any side effects which had occurred with their treatment at home. And this wasn't just limited to the matters which the Tribunal has spent so much time in considering, it wasn't limited to side effects like hepatitis; it covered things like blunt needles, the ease of undoing packets to get hold of treatment, the ease with which you could take treatment away with you on holiday or business. So all these things were fed back mainly through the nursing staff, and were taken into consideration when we looked at the sort of products we should be looking at in the bids for future treatment.

Q. Yes. And then in relation to the numbers of patients that you were treating, I think you mentioned the Northern Regional Haemophilia Service served a total general population of 1.1 million people, is that correct?
A. Yes.

Q. Slightly underestimating the population of this country if you're comparing it directly with that?
A. It was 1.3 when it started and it had shrunk to 1.1.

Q. Yes. And you mention that, "In May 1980, at the time the new centre opened, 303 people with a hereditary coagulation disorder from 211 families were seen regularly at the centre. And 78 people with haemophilia were on home therapy" at that time?
A. Yes.

Q. In May 1980, isn't that correct?
A. Yes.

Q. And then at the beginning of the HIV epidemic, 143 people with severe Haemophilia A or B attended the centre. And then by the end of the 1990s, around 550 patients with either a diagnosis of a bleeding disorder or a diagnosis of obligate or possible carrier status were on the regional register?
A. Yes.

Q. I think you then deal, Dr. Jones, at page six, with the actual procedure which was followed in telling people of a diagnosis either of haemophilia (sic) or of HIV, a HIV antibody-positive result?
A. Yes, on page five and six.

Q. Yes. And can you just explain to us what that procedure was, Dr. Jones, can you summarise it for us?
A. Do you want me, Mr. Finlay, to go on all the points on the document.

Q. I don't want to limit you in any way; whatever way you find convenient to explain to us what the procedure actually was. If it's convenient to use the document, do; if you prefer to summarise it --
A. I think the essential point was that "procedure" sounds like something that's written down in a document and is either followed or not followed.

Q. Yes.
A. The essential point is that I think we ran a service which we did our -- in which we did our best to answer the needs of the patient and the family.

Q. Yes.
A. And therefore, because people differ so much in their needs and their wants and their aspirations, the procedure was tailored to meet the individual in the family. So the list which I gave in my statement is certainly a list of the points which we would have followed, but it would differ.

Q. Yes.
A. And if I may summarise this in an anecdote: Dr. Charles Rizza, who was the director of the Oxford Haemophilia Centre and a great expert and champion of haemophilia care, said to me at the beginning of the litigation which took place in the United Kingdom with regard to HIV infection, he said, "it's going to be very difficult to find all the records because so many consultations take place in the carpark".

Q. Yes.
A. And that reflected the friendliness with which a lot of these consultations did take place. The patients would stop you and ask questions anywhere. And one answered them and talked to them, not as patients but as friends. And that was very much the way that we -- all of us in the haemophilia team tried to run the centre. So when hepatitis -- when HIV came along and was such a frightening threat, then, yes, we drew up this list and we stuck to it. But sometimes "procedure" was too strong a word for what we were up to. The list -- the first thing is that we never telephoned a patient with a result or gave a result to a third party to impart to a patient outside the centre. Secondly, that a senior doctor would give the result, the HIV result, in the privacy of the consultant room.

Q. Yes.
A. And that the nursing sister or her deputy was always present when that diagnosis was given. The consultant room was the room I described earlier in my evidence. It was informal and nonthreatening. There was no table between the doctor imparting the information and the family sitting around with the patient, and that meant that one

could employ touch. When somebody is given any severe diagnosis, whatever it is, we felt that it was so important to touch them.

Q. Yes.
A. Even if it was just shaking hands as they came into the room. But people being given these devastating diagnoses needed to be held, sometimes held for some -- for a considerable time; hugged. The nurses were particularly good at that. Doctors aren't taught very well to behave like that.

Q. Yes.
A. And there was also, within the informality of this room, an implied permission to cry. So often one found that people being given diagnoses of life-threatening disease, the staff would leave hurriedly to let them display their emotion without the staff being there. We felt that was wrong initially, but then we did give them time; we went out of the room and we left them to themselves once the diagnosis had been given, and then one of the nurses would take in a cup of tea or a glass of brandy and sit with them until they had recovered from the initial onslaught. The parents of young children were seen alone initially. The child would be distracted in the play area of the treatment room. When we had adolescents, it really depended entirely on their age and their emotional state, whether we told them with their parents or not. We usually tried to tell them with parents. And sexuality and mortality were always discussed at some stage, with, again, a senior member of staff. It would either be a senior social worker or myself or the sister. Once things had settled down, once people had had time to take a breath or go for a walk, then, again, the doctor would go in to see them. And the object of that was two-fold: Firstly, to answer any questions that were immediate - "am I going to die?""What's going to happen to my wife?" "Is my son going to be in pain?" And secondly, to start to destroy myth. And at the beginning of HIV there was an enormous amount of myth and fear, which I'm sure the Tribunal has already addressed.

Q. Yes.
A. But we tried to reassure them and, again, touch came in because initially people were frightened that HIV was contagious and that other members of the family would catch it just simply by sharing baths and beds and everything else. Once that had happened, and sometimes it took an hour or two, then they were given the chance to go and sit in a sister's room or the social worker's room and again express any fears and wants that they had. And later on, the sister or the social worker would arrange to visit them at home.

Q. Yes.
A. And that, again, took them out of the hospital setting, allowed them to talk openly, as people, within their own family home. And all sorts of problems and things emerged by doing that that weren't apparent in the hospital setting.

Q. Yes.
A. They were then encouraged, and indeed they always have been encouraged with the haemophilia, to come in to the centre at any time they wanted, day or night; if necessary, they could pick up a telephone and talk or they could just walk in through the door and somebody would try to answer their needs. And finally in this list, the Haemophilia Society were absolutely tremendous, right from the beginning of this

threat, and they were partners in looking after people with haemophilia. So we encouraged people with haemophilia and with HIV and then Hepatitis C to talk to other people who had already been through the problems. And so there was a sort of buddy system, which I initially learned about when I went to San Francisco and New York in the early days of the HIV epidemic. And so they were encouraged to talk things through with other people who weren't medical staff.

Q. Yes.
A. And that was very supportive indeed.

Q. Yes. Now, I think, Dr. Jones, we'll see, when we move on to your second paper, you refer to a report which you -- you and some of your colleagues produced to the British Medical Journal in September of 1985 --
A. Yes.

Q. -- reporting on the incidence of HTLV-III infection amongst your population of persons with haemophilia?
A. Yes.

Q. And unfortunately, it was very large, isn't that correct, in terms of numbers?
A. It was, and it shocked us initially -- well, it still shocks us. It looked large in comparison with others at that time.

Q. Well, we'll come to that in a moment. But just simply, the total number of persons who were found, on testing, to be HIV-positive; what was that, Dr. Jones?
A. Yes. We tested 143 people who had been multitransfused, and, of those, 99 were found to be HIV -- well, HTLV-III positive. Of the people with severe Haemophilia A, 76 people.

Q. Those results would have become available -- when would they have become available?
A. We started testing December 1984 /January 1985, and the results reported in this paper were complete by May of 1985.

Q. And how did you organise the sort of system that you've described for us for that number of people; for approximately 90 people, did I understand you to say?
A. 143 we tested, and we also tested members of staff. There were 68 members of staff as well. How did we organise it?

Q. Yes? I mean, how was -- physically, how was it possible to provide the kind of service you've described to us to that number of people?
A. It was extremely difficult but we did it.

Q. And how was it organised?
A. Well, firstly we needed the testing. And because at that date, the sensitivity of the testing -- the question of false positives and false negatives had arisen. So initially we worked with Dr. Richard Tedder, who has already given evidence to the Tribunal, and he very kindly agreed to test patients' bloods in his laboratories in London. And then as it became available, Dr. Arthur Codd, who was a member virologist working with the Public Health Laboratory Service at the General Hospital in Newcastle, set

up the procedures to test patients there. And if we had a questionable result, we always checked it with the other laboratory. So the laboratory side of it was there, was evolving, and we used this right from the beginning. Secondly, we knew that we had a potential problem, and we thought it extremely important that that problem was addressed for all the families as soon as was absolutely possible.

Q. Yes.
A. The worst thing at this stage was living with the uncertainty of a diagnosis that was then considered to be potentially life-threatening. So we simply, with the help of everybody in the team, got on with it and tested people, and told them the results as they came through.

Q. And how was that done? I mean, just take a hypothetical case of an individual person who was tested, say, in March or April of 1985?
A. They would be invited to have their blood tested.

Q. Yes.
A. That blood would be sent off to one of the laboratories and, when the result came through, these people would be invited back again and the diagnosis would be given to them.

Q. And how was that done? I mean, would they be contacted specifically for the purpose of coming back to receive the results of the test?
A. Most of them were in and out of the haemophilia centre very, very frequently at that time, because they were -- they wanted to know what the results were and what the implications were.

Q. Yes.
A. At the minimum, people were followed up every three months anyway because of their haemophilia. So the maximum time between taking blood and getting the result, if they just went for follow-up, was three months.

Q. So -- just so we'll be clear: If somebody didn't happen to come in to the centre in that three-month period, would they be sent for or contacted by the centre to be told that the test is now -- there is a result from the test or --
A. It depended very much on the family and what we knew of the family and the people concerned. At one extreme, there was one young man who did not want to know his result, and even by the time I left did not want to know his result.

Q. Yes.
A. And at the other extreme there were people who were practically living in the centre, wanted to know what the results were as soon as they became available.

Q. Yes.
A. In general, people either came in to see a sister or rang up and said, "is the result available yet?" And sister would say, "would you like to pop in and see me?" But invariably that result was always given within the centre to the people directly.

Q. Yes. But what I just want to understand, if that didn't happen: Supposing somebody comes in and they give a blood sample and their next appointment would

be three months hence - as I understand, the next routine appointment - and for whatever reason they don't contact the centre in the intervening period; when would they have been told of the result?
A. At three months, when they came in for their follow-up, unless there were other worries within the family. And in that case the sister or the social worker would actually go out to the family; they would be encouraged to come in.

Q. Yes. So -- but unless one of those things occurred, what would happen would be it would be left to the next routine visit?
A. Yeah, but that was pretty rare at that time.

Q. I understand.
A. But that was the -- that was the long stop, if you like, to use a cricketing analogy; that the three-month appointment, that was the time that the result would be given to them.

Q. Yes. And you've mentioned that it might take more than an hour, an hour or two, for a senior doctor to give somebody the news of this diagnosis of a HIV-positive diagnosis?
A. Yes.

Q. I mean, how was that organised in terms of having enough man-hours available during this period when you had a very large number of people to deal with?
A. We did it.

Q. Was it done by --
A. We just went in working. We just did it. I sat in my room and sister was there and we just worked through it. And once we'd worked through all the initial trauma of it, then we went on and organised meetings of groups of people --

Q. Yes.
A. -- so that we could answer the questions in that way. But you always had to leave leeway for individuals to come and express their fears by themselves within the consulting room; and there wasn't any other answer, we had to do it.

Q. Yes.
A. I'll give you, if I may, Mr. Finlay, an example of what it was like, because the Tribunal brings back memories to us all.

Q. Yes.
A. Some of the bloods that we sent down to Dr. Richard Tedder were from members of staff as well as from patients. And I actually had the results phoned through to me in the beginning of a clinic, which went on for three hours. And one of the results from a member of staff was positive. And I sat through a three-hour clinic not knowing if it was me or a nursing sister or which member of staff it was. And at the end of the clinic, I managed to get out of the room and check the results and it was a typographical error and it was a patient. But that was a personal anecdote to illustrate the sort of strain that was involved. And if that was a strain for us, we recognised what a strain it was for the families. And that sounds very patronising at this stage, but we got on and we worked as a team and we did it.

Q. Yes. Now, I think you mention in your statement, at page six, that -- what you say is that: "At the time of testing for Hepatitis C, an antibody-positive result was considered less threatening than these diagnoses" - that was a diagnosis of haemophilia or HIV - "and was given in the privacy of a follow-up clinic although, when appropriate staff were ready to follow the procedure."
A. Yes.

Q. So would I understand from that that there was a difference between telling persons of a positive HIV antibody status and telling persons of a positive Hepatitis C antibody status?
A. Yes, there was a difference in terms of urgency of telling the result. The reason for that was that, at that time, HIV was considered to be such a devastating diagnosis that we had to get on with it. With Hepatitis C, we already knew we were dealing with a long, drawn-out disorder; at that time thought to be perhaps 40 or 50 years before there was any overt sign of disease. So there was not the urgency of divulging the result to people.

Q. Yes. And would I understand from your statement, in the case of Hepatitis C, that the telling of the diagnosis was, in fact, left to the next routine visit by the patient?
A. Yes, it was, unless they wanted it earlier.

Q. Yes. And was considered less threatening than the diagnosis of HIV; considered less threatening by whom, Dr. Jones?
A. By the patients and by us.

Q. Yes.
A. And the reason for that was this chronicity, or the assumed chronicity, of the disorder. HIV carried with it, from the very early days, a death threat, which was pretty immediate; whereas Hepatitis C was more likely to be a prolonged course before any overt disease became evident.

Q. Yes. And would there, on occasion, particularly perhaps in relation to Hepatitis C, would there be patients who wouldn't attend at their regular review appointment?
A. Oh, of course.

Q. Human nature is not very different in Newcastle from anywhere else I presume; I mean, not everybody likes to attend appointments?
A. That's absolutely true, anywhere you go, yes.

Q. And so what happened if somebody didn't attend for a scheduled review appointment?
A. Then we tried to chivy them up. Most of the people who were Hepatitis-C-infected were people who had been multitransfused. Again, and so they had to come in to get their supplies of treatment anyway - most of them would be on home therapy. And at that stage, time would be found to tell them what the diagnosis was.

Q. I see. Thank you. Could we move then, Dr. Jones, to the second statement which you made available to the Tribunal relating to the Armour product. And I think in the

first two pages, you give, again, a general introduction to the situation as it developed at the beginning of the 1980s. And unless there's something that you particularly want to refer me to, I think we've dealt with those matters and the Tribunal has had that general evidence from a number of people?
A. Yes, I'd agree.

Q. Very good. Your own personal experience you deal with at the bottom of page two, Dr. Jones, isn't that correct?
A. Yes.

Q. And you refer there to the fact that your professional experience of haemophilia in its treatment began soon after qualification in 1962.
A. Yes.

Q. And continues in your role as an Executive Member of the World Federation of Haemophilia?
A. Yes.

Q. And so you've seen the evolution of the treatment described in the introduction to the report and the results of the treatment yourself?
A. Yes.

Q. Yes. Now, I think do you mention that you had a particular experience which perhaps not all treating doctors in the UK would have had in relation to the commercial companies producing drug products?
A. Yes, I did. Early in my career, before I could -- before I became director of the haemophilia centre, I was evaluated for the post of medical director and medical director, Europe, of one of the major pharmaceutical companies producing drug products. And in the course of that evaluation, my wife and I went to be evaluated to assess whether or not, at one stage, we'd move to the United States. And we decided in the end not to. And for another part of my early career I worked with a major pharmaceutical company at their European headquarters in Brussels while holding a post in Newcastle, with the approval, of course, of the hospital authorities. So I saw it firsthand before AIDS, something, just a taste of how pharmaceutical companies worked, considered research and produced products for treatment of patients.

Q. Yes. And so did that give you a particular interest in that area?
A. Yes, it did. I became extremely interested in how the international demand for pharmaceuticals, how it was planned to meet the demand, how the supply problem was going to be met. And even in those days, and unfortunately still now, the majority of people with (inaudible) haemophilia in the world do not receive any treatment at all because there simply isn't the supply available for them.

Q. Yes. I think we've already briefly referred, and you refer yourself in your statement at page three, towards the end of page three, to the results in your own haemophilia community in relation to testing for HIV antibodies, isn't that correct?
A. Yes. That's the 76 of 99 patients with Haemophilia A that I referred to earlier.

Q. Yes. And those results were published in an article which was in the British Medical Journal of the 14th of September, 1985?

A. Yes, that's the article we've referred to already.

Q. And if we could just perhaps look at that briefly, Dr. Jones. I just want to ask you about one -- well, a couple of things in it. First of all, if we -- the internal pagination, the black numbering at the top, page two, second page; I think your Table 1 here, does that show - it's rather hard to make out. It's a bit easier on the screen because it's magnified, Doctor - does that show the origin of the blood products given to 163 patients together with their antiHTLV-III status?
A. 143 patients.

Q. Sorry, 143, yes, indeed?
A. It does.

Q. And then that's set out in a tabular form underneath that, isn't that correct?
A. Yes.

Q. First of all, you have the number of patients exposed to treatment, and that gives you a total of 143 patients; that's the first column, isn't that correct?
A. Yes.

Q. And the next column is the number of patients tested for antiHTLV-IIIs, and that's 120?
A. Yes.

Q. So not all the patients were tested; there were 23 who hadn't been tested?
A. Yes.

Q. Then the number positive was 81, is that correct?
A. Yes.

Q. So that, unfortunately, out of 120 patients tested, 81 were positive?
A. Yes.

Q. Now, in term of identifying the product which had been received by the patients, the overwhelming majority had received both NHS and commercial Factor VIII, isn't that correct?
A. That's true. That's true.

Q. A total of 88 patients, in fact?
A. Yes.

Q. And of those 88 patients, 73 were positive?
A. Yes.

Q. And they were all obviously Haemophilia A patients?
A. Yes, because they had been treated with Factor VIII.

Q. In terms of Haemophilia B patients, I think if you look at the second line down, "NHS Factor IX only," seven patients were tested. Unfortunately (sic) they were all negative?

A. Fortunately, yes.

Q. And then the next column down, 10 patients had received a combination of NHS and commercial Factor IX heat-treated and they were all negative?
A. Yes.

Q. So do I understand from that, Dr. Jones, that there would have been no commercial Factor IX used which wasn't heat-treated?
A. There was no commercial Factor IX used. It wasn't heat-treated, yes.

Q. It would all have been NHS Factor IX?
A. There was enough NHS Factor IX, before heat treatment came in, to satisfy the needs of our patients.

Q. Yes. Now, if we look at the next column, which is "NHS Factor VIII only," there are a very small number of patients tested who came into this category; there were, in fact, only three?
A. It was commercial Factor VIII. Forgive me, Mr. Finlay.

Q. Sorry, just immediately above "commercial Factor VIII," "NHS Factor VIII only."
A. Forgive me, yes.

Q. A total of seven patients received that treatment; three of them were tested and one only was positive?
A. Yes.

Q. Sorry, the next line down --
A. Yes, I'm with you.

Q. -- is "commercial Factor VIII only," and again, there were seven patients who came into that category; four of whom were tested and three were positive?
A. Yes.

Q. So I mean, what one can say is there were a very small number of patients who were Haemophilia A patients who had received exclusively either commercial or NHS concentrate?
A. That's right.

Q. So that perhaps, although you can say that one out of three patients who received NHS Factor VIII only became infected compared with three out of four patients who received commercial Factor VIII only, I mean, I wonder whether the numbers, the absolute numbers involved, being three and four, are sufficient to enable any great inference to be drawn from that?
A. No. I mean, the inference, as later on in the paper is drawn out, is that if we had treated everybody with a National Health Service volunteered donor product, then the likelihood of them becoming positive, becoming infected with HTLV-III, would have been less than treating them with a commercial concentrate.

Q. Yes.

A. That's clear and true.

Q. Yes. Yes. And I think that's -- I mean, that's a proposition that I think wouldn't be generally disputed?
A. No, not at all.

Q. Yes. But perhaps it's not possible, on the basis of the very small numbers who would have received only one or other product, to try and put any percentage on that, Dr. Jones?
A. No, that, again, is true. And of course, it begs the question, which I'm sure that you will come to, Mr. Finlay, of why there was this mix.

Q. Yes. Yes. And then just to finish, there's a peculiar category which is NHS Factor IX and commercial Factor VIII, three patients.
A. That is explained at the end of the second paragraph --

Q. Oh, right.
A. -- under "Patients and Methods" on the left-hand side there, the last sentence: "Three patients had received commercial concentrates and treatment of unspecified origin at other centres."

Q. Or I wonder is that actually the patients with Factor VIII inhibitors, would that be -- no?
A. It's question mark whether they received NHS.

Q. Yes -- no, but I'm sorry, I think I can see the answer. I was looking at further up under the "commercial Factor VIII only"; there's "NHS Factor IX and commercial Factor VIII," but there is a note. And if we come down to the bottom: "Patients with Factor VIII antibodies."
A. Yes. One of the treatments with people for Factor VIII antibodies is Factor IX concentrate.

Q. Yes. Yes. Now, I think in your discussion in this article, Dr. Jones, I think you drew attention, if we go to page four, to the problems that this situation created for providing treatment for persons with haemophilia?
A. Yes.

Q. Isn't that correct?
A. Yes, at the end of the article.

Q. Yes. It -- it's towards the last paragraph on page four there, where I think you say that, The problem had transformed your relationship with haemophilic families and your patterns of working at Newcastle, and that AIDS consumes the time of staff concerned in the care of those at risk. "Quite apart from having to learn to apply and work within the guidelines laid down by professional bodies and keep abreast of both medical and scientific developments (as well as what the lay media had to say) is the time needed to talk calmly with and to counsel patients and their families. This is especially difficult in the context of haemophilia because of the familial and social interactions of the disorder. Although an overall impression can be presented in open meetings and through newsletters, it was only in the privacy of the consulting room or

the family home that many of those worried by AIDS can be helped. Consideration must also be given to the well-being of staff, many of whom have known affected families for years and have watched the hitherto successful application of home therapy and prophylaxis. "To cope, we think it imperative that the medical, nursing, social work and laboratory support provided to every centre treating people in any group at risk, including haemophilia centres, should be assessed as a matter of urgency. Extra support is also needed by the voluntary societies concerned with the care of patients with AIDS in the community." So there you were clearly identifying the burden that had been placed on the staff at Newcastle by this unfortunate --
A. Yes.

Q. -- number of people who were infected?
A. Yes.

Q. And, in fact, I think from the article, unfortunately a number of people were not alone HIV but had, in fact, developed AIDS --
A. Yes.

Q. -- even by October of 1985, isn't that correct?
A. Yes. With hindsight I can't remember how many.

Q. Yes. I understand.
A. A few.

Q. Yes. Now, just in relation to -- you deal at the end of page three, Dr. Jones, with the treatment changes which are made in late 1984 -- sorry, of your statement, I beg your pardon, Doctor. Sorry.

THE CHAIRPERSON: What page?

MR. FINLAY: At the bottom of page three.
A. Yes.

Q. The treatment changes which you made at the end of 1984 and beginning of 1985?
A. Yes.

Q. Can you just describe those to us?
A. Yes. Being a director of a reference centre, I obviously worked with my colleagues at the other reference centres and we met frequently, and more and more frequently as AIDS evolved. We had an AIDS taskforce and AIDS committee of the United Kingdom Haemophilia Centre Directors, and we were frequently in communication by telephone as well. We knew that methods were being investigated to try to remove viruses from blood products, and I'm sure that these methods have already been described to the Tribunal.

Q. Yes.
A. But in October of 1984, the Medical and Scientific Committee of the American Haemophilia Foundation, the American Haemophilia Society, came out with a specific recommendation that heat treatment should be considered --

Q. Yes.
A. -- for the treatment of people with Haemophilia A and B. And the directors agreed with that statement. And so in December, following a meeting of my colleagues, I decided that all patients in Newcastle should be offered heat-treated material, either Factor VIII or Factor IX.

Q. Yes.
A. And I had to take that, of course, to the people looking after the pharmaceutical products within the hospital; and that I did. And there was no delay. We immediately instituted heat-treated products in Newcastle and the northern region --

Q. Yes.
A. -- for both patients with Haemophilia A and Haemophilia B. It was more difficult for Haemophilia B because we had been using National Health Service Factor IX before that date, and there was no heat-treated alternative other than a commercial product. So we swapped to a commercial product.

Q. Yes. And are you saying you did that in January of 1985?
A. Yes.

Q. And then did you continue - if we just stay with Factor IX for the moment - did you continue to use heat-treated Factor IX, commercial Factor IX, until the NHS heat-treated Factor IX became available?
A. We did, yes. And then it became a question of tender again as to which product we used, after taking into account safety and efficacy.

Q. Yes. And in terms of Factor VIII, did you move to, presumably in January of 1985, commercial heat-treated Factor VIII?
A. Yes.

Q. Because I don't think there was any NHS heat-treated --
A. No NHS heat-treated Factor VIII at that time. It didn't come in until later in 1985.

Q. And would you then have moved to, when NHS heat-treated Factor VIII became available, would you have moved to that or would you have stayed with the commercial?
A. Again, it came down to the safety and the efficacy and the cost.

Q. Yes.
A. So all these things went into the equation, as to which product we chose. But overriding our principle, I think at that time and later, was we always tried to go with licensed products, products which had been licensed by the Committee of Safety of Medicines in the United Kingdom rather than a single doctor prescription.

Q. Yes. Yes. Now, I think you mention at the top of page four of your statement that there was an exchange of information, obviously, amongst people who would have been involved in the treatment of persons with haemophilia and involved in the scientific end of this world, would that be correct?

A. Yes.

Q. And I think you specifically mention Dr. Bruce Evatt of the Centre for Disease Control in Atlanta?
A. Yes.

Q. Why do you specifically mention him?
A. Because Dr. Evatt and I have been colleagues for many years and he is an Executive Member of the World Federation of Haemophilia, as I am. And in these early days, he was in charge of looking at haemophilia and AIDS for the Centre for Disease Control in Atlanta.

Q. Yes.
A. So in the same way that I talked frequently to colleagues like Dr. Peter Levine in Massachusetts, I was in contact with people like Dr. Bruce Evatt in Atlanta.

Q. Yes. Now, you mention now in your statement that an article of the 22nd of June, 1985, or a letter to The Lancet from Jay Levy and his colleagues, gave rise to some concern on your part, is that correct, caused you disquiet?
A. It did cause me disquiet and the reason it caused me disquiet was two-fold: Firstly, in 1985, in order to find out about AIDS and how to look after people with AIDS, I went to New York and San Francisco, as I've already said. And whilst I was in San Francisco, there was questions raised about heat treatment of blood products and whether or not it was 100 percent successful. But it wasn't until the June 22nd letter from Jay Levy, who was a respected scientist in San Francisco, that we had evidence that perhaps some of the heat treatment might not be 100 percent successful.

Q. Yes. Now, I think that letter appears at pages six and seven of your book, isn't that correct?
A. Yes.

Q. And would it be correct, Dr. Jones, that what you would have been -- again, it's rather small type, but might it be that what you would have been concerned with was the information contained in table two at the top of page seven there, which deals with the effect of heating for various -- heating at 68 degrees Centigrade for various periods of time on what's described as ARV-3, isn't that correct?
A. Yes.

Q. And that ARV I think was a form of HIV?
A. Yes, it was. It was an early term for HIV.

Q. And what one has is first of all the purification or -- I think the lyophilisation had some reduction of the virus, isn't that correct; that's the first column?
A. Yes. If I can perhaps help the Tribunal here in my thinking: The table refers to log kill.

Q. Yes.
A. And I know that has been explained to the Tribunal already.

And it's not a term with which I was familiar up until AIDS came into being. The suggestions - the arguments, not suggestions - the arguments that one could tell the safety of a product by log kill seemed to me to be fallacious --

Q. Yes.
A. -- because it did not take into account the sensitivity of the method that was being used and the way virus could get through into a blood product no matter what the log kill was; in other words, you weren't measuring the virus directly.

Q. Yes.
A. And that was exemplified to me by the fact that, in those early days, none of the concentrates that were known to have infected patients, because of epidemiological studies, proved to be positive for the virus; in other words, nobody was able to find the virus in concentrates which must have contained it. So I thought that whilst log kill was an indicator of the efficacy with which one could remove virus, it was a very poor measure of that.

Q. Yes.
A. So in reading tables like this, I was always skeptical.

Q. I see. Well, what this table appears to show, is this not the case, that dry heating at 68 degrees Centigrade for 10 hours, 24 hours, 34 hours, and then -- then I think 40 -- 48 hours --
A. 48 hours, yes.

Q. -- that there was - if we look at the right-hand column - there was still some measurable quantity of virus after the heat-treating at 10, 24 and 34; and it's only when one gets to 48 hours that -- the "NV" I think indicates no virus?
A. Yes.

Q. Yes. And what the authors say at the top of page seven, it would be towards the end of the article, is: "The comparable results with the mouse and human retrovirus suggests that heating lyophilised Factor VIII for 72 hours at 68 degrees Centigrade or the liquid product for 10 hours at 60 degrees Centigrade will eliminate infectious ARV if it is not present in the plasma at more than ten" -- sorry, "more than six logs infection. "Is that correct?
A. Yes.

Q. Now, of course, this communication I think comes from a research institute which would have been associated, am I correct, with the Cutter Laboratories?
A. It's signed by Cutter Biological, Berkley, in California, yes.

Q. And that was, of course, the 68 degrees Centigrade for 72 hours, was their heat treatment protocol?
A. Yes.

Q. So essentially what they're saying in their article is that their heat treatment protocol, they believed to be safe?
A. The dry heat or the liquid product, yes.

Q. Yes. Because, in fact, I mean, the table doesn't, in fact, go to 72 hours, isn't that correct?
A. No, that's right. It goes to -- I think it goes to 56 -- 48 or 56.

Q. Yes. So what they're saying is that they believe that their procedure at 68 degrees for 72 hours was safe?
A. That's what they're intimating, yes.

Q. But the inference you drew from that was that a lesser period of heat --
A. Was perhaps not safe.

Q. Yes.
A. And that fitted in with what I learned when I was in San Francisco.

Q. Yes. Now, would you also have considered at the time, Dr. Jones, would you have been aware -- if we look at page eight, an article in The Lancet a little later, a few months later, in October of 1985.
A. Yes.

Q. A letter which is signed by John Petricianni, Steve McDougal and Bruce Evatt, who you referred to, your colleague, is that correct?
A. Yes. John Petricianni was the head of the Food and Drug Administration at this time in relation to these products, and Bruce Evatt and Steve McDougal worked for the Centre for Disease Control.

Q. Is this correct: Are you familiar with this article, Dr. Jones?
A. Yes, I am.

Q. And is it correct that the first part of the article contains a somewhat complicated calculation of what level of virus was likely or possible to have been present in commercially fractionated concentrate?
A. Yes.

Q. Isn't that what it sets out to do?
A. Yes.

Q. And having done so, it then considers the level of virus inactivation which is -- was achieved by dry heat-treating at 60 degrees?
A. Yes.

Q. And if we look at page nine, as is shown on the screen there, it shows the amount of inactivation resulting from heat treatment at 60 degrees, isn't that correct?
A. Yes.

Q. And it goes on to say -- easier to read from there: "Heat inactivation kinetics data show that when LAV or HTLV-III is added to liquid AHF and the mixture is heated at 60 degrees Centigrade, one log is inactivated in about half a minute. Lyophilised AHF requires about 30 minutes of heating at 60 degrees Centigrade for the inactivation of one log of added LAV/HTLV-III. Since the minimum temperature and heating time used by commercial manufacturers of AHF are 60 degrees

Centigrade and 10 hours, respectively, the extrapolated minimum reduction of virus would be 20 logs." So am I understanding it correctly, Dr. Jones, that what this letter is saying is that heating at 60 degrees Centigrade for 10 hours, they estimate, would have a minimum reduction of virus of 20 logs?
A. Well, again, this is past my expertise, to be able to come at it from the scientific point of view. But I mean --

Q. Simply reading the article, that's what they're saying?
A. From a clinician's point of view, that is what they're saying.

Q. And they go on then to say, in the final paragraph, that: "Even after taking into consideration the administration of doses of AHF as large as 100 millilitres, and the possibilities of nonlinear inactivation kinetics at very low virus concentration and a human ID substantially smaller than that required for in vitro assays, there still seems to be enough of a safety factor afforded by AHF heat treatment to permit the conclusion that infectious LAV/HTLV-III is unlikely to be present in currently licensed heat-treated AHF and that the use of such products should not result in additional cases of AIDS in persons with haemophilia. LAV/HTLV-III is much more labile than other viruses and efforts to improve virus inactivation procedures should continue in conjunction with studies aimed at stabilising proteins in plasma derivative products."
A. Yes.

Q. Did that not reassure you, Dr. Jones, if you were concerned about the original article that you referred us to?
A. It's certainly reassuring that it came from these people, in that we changed people to Factor VIII and Factor IX heat-treated products already, and this was an additional piece of information that was coming from laboratory studies. But it did not reassure me in the -- in my meetings that we were not home and dry; because the proof of the pudding is the epidemiological work, whether people become infected.

Q. I completely accept that, Dr. Jones, of course. But I thought that the first article you referred us to, the Levy article, that's not an epidemiological article; it has nothing to do with clinical experience. It's a purely scientific article in relation to his view of the effectiveness of heat treatment?
A. Yes.

Q. Isn't that correct?
A. It is. And that suggested that you had to heat at relatively high temperature for a relatively long period of time in the dry state in order to have a 'guarantee', in inverted commas, of safety. Whereas this article suggests that the safety is already there.

Q. Yes. Yes. Very well. And did --
A. There were two sides to the equation, and I was still not happy that this work gave that guarantee.

Q. I understand. But --
A. If I can just take that a little bit further: The barriers to the transmission of a virus or any pathogen within a blood product are, firstly, the exclusion of that

pathogen in the first place - in other words, donor exclusion; secondly, testing for the pathogen; and thirdly, inactivating.

Q. Yes.
A. Now, this article begs the question of somebody who is at the beginning of HIV infection and who is very viraemic and, therefore, capable of infecting somebody, but at this stage was in the window period; in other words, a donor coming along, perfectly well, perfectly fit member of the community, and testing negative for any test that you care to give him, but in fact, that he's highly viraemic and the plasma which he gives, and from which blood product is derived, is teaming with pathogen. Now, if the method -- if there's any question about the method of viral inactivation, then it always seemed to me that that last barrier could possibly fall.

Q. Yes. I mean, I think one would now know, Dr. Jones, that the estimate that there was a minimum reduction of 20 logs involved in heat-treating at 60 degrees Centigrade for ten hours, that -- I don't think subsequent events would prove to have been correct?
A. No, it was wrong.

Q. Yes. But nonetheless, this was the information which was being published at that time by --
A. Oh, yes.

Q. -- amongst others, Dr. Evatt, who you specifically identified as somebody whose view you would have respected greatly at the time?
A. Of course I would, yes, and still do. But in this case the result was wrong.

Q. Yes. But not at the time identified as such?
A. No. This was a view that was held and it was held -- it was held with faith as much as with science at that time, that heat treatment worked and that we weren't going to see any more people infected with HIV.

Q. Yes. Now, I think you deal in your statement then, Dr. Jones, with some information - I don't quite know how to describe it, perhaps you can describe it for us - about a possible seroconversion that emerged in 1985. I think you deal with this at page five of your statement.
A. Yes. We -- as I've said already, Mr. Finlay, we met regularly with the AIDS group of the United Kingdom Haemophilia Centre Directors.

Q. Yes.
A. And we were Reference Centre Directors. And there was talk; it was reported, but not formally, that a patient at one of the London hospitals had seroconverted following treatment with one of the heat-treated products. And the part in my statement, in the paragraph at the top of page five, refers to that patient.

Q. Yes. And what exactly was the status of that information at the time, if I put it that way?
A. The status was that if somebody had seroconverted whilst on a heat-treated product, it raised that spectre that we were not able to guarantee heat treatment as a totally efficient way of removing HIV.

Q. Yes. I mean, I think I can understand the significance of it. But was this concrete, solid information that there had been such a seroconversion, or how would you characterise it?
A. I would characterise it at that time as anecdotal. There was no formal notification to us, as haemophilia centre directors, that this patient had seroconverted.

Q. Are you able to tell us when that meeting was, Dr. Jones, can you remember?
A. From memory I can't tell you, but I believe it was in the first six months of 1985 but I -- the dates that I have from subsequent information are that there was correspondence in July.

Q. Yes. But I mean, perhaps if you could just see whether you can, from your own memory, recall when that meeting was that you attended?
A. There was so many meetings that I can't recall, I'm afraid.

Q. I understand. I think you did receive a letter, Dr. Jones - sorry, just to revert to the previous page, page four of your statement - you did receive a letter from Armour in relation to one of their products, which we see at the 10th of May, 1985, at page ten, is that correct?
A. Yes, that is correct. This was a letter on May the 10th from Mr. Chris Bishop who worked -- was an employee of Armour in the United Kingdom. And he wrote about a heated batch - and the batch number is given there - which was distributed between December 1984 and January of 1985. And he asked for the return of any remaining vials. Of that, he identified that batch as coming -- some of it coming to my centre. And he later wrote on June the 4th --

Q. Just before we come to that, did he not, in this letter we see at page ten, did he not identify that, in fact, one of the donors to that batch had subsequently developed AIDS?
A. Yes.

Q. Yes.
A. Yes. Whether it was in that letter --

Q. I think if you look at page 10 of the book of documents?
A. Okay. I was in my statement. Yes, in the second paragraph he says: "When this donor was giving plasma, we exerted our strict routine screening. The donor showed no indications of ill health, stated he was not a member of any risk group associated with AIDS and was on active military duty."

Q. Yes. But the preceding paragraph mentions that that particular donor had, in fact, developed AIDS?
A. Yes.

Q. Isn't that correct?
A. Yes.

Q. Yes. And then the letter goes on to identify that the batch in question was a heat-treated batch?

A. Yes.

Q. And as you say, they ask you: "If you still hold any of the batch, could you notify Armour and return it to them"?
A. Yes.

Q. And that they would either reimburse or replace it?
A. Yes.

Q. Yes. Now, did you receive a subsequent letter then on the 4th of June - page 11, the next page in the book of documents?
A. Hopping between one and another. Excuse me.

Q. I beg your pardon.
A. Yes. June the 4th. And this was from Mr. Christie, who was the director of clinical sciences at Eastbourne for Armour.

Q. Yes. And essentially this letter I think seeks information about any patients who had received material from that particular batch?
A. Yes.

Q. Isn't that correct?
A. Yes.

Q. And did you have any information yourself to supply to Armour about that batch, Dr. Jones?
A. I can't recall. If we had, we would have passed it on to them, because we passed on any information that we could at this stage.

Q. Yes.
A. To my memory, we'd used the batch and it would all have been used, and some of the patients would be in the tables that you've referred to.

Q. Yes. Now, if we -- sorry, if we just revert to your statement for a moment, Dr. Jones. Apart from the information at the meeting about the possible seroconversion, the information at the UK reference directors, did you receive any other information in 1985 about possible seroconversions of patients who were receiving heat-treated product?
A. Yes, I did. I was working with a colleague called Dr. Breederveld in the Netherlands. We were particularly interested at that time in Factor V deficiency. And he told me that they were looking at a patient who he thought had seroconverted following treatment with the Armour heat-treated product.

Q. When was that?
A. Again, I can't recall the date. We didn't correspond in writing, I think we just met at a meeting and talked about it then. And I also heard questions about a further possible three cases, one of which seemed to be pretty definite in the United States of America.

Q. And what was your source of knowledge about that?

A. That was Dr. Peter Levine in Massachusetts who told me they were looking at that, and he was concerned with the National Haemophilia Foundation at that time. So it was in the circuit, if you like, for information, before it became published.

Q. And would that, again, have been a personal communication?
A. Personal communication, yes.

Q. And in respect of the communication from Dr. Breederveld, was the product involved identified to you?
A. Yes, it was identified as the Armour product.

Q. The Armour, 60 degrees for 30 hours?
A. Yes.

Q. And in respect of the other communication from Dr. Levine, was any product identified?
A. I think that, again, Armour was identified, but not in all three cases. But I think the big question mark was not by the name of the product, but was by the 60 degrees for 30 hours, which was only the Armour product, and dry heated.

Q. And do you think that the product was identified to you by Dr. Levine?
A. I can't recall. I think -- my recollection is that in one case it was, but the other two cases was a question mark.

Q. I see. And I think at the time, was there a conference organised for February of 1986, Dr. Jones?
A. Yes. We organised a conference on AIDS in Newcastle.

Q. Yes. I think the programme for it is at page 15 of the book of documents.
A. Yes.

Q. Isn't that correct?
A. Yes.

Q. And would I understand that this wouldn't have been confined to persons with haemophilia, or would it?
A. No.

Q. No. A general conference on AIDS?
A. This was a general conference on AIDS.

Q. Yes. And then in the book of documents, if we go to page 19, we have the text of a paper which you delivered to that conference, isn't that correct?
A. Yes.

Q. And perhaps, without going through it all, if we might just identify -- I mean, if we start at pages 19 and -- to 22, there was a general introduction to the whole topic of haemophilia and the treatment of persons with haemophilia?
A. Yes.

Q. Presumably reflecting the fact that it wasn't a conference confined to persons with haemophilia?
A. That is correct, yes.

Q. Designed for a general audience. And then at page 22, you dealt with some of the results which there had been of the recent testing of persons with haemophilia for HIV antibodies, isn't that correct?
A. Yes.

Q. And the percentages. And then the prognosis you dealt with at page 23?
A. As it was then known.

Q. As it was then known.
A. Or "thought," I think, probably is a better word.

Q. And, I mean, again, this is something that the Tribunal, I think, has seen on a number of occasions. But the prognosis, as it was then known, was, in fact, considerably more optimistic than unfortunately turned out to be the case?
A. It was very optimistic for that interim period before we had treatment, yes.

Q. Yes. And then you moved to the question, at page 25, you moved to the question of heat treatment, isn't that correct?
A. Yes.

Q. And perhaps if we just look at the -- it's really two paragraphs, we should look at them in full. You said: "Laboratory experiments show that the AIDS-related virus does not like heat and is readily destroyed. Most manufacturers now use heat during the preparation of the concentrates, although chemical methods of viral inactivation are also being studied. Whatever method is used, complete AIDS inactivation cannot yet be guaranteed; hence the enormous importance of discouraging people in high-risk groups from donating and of continuing to check individual donations by the most sensitive test available. Only time and careful follow-up will tell us how effective introduction of the more expensive heat-treated materials has been. To date, I know of four possible breakthroughs; three are known to CDC and have been described to me by Dr. Peter Levine as being probable seroconversion to antiHTLV-III positivity in one case and possible seroconversion in two others; the fourth case is about to be reported by Dr. " -- what is the name?
A. Dr. Breederveld was my colleague, but Dr. ten Cate was the head of that unit.

Q. -- "and is perhaps the most convincing. This patient is known to be in no other risk group and was seronegative when started on heat-treated material, becoming positive after almost a year's treatment. This takes him well past the known incubation period between infection and seroconversion. "Given that haemophilia has to be treated, the alternatives available -- now available lie between a reliance on heat-treated concentrate, perhaps with adjustments in terms of time and length of heating, and tested cryoprecipitate for Haemophilia A, or fresh frozen plasma for minor bleeds in Haemophilia B. In the case of mildly or moderately affected patients with Haemophilia A or those with von Willebrands Disease, the alternative to blood product is DDAVP, or Desmopressin, which carries no risk whatsoever from either hepatitis or AIDS, but is useless in severe haemophilia."

A. Yes.

Q. And is that the relevant -- sorry, your paper then goes on to deal with the impact of HIV-positive -- positivity, and AIDS, on persons with haemophilia.
A. Yes.

Q. And the necessity of the matters which are required to provide appropriate services for such persons?
A. Yes.

Q. But are those two paragraphs the relevant paragraphs of your paper --
A. Yes.

Q. -- in relation to this question?
A. Yes.

Q. The information wasn't specific to any particular form of heat treatment?
A. No. It was made nonspecific, it just -- I just wanted to raise the question that we might have a problem.
Q. Yes. And to anybody reading the paper or hearing of the paper, the nature of the problem other than that there may be seroconversions for persons who were receiving heat-treated product is not more specifically identified than that, isn't that correct?
A. No, that's correct.

Q. Now, I think following that paper, Dr. Jones, did you have communications with a number of persons; and I think you -- if we look at page 32 of the book of documents, and page six of your statement, you deal with the situation immediately after you delivered your paper, isn't that correct?
A. Yes.

Q. And the document at page 32 was a letter that you wrote addressed "Dear colleagues," dated 17th February, 1986. To whom was that addressed?
A. I wrote to my colleagues, the Reference Centre Directors, and I copied to all the directors in my own region, the haemophilia centres.

Q. Yes. And as is clear from page 32, you enclosed a copy of the paper which you had given at the conference in Newcastle last week?
A. Yes.

Q. And you say in the first paragraph: "In sending this to you, I apologise for any distress caused by the suggestion that heat treatment may not always be effective. I have passed the information I have to the Department and to the Committee on the Safety of Medicines, where expert authority can decide whether any action should be taken."
A. Yes.

Q. And then in the second paragraph you say you thought a great deal about whether such soft data should be presented at the conference. "My view was that because of the paucity of seronegative cases on a variety of heat-treated materials, and the time lag involved, that we could not afford to wait until sufficient 'scientific'

evidence was available. My decision to include the four cases in the paper was based on this view on the strength of the personal reports that I had received from reliable doctors, and on the evidence that I was given in California that live virus had been found in concentrates dry heated for short periods. The argument has been put to me that, because of the extremely low incidence of seropositivity in blood donors tested in this country, together with heat treatment, that there is no longer any threat to haemophiliacs. I do not think this is true and I felt the warning justified." The reference to the information you were given in California that live virus had been found in concentrates dry heated for short periods, that wasn't included in your paper?
A. No, that was anecdotal evidence for when I was in San Francisco.

Q. Yes. And then I think the rest of the letter is really personal to your own concerns in Newcastle, would that be correct?
A. Yes.

Q. Now, I think did you also, Dr. Jones, did you write on - if you look at page 33 - on the 18th of February, 1986, to the medical assessor of the Committee of Safety of Medicines in London?
A. I did.

Q. What is that committee?
A. This is the Committee of Safety of Medicines which has the remit for looking at the licensing of all pharmaceutical products, including blood products, within the United Kingdom.

Q. Right. And you say that: "I enclose information I have that suggests HTLV-III seroconversion in previously seronegative haemophiliacs being infused with some types of Factor VIII concentrate, especially that heat-treated in the dry state for less than three days. I do realise that the evidence is only suggestive but I thought it sufficiently worrying to mention the possibility that we are not out of the woods yet in my paper to the AIDS conference. A copy of this is enclosed, together with a covering letter written to haemophilia centre directors. "In this centre, in addition to available National Health Service concentrate which is at least heated for 72 hours, we have changed our patients to the Alpha material because of a report to me by Dr. Koerper that it was free of virus, after testing by Dr. Levy in San Francisco. It is my personal opinion that unless there is irrefutable evidence to the contrary, the Armour material should be withheld until its safety can be endorsed by the CSM." Just in relation to your own practice at the time, you were saying that in addition to the available NHS concentrate, which would have been, at that time in February of '86, heat-treated, isn't that correct?
A. Yes.

Q. To 80 degrees for 72 hours?
A. Yes.

Q. "We have changed our patients to the Alpha material." What Alpha material was that?
A. This was a pasteurised material. This was heated in the wet state.

Q. Yes. And you don't refer there -- what about factor -- Haemophilia B patients, what was your practice at the time?
A. Our practice was to use a, in 1986, commercial Factor IX because -- have I got this right? 1984 /'85 -- forgive me. My mind is a bit like scrambled egg with dates at this stage.

Q. I think by October of 1985 there was heat-treated NHS Factor IX?
A. That's right. It depended on the question of cost and efficacy and everything else. So it went for tender at that stage.

Q. Yes.
A. And I cannot recall whether the Factor IX we used was NHS or not at that stage. We had patients on commercial Factor IX earlier on, and indeed that also was the Alpha pasteurised material.

Q. Yes. So just looking at this paragraph, I was drawing an inference that you were avoiding dry heat-treated product apart from the National Health Service dry heat-treated product?
A. Yes, I was. Yes, I was.

Q. That's what it seems to be saying in relation to Factor VIII?
A. Yes.

Q. But the same -- from what you're saying to me now, the same consideration perhaps didn't apply to Factor IX?
A. If we -- if there was a question of whether or not we had dry heat-treated Factor IX for commercial donors at that stage, the same question mark would have been raised.

Q. Yes. Now, I think you also wrote, Dr. Jones, to a -- one particular -- sorry. You wrote to Dr. Harris of Armour on the 25th of February, 1986?
A. Yes.

Q. At page 34. And you sent him a copy of your paper?
A. Yes.

Q. "You will see from this paper, and from subsequent publication in the New Scientist on the 20th of February, that it is the Dutch case that I'm particularly concerned about. In my original paper I didn't think it proper to refer to the product used in this case, although now you have confirmed that it was in fact Armour factorate heat-treated. The information about the American cases was given to me by Dr. Peter Levine and I subsequently discussed them with CDC. I'm afraid that I am not party to the products involved in these cases, although it is possible that one of them which has been reported to Professor Mannucci was on the Travenol material." So, at that time on the 25th of February, you were certainly writing to Armour to the effect that you didn't know what product was involved in Dr. Peter Levine's seroconversions?
A. As I said earlier, there was one possible one with Armour, but the other two I didn't know. And at this stage, again, from memory, there's the question of the Travenol one. But I did not know with certainty on any of the three. The question of

Armour was a possibility in one of them, to my memory, but the question of Travenol, again, was something that perhaps was raised later.

Q. But you're not informing Dr. Harris that your understanding was that it was possible that one of the patients referred to by Dr. Levine was receiving an Armour product?
A. No. I've said I'm afraid I'm not party to the products involved in these cases. I wasn't. Except that there was the question of the Armour product being raised to Peter Levine and I didn't put it into this letter. But by that stage the question of whether Pier Mannucci, who was collecting these cases, had been informed of a Travenol material, I honestly don't know.

Q. Yes. But I just wonder, Dr. Jones, would it not be that in fact this letter is accurate, that you didn't know what product was involved in Peter Levine's patients?
A. No, I didn't. I think that one of the cases was an Armour product. And subsequently, if I can use --

Q. No, never mind subsequently for the moment. At this time, and at the time you delivered your paper in Newcastle --
A. I thought when I delivered the paper that these three cases were dry heated products.

Q. Yes.
A. Yes.

Q. But you told us that you thought possibly one of them was an Armour product?
A. Yes, and to my memory one of them was an Armour product.

Q. But I --
A. Yes, you're right. There is a discrepancy in the letter that I mention Travenol in this letter.

Q. Yes.
A. "Although it's possible that one of them which is being reported to Professor Mannucci --" now, we were also -- Professor Mannucci was also a member of the World Federation of Haemophilia, so he was in the network of people who were constantly discussing all these products.

Q. I understand that.
A. And it may about be at this stage when I was checking that I'd heard that he was looking at a Travenol product.

Q. Yes. But, Dr. Jones, would there have been any possible reason why you wouldn't have mentioned to Armour, if such was the case, that you understood it was possible that one of the Peter Levine patients was receiving Armour product?
A. Yeah, I can't recall why I haven't put Armour in the letter.

Q. Well, might it not be that, therefore, your recollection that at the time you thought that one of the Peter Levine patients was receiving an Armour product mightn't be so?

A. That's absolutely correct, yes. I'm relying on memory and not on written communications. That was later.

Q. I understand. You see, there was in the Peter Levine -- you mention in your paper, there was a distinction, but I wonder is this perhaps what you're recalling: That in relation to one patient, he thought it was a probable seroconversion; and in relation to the other two patients, you mention in your paper he thought it was only a possible seroconversion?
A. That's right.

Q. I wonder is that the distinction, rather than a question of what product was involved?
A. It may very well be. My memory is that the seroconversion was concerned with the dry heated material, which was the Armour product.

Q. Yes.
A. But that's memory.

Q. Yes.
A. I don't have any report of that in writing.

Q. Yes. And you certainly didn't say it in your paper?
A. Well, no, I didn't identify. I thought it was wrong to identify, because at this stage, all this was supposition, and if I can use the word, conjecture. There was no proof that there was a problem here. There was a suggestion there was a problem.

Q. Yes. But here you are now writing in private to Dr. Barry (sic), the medical and technical director of Armour?
A. Dr. Harris.

Q. Dr. Harris, I beg your pardon. And obviously if you thought at the time that one of the Peter Levy (sic) patients may have been receiving an Armour product, I presume he would have had an interest in knowing of that?
A. Again, I must have -- you know, involved conjecture. And for some reason I've got the Pier Mannucci investigation involved here.

Q. And that, of course, according to this letter, related to a Travenol product, not to an Armour product at all, isn't that right?
A. Yes, it did. But whether or not that was one of the original ones, I can't tell.

Q. Yes.

MR. FINLAY: I don't know, Madam Chairperson. I'm going to be a few minutes more certainly with Dr. Jones. I wonder is it a convenient time.

THE CHAIRPERSON: Whichever you prefer. If you wish to continue or to -- or Doctor, perhaps we'll leave it for today and come back tomorrow.
A. Thank you Madam Chairperson. Whatever you'd like.

THE CHAIRPERSON: I think we've had enough for today. We'll take it up at 10:30 tomorrow morning.

THE TRIBUNAL THEN ADJOURNED TO THURSDAY, JULY 12, 2001, AT 10:30 A.M.

THE TRIBUNAL RESUMED ON THE 12TH OF JULY, 2001, AT 10:30 A.M., AS FOLLOWS:

CONTINUATION OF EXAMINATION OF DR. PETER JONES BY MR. FINLAY AS FOLLOWS:

Q. MR. FINLAY: Good morning, Dr. Jones.
A. Morning, Mr. Finlay.

Q. Now, I think, Dr. Jones, you provided the Tribunal since yesterday with a document which now appears at page 33 A in the book of documents?
A. Yes.

Q. And can you just explain, if we go back to page 33, this is a letter from you dated the 18th of February, 1986, to the medical assessor, the Committee on Safety of Medicines at Market Towers in London?
A. Yes.

Q. And you referred to that yesterday in your evidence?
A. I did, and 33 A was attached to that letter.

Q. Yes. If we just look at the letter at page 33. It says: "I enclose information I have that suggests HTLV-III seroconversion in previously seronegative haemophiliacs being infused with some types of Factor VIII concentrate, especially that heat-treated in the dry state for less than three days." And was the document that appears at page 33 A; was that attached to that letter?
A. Yes.

Q. Was that the information that was enclosed?
A. Yes.

Q. Yes. So, perhaps if we could look at that, since we didn't look at it yesterday, Dr. Jones. It sets out in a tabular form on the left-hand side, evidence about seropositivity following heat-treated factor concentrates; in the middle, the product; and on the right-hand side, the source of information, is that correct?
A. That's correct.

Q. And the first entry is "adult haemophiliac followed for almost a year on HT material; heterosexual; no other risk factors; repeatedly tested after being seronegative". The product is identified as Armour, and the source is Dr. Breederveld?
A. That's correct.

Q. And that was the -- the individual case referred to in your paper?

A. It was.

Q. Yes. And it was, in fact, subsequently, as we will see, published, a letter about that was published in The Lancet?
A. It was, by Dr. Breederveld and his colleagues.

Q. Yes. Now, the next entry is: "Three haemophiliacs all reported to CDC, who appear to 'probably' fulfill criteria for seroconversion in one case and 'possibly' fulfill criteria in two cases." And under product you have "not known"?
A. Yes.

Q. And under "Source of information: Dr. Levine, permission to quote given in February 1986"?
A. Yes.

Q. I think were they the three American cases referred to by you in your paper --
A. They were, yes.

Q. -- at the February conference. And at this stage, in reporting on the 18th of February to the Committee on Safety of Medicines in the United Kingdom, you are not in a position to identify the product?
A. No. I thought that one of those was Armour, but that was -- that was memory.

Q. So, just to be clear, Dr. Jones: Is it the case that at that time you would not have been aware of what the product involved in --
A. I was not aware of those three cases, although you will see from this document there is a fourth case underneath with Armour written by it. And if my memory serves me right, there were two cases of possible seroconversion which I thought were related to the Armour product. But because the words "possibly" and "probably" were being used and these cases had not been published, that was why I did not refer to the product specifically in the course of my paper to the AIDS conference. But in putting the evidence together to send to the Committee of Safety of Medicines, I included everything that I knew at that time, so that they were aware of where that supposition had come from.

Q. Yes. But let's just take it in stages: What you refer to in the conference -- in your paper at the conference are the entries contained at the first two entries --
A. That's right.

Q. -- on this list?
A. That's right.

Q. Isn't that correct?
A. That's correct.

Q. And in relation to the second -- in relation to the first entry, you were aware, and you were aware at the time you delivered your paper, that Armour was the product involved?
A. Yes.

Q. Isn't that correct?
A. It is correct.

Q. In relation to the second entry, the three cases referred to by Dr. Levine, were you or were you not aware or -- of what product was involved in February of 1986?
A. I was aware that there was a probable case in America, and I was also aware that that had been linked to the Armour product, but I was not as aware of that as I was of the Breederveld case which was the most telling case that I had at that time, suggesting that the Armour product was not safe.

Q. So you are saying to me that you still think that you, at the time, were aware that one of these three cases; one of these three Levine cases was possibly linked to the Armour product?
A. Yes.

Q. But you don't mention that --
A. No, the -- this was supposition. You know, we are playing with words, Mr. Finlay, conjecture and guessing and things like this. I'd heard from respected colleagues who I had known for many, many years, including Peter Levine and C. Breederveld that they had serious concerns about seroconversion of patients as a result of using this dry-heated product.

Q. Yes.
A. Now, because that had not been published and was not in the public domain, although the words Armour were used, they were not used by me in the public domain at that time. And all this evidence here is what I sent to the Committee of Safety of Medicines. The Armour product which appears under Dr. Koerper was not mentioned by me at the conference; the three cases from Dr. Levine were. And from memory, one of those was an Armour case. And I'm constrained in my evidence, as you know, but I know that one of those cases was subsequently proved to be an Armour case.

Q. I know, but -- all right. I'm just interested, at the time you had no difficulty in identifying the Armour as being the product involved in the Breederveld case?
A. No, none at all.

Q. Yes. But you don't identify it as the product involved in any of the three cases referred to by Dr. Levine?
A. No, because there was dispute at that time about what products the particular patient concerned had been taking.

Q. I see.
A. And I think, from memory, that my knowledge was there was several products, whereas the -- including Armour, whereas the Breederveld case was only Armour.

Q. Yes. Well, I mean, I understand the distinction then that you are making. The next entry is under the heading "Evidence about seropositivity: Virus detected in material subjected to heating for less than 34 hours; one product said to cause seroconversion." The source of that information -- the product involved was said to be Armour. The source of the information is Dr. Koerper, University of California, also quoting work of Dr. Levy in December of '85?

A. Yes. I told you yesterday that I visited California. I had met these people, and the first suspicion that there might be something wrong came to me in that -- in the course of that visit.

Q. Yes.
A. And then later Dr. Levy published his letter, which we went through yesterday.

Q. Yes. Well, you refer there to your source of information being Dr. Koerper, referring to work of Dr. Levy in December of 1985?
A. Yes.

Q. So, I thought you said to me you went to California and became suspicious, and then those suspicions were confirmed by publication by Dr. Levy in the middle of 1985?
A. He had published, but from memory I was in California in the early part of 1985, but the -- before the publication people were talking about the effect of heat and solvent/detergent and beta-propiolactone and UV light on the virus. And there were questions being raised about how long these particular methods should be used and what side effects could possibly occur as a result of the methods.

Q. Yes. But do you not identify here the source of information as being December of 1985?
A. No. She quoted Dr. Levy, of December 1985.

Q. Well, I just want to be clear, Dr. Jones: If that was the case would it not suggest that that communication is made to you after December of 1985?
A. No. That knowledge was with me in 1985. Now, I can't place the exact time of it, but I think that this quote here, Dr. Levy is quoting him in December 1985.

Q. I see.
A. I'm sorry I can't be more specific at this time.

Q. No, it's all right. And I think that piece of information was not referred to in your paper at Newcastle --
A. No, it wasn't.

Q. -- isn't that correct?
A. That's correct.

Q. Yes. Now, the next entry is haemophiliac without other risk factors treated at Chapel Hill and was reported as seroconversion after heat-treated material. The product is identified as Hyland and it's -- the source of information is identified as reported to Professor Mannucci in February of 1986?
A. Yes.

Q. Now, we will be seeing in a moment a publication in The Lancet by White and others of a seroconversion in a patient, which I think was a patient treated at Chapel Hill, is that correct?
A. That's correct.

Q. And is that in fact the same --
A. I believe now -- I believe now with hindsight that that case is one of the Levine cases. And is the North Carolina patient who seroconverted after Armour heat-treated material. But at the time, as I set out here, this was my state of knowledge when I gave my paper. And the Hyland material was the one that had been questioned.

Q. Just so we be clear: This reference here, the reference to Hyland, that's not a reference to the patient who was subsequently published by White?
A. If Hyland material was concerned with that, it was Armour material that was involved with the White case, but the North Carolina case was Chapel Hill.

Q. And so is the White case the North Carolina case?
A. The White case is the North Carolina /Chapel Hill case.

Q. That's just what I'm wondering: Is that, in fact, this piece of information here, is that referring to the same case, the case at Chapel Hill or North Carolina that was subsequently reported by White?
A. I believe that that is, yes, and I believe it was also one of the cases that Peter Levine told me about.

Q. Yes. So at the time the reference to Hyland, the -- the subsequent publication that we see, we will see in a minute in The Lancet, would indicate that that information wasn't correct?
A. That's correct.

Q. That, in fact, it was -- Armour was the product involved?
A. It's not correct; Armour was the product involved, yes.

Q. Yes. Fine. Now, the last -- of course, again, this particular case was not referred to by you in your --
A. No.

Q. -- paper?
A. Well, it was in the relationship to Peter Levine.

Q. Oh, yes. So -- all right. So, in fact, if it's the case that that was one of the cases referred to by Dr. Levine, then obviously this wouldn't be an additional case, that would also be there?
A. I think that's the probable case of Peter Levine's.

Q. I see. I see. Now, and then the last entry is: "Seroconversions in the FDR were also reported to a meeting of the haemophilia society in November of 1985." And your source of information for that was Dr. Watters, the coordinator of the Haemophilia Society in London?
A. Yes, Mr. Watters.

Q. Sorry, Mr. Watters. And the -- the time of the information was February of 1986?
A. That's correct. The conference was organised by us in conjunction with the Haemophilia Society and the Department of Health and Social Security of the United

Kingdom. And David Watters was at the conference and he told me that there were worries expressed at one of his meetings.

Q. Worries expressed?
A. Worries expressed that there were cases in the medical Democratic Republic, Germany, at that time; that there had been seroconversions on heat-treated material. But because, again, this was so nebulous --

Q. Yes.
A. -- and Mr. Watters - a colleague and friend but not a medical man --

Q. Yes.
A. -- because of that, I didn't mention those in my paper.

Q. Yes. Fine. Thank you, Dr. Jones. Now, I think your -- the conference was reported in a journal called The New Scientist on the 20th of February of 1986, is that correct?
A. It is correct, yes.

Q. And the report is contained at page 35. How would you characterise the journal, The New Scientist, Dr. Jones?
A. It's a well-respected journal, referred to by scientists of any nature. It's written in a style which is easy to read and is a reputable publication.

Q. I see. And if we could just look at some aspects of the report of the conference; obviously particularly the matters relating to your paper, Dr. Jones. I think if we look at the first column, having made some introductory matters, the third paragraph from the end of the first column: "In addition to this, scientists fear that blood products used to treat the haemophiliac population may not be entirely safe, putting such people at risk of contracting AIDS. The fears rest on growing evidence that the heat treatment used to kill the virus in infected blood products is not always effective." So that was a reference I think to your paper, is that correct?
A. It was, yes.

Q. Yes. Now, and -- they go on then in the next column, in the second column, in the middle of the second paragraph, where they have referred to a delay in the manifestation of antibodies in a person who becomes infected. "This delay in producing a positive result in a blood test could account for the allegations made last week that heat treatment of blood products to kill the AIDS virus may not always work. Peter Jones, the director of the Regional Haemophilia Centre in Newcastle-upon-Tyne, said that there are four possible instances of haemophilia patients producing antibodies to AIDS after receiving heat-treated Factor VIII, the blood clotting agent which haemophiliacs are unable to make. Three of the cases have occurred in the US, he said. "The fourth case which occurred in the Netherlands is the strongest to support the idea that the AIDS virus may be able to survive heat treatment, Jones said. This particular haemophiliac, who is not in any of the other risk groups for contracting AIDS, was antibody negative for a year after he was given heat-treated Factor VIII. He was later tested again and found to be antibody positive, showing that he had come into contact with the AIDS virus. The crucial question is

when." Then I think they go on to deal with the reaction at the conference to your paper, Dr. Jones, isn't that correct?
A. Yes, that's correct.

Q. They say: "After Jones had presented doubts about the efficacy of the heat treatment process, virologists and immunologists questioned whether the haemophiliacs in question could not have already been infected with the AIDS virus. Richard Tedder, Consultant Virologist from the Middlesex Hospital in London, said that the incubation period between infection with the AIDS virus and the creation of AIDS antibodies could be longer than a year. "However, Paul Volberding, who has treated hundreds of AIDS patients at the San Francisco General Hospital, says that the incubation period was between one and two months and 'less than six months in all cases'. "Acheson told the conference that, in 1983, 'the bombshell dropped on us' as it became apparent that the AIDS virus could infect blood products.' now that all Factor VIII used in Britain is heat-treated, he said, this risk has ceased. Acheson was quick to deny Jones' claim that Factor VIII is unsafe. Jones was 'premature' in his statement, he said." Who was Acheson?
A. Donald Acheson was our Chief Medical Officer, and he was at the conference.

Q. Sorry, Chief Medical Officer?
A. For the United Kingdom government.

Q. Yes.
A. Well, for -- to be precise, Mr. Finlay, the Chief Medical Officer for England and Wales.

Q. Yes. And is that a fair summary of the reaction which there was to your paper at the conference?
A. It's a very fair summary, yes.

Q. I see. The article goes on then to deal with the dry treatment and wet heat treatment in the next paragraph, and then it goes on to say: "The length of time and the temperature at which the Factor VIII is kept can vary among the organisations that prepare Factor VIII. Britain's own Blood Products Laboratory at Elstree in Hertfordshire heats the protein in the dry state at 80 degrees Celsius for 72 hours. The laboratory advises medical workers that heating at 68 degrees Centigrade for 72 hours will destroy the AIDS virus, but, it adds, 'this remains to be confirmed by prospective studies'. The laboratory warns that blood concentrate'cannot be assumed to be free from viral infection' even when heated at 80 degrees Centigrade." Then it goes on to deal with self-sufficiency. And then in the next paragraph: "About 60 percent of the Factor VIII that Britain uses is imported from the US. It companies from companies such as Alpha, Cutter Biological and Armour. "Armour heats its Factor VIII in the dry state for 30 hours at 60 degrees Centigrade, far less than Elstree recommends as safe. Cutter Biological heat the protein in the dry state but for 72 hours at 78 -- "
A. "68".

Q. Sorry, "68 degrees Centigrade. The problem of lengthening the time and increasing the temperature is that more and more of the final product is lost. "Tedder claimed that the virusis 'certainly not a sturdy beast'. He said that the protein envelope that surrounds it is not strong enough to withstand trauma, such as being

heated at high temperatures for long hours." So the -- the quote from Elstree was to the effect that heating at 68 degrees Centigrade for 72 hours would destroy the AIDS virus, but that that required to be proved by prospective studies, isn't that correct?
A. Well, prospective studies are what we referred to yesterday, and the vernacular proof of the pudding is when patients become infected.

Q. Yes.
A. And the state of knowledge at that time, which was not in the public arena, was there were question marks being raised about the safety of the heating process; and particularly with regard to heat that wasn't being applied in either high enough a temperature or for long enough, and that was the Armour product. So these doubts that have been expressed here are doubts being expressed by other people with the Armour product.

Q. Yes. But just to identify what is being said: The article attributes to Elstree a statement that "heating at 68 degrees Centigrade for 72 hours would destroy the AIDS virus."
A. Yes.

Q. Subject to the rider "it remains to be confirmed in prospective studies"?
A. Yes.

Q. Isn't that correct?
A. Yes.

Q. And then the article, towards the end of the page, the author of the article comments that the Armour system of 30 hours at 60 degrees Centigrade is far less than Elstree recommends as safe.
A. Yes.

Q. That appears to be a comment by the authors of the article?
A. Yes.

Q. You would agree?
A. Yes, I would.

Q. It doesn't appear, certainly from the way in which the article is published, that Elstree were asked specifically to comment on that particular method of heat treatment?
A. Well, I can't really comment on that because I'm not the author of the article.

Q. No.
A. That is what it appears, yes.

Q. Yes. Now, I appreciate that, Dr. Jones. Now, I think, Dr. Jones, did you receive a letter from Armour of the 13th of March of 1986 that appears at page 37 of the book of documents?
A. Yes, I did.

Q. I think if we look at page 38, at the very last sentence of the letter, it says: "I am sending this letter to UK haemophilia centre directors who are likely to have used factorate in the preceding 12 months."
A. Yes.

Q. And I presume from that, Dr. Jones, one can infer, and you would have been aware, that that was a standard letter which was being sent to all relevant --
A. It was.

Q. -- directors at the time?
A. It was, yes.

Q. Yes. Now, the Tribunal has already been referred to this letter - not the copy of it addressed to yourself, Dr. Jones - but has been referred to the letter in another context, and is aware of its contents. Do you want to comment on any particular aspect of it?
A. Yes. I would like to, if I may.

Q. Yes.
A. To start off with, this letter comes from Dr. Harris, who was employed by Armour in the United Kingdom. And we knew him and we knew the other employees of Armour in the United Kingdom who subsequently and -- before this letter had actually written to us about the problem --

Q. Yes.
A. -- including Chris Bishop and Robert Christie. Harris was the doctor concerned. And the first thing I'd like to comment on with the letter is they are referring again to log kill, and setting out their evidence on log kill as a suggestion that that made the evidence -- the evidence made the product safe.

Q. Yes. I think you have already told us, Dr. Jones that you had -- you had views in relation to log kill and how reliable it was as an indicator of safety?
A. That's right. So this didn't mean very much to me. I mean, it didn't say to me that 'this evidence is watertight; the product is safe because of the evidence that he's given.'

Q. Yes. Would that view, Dr. Jones, that you had as to the lack of cogency of log kill evidence in terms of the safety of a product, would that have been a view which was shared by your colleagues at the time?
A. Oh, yes. Yes. We debated this several times.

Q. And do you -- in your recollection, would that have been a consensus view, a majority view amongst your colleagues?
A. Yes. I think it was the best that we had, because you will see in the fourth paragraph, in the last sentence in which Harris says: "Finally, live HTLV-III virus has never been isolated from heat-treated factorate." At that stage it had never been isolated from anything that we knew of. There was no published work at all, and yet we knew the live virus was there, because of the epidemiological studies that were being performed. And so a lot of this I regarded, and my colleagues regarded, as - if I may put it, again, in the vernacular - pseudoscience. We were much more concerned

with looking at what was happening in the patients, in the patient cohorts for which we had responsibility. And again, we come back to the proof of the pudding. So, the -- the science we thought was inadequate, and this was discussed ad nauseam at meetings and between colleagues.

Q. I see. And do you know, would that view have been in relation to log kill; would that -- do you know would that have been, that suspicion of log kill, would that have been a view that would have been held by virologists and fractionators?
A. I discussed it with virologists and fractionators. AIDS -- if I can just digress for a moment, because I think it might help the Tribunal: As haemophilia centre treaters, we were not, until AIDS, fully conversant with all the work of virologists --

Q. Yes.
A. - true, we knew about hepatitis -- or immunologists, so we were on a very steep learning curve --

Q. Yes.
A. -- at the beginning of the 1980s. And virology and immunology impacted on us very severely. And one of the ways of course of dealing with a steep learning curving is to talk to colleagues, and we did that daily during the early years.

Q. Yes.
A. And there was the doubt expressed: If you turn it around and you look at log kill experiments, they don't achieve an arbitrary standard which was set at either five or six logs, within all the evidence the Tribunal has seen.

Q. Yes.
A. Then that raises the suspicion even further, and I think that within the evidence is the work of Dr. Prince. And the Tribunal have heard from Dr. Prince.

Q. Yes.
A. And so, that evidence raises suspicion even more that we are dealing with unsafe material.

Q. But I just don't quite follow this, because if you don't regard evidence about log kill as being relevant in terms of considering safety of a product, then how is it relevant if the evidence of the log kill seems to be inadequate; if it's not a reliable indicator of whether or not there is safety in the product?
A. I think that it's a measure, and, as I have said, it's an arbitrary measure. The scientists using log kill set a cut-off which is five or six logs, depending on the literature you use. And they said that if you could kill that amount of virus in the material, spiked virus in the material, then they regarded the product as safe.

Q. Yes.
A. However, if you -- if you take the converse: If you had products in which it was clear that the virus was not being killed to that extent --

Q. Yes?
A. -- then it made it unsafe --

Q. I think I can follow that.
A. -- in relation to the general adoption of heat-treated product at the end of 1984.

Q. On the recommendation essentially, I think you said, of the CDC, is that correct?
A. It was CDC. It was the medical and scientific committee of the National Haemophilia Foundation in America.

Q. Yes. Wasn't the basis of that the work which was done in the autumn of 1984 under or in conjunction with the CDC, which showed a capacity of heat treatment to destroy some of the newly identified HIV virus, and in effect, showed an element of log kill of HIV virus?
A. Yes, that's true. But it was a consensus and it wasn't -- if you read the MASAC article, you will see that they are not making a strong recommendation; they are -- they are saying that we do not have the evidence, but we have sufficient evidence to suggest that, et cetera, et cetera, et cetera.

Q. Yes, I understand. But just the basis for that evidence was essentially log kill, isn't that correct? There was no --
A. Well, of course. That was all we had, except for the epidemiological evidence.

Q. Yes.
A. And the epidemiological evidence was evolving, which was why, at that time, I felt it so important that if patients appeared to be seroconverting, colleagues who were treating patients with haemophilia should know that.

Q. Absolutely. Yes. One can understand that. To return to the Armour letter, Dr. Jones, I think that in effect referred to the fact that there might be product which hadn't been -- made from donors who had been screened in the possession of persons in the United Kingdom, isn't that correct?
A. That is correct. In the final paragraph on page 37 --

Q. Yes.
A. -- "Our typical donor is a multiple visitor and undergoes thorough medical examination and follow-up". And each donation is now specifically screened; in other words, the antibody test is being applied.

Q. Yes.
A. There was debate about whether in fact the product, by the time it came through to the treaters, was from individually tested donors. And that was referred to in correspondence which I know has been disclosed to the Tribunal already.

Q. Yes. But there is a specific reference in this letter from Armour at page 38 to the fact that -- although what the letter is saying, that donors who were then donating to Armour were being individually screened for HIV - at the top of page 38 - "However, it should not be overlooked that there might be material in centres or in the home that is not derived from donors tested for antiHTLV-III"?
A. Yes.

Q. In other words product that would already have been issued, isn't that correct?
A. Yes, that's right.

Q. And --
A. And they are asking if that material is there. And that, again, led me to wonder why on earth should a company who were at great pains at this stage to stress that their product was safe --

Q. Yes.
A. -- be worried about material that hadn't been individually donor tested.

Q. Yes.
A. It could only be worried if they recognised that the barriers, the first two barriers we described again yesterday - donor exclusion and donor testing - once those had gone, the only barrier remaining was their heat treatment. And if they were so sure their heat treatment was efficacious, then why were they bothering to worry everybody about the fact that there was none individually donor tested material still out in the marketplace.

Q. Yes. And I think arising out of that concern, Dr. Jones, did you write, again, to the medical assessor on the Committee of Safety of Medicines on the 17th of March of 1986?
A. I did.

Q. Which appears at page 39?
A. Yes.

Q. And what you say in the first paragraph is that: "It would appear from Dr. Harris's letter that, contrary to an earlier statement made by a representative of the company, Factor VIII concentrate which has not been individually donor tested for antiHTLV-III is still in circulation in the United Kingdom."
A. Yes.

Q. You go on I think to deal with the questions about, in the next paragraph: "Dr. Harris has kindly given details of the heat inactivation process and its efficiency in vitro, but the fact that he is now looking to recall material that has not been individually donor tested implies that he too is aware that there may still be in vivo risk of seroconversion. We are still seeing fluctuations in liver function tests of the type associated with non-A non-B Hepatitis (which may indicate retroviral infection) in our patients, despite the use of heat-treated material."You go on to say: "I understand fully the difficulty of taking action in this 'grey' area, but given this further piece of information, and despite the obvious worry it may give to some patients, urge that any material which has not been, A, collected in low-risk areas; B, individually donor tested; and C, heat-treated in a manner approved by the Committee on Safety of Medicines, be withheld, at the very least, from seronegative people."
A. Yes.

Q. Now, were those recommendations made by you, were they adopted at the time?
A. In March of 1986, no, they were not adopted.

Q. Yes. And what was the -- what was the practice amongst treating doctors, do you know, at that time in the United Kingdom in relation to this Armour product in particular?
A. There was concern. We are in -- I refer to it as the "'grey' area" in this letter in the final paragraph.

Q. Yes.
A. I, as I think I have made clear, Mr. Finlay, was in touch with people who I trusted for many years and were looking after patients with haemophilia --

Q. Yes.
A. -- in other countries.

Q. Yes.
A. My concern arose from these probable seroconversions.

Q. Yes.
A. Now, I transmitted that concern in my paper at the AIDS conference. And I showed to all my colleagues the publication and the details which I had, and I also told all the regulatory authorities of the evidence that I had.

Q. Yes.
A. Now, the regulatory authorities chose at that time -- and again, as I have said in evidence, I don't know what other information they had, because it's secret. But they chose at that time to continue their surveillance but not to act as I wished them to act and say that seronegative people should not be treated with the Armour product --

Q. Yes.
A. -- until October of 1986, when the two boys in Birmingham were shown to have seroconverted as a direct result of using this material.

Q. Very well. So that is the regulatory authorities, and I think that's clear?
A. Yes.

Q. Now, what I wanted to know, Dr. Jones, if you are in a position to assist the Tribunal with this evidence: What was the practice amongst treating doctors in the United Kingdom about the use of this Armour dry heat-treated product at this time? First of all in March of 1986, were there treating doctors in the United Kingdom who were continuing to use the Armour product?
A. Well, my knowledge is that Birmingham was, and that's how the two boys became infected. But I cannot tell the Tribunal of which doctors withdrew and which doctors didn't. We certainly stopped using Armour material.

Q. I understand that. It does seem, as you say, it's perfectly clear there were some doctors who continued to use the Armour heat-treated product?
A. I think they did, yes.

Q. And what I was wondering is whether you are in a position to assist the Tribunal as to how many or what proportion of doctors --

A. No. People queried, and it was discussed, and it went on being discussed throughout the year.

Q. I see.
A. But effectively, Mr. Finlay, I'd blown a whistle. And whether people respond to the whistle is a matter of individual choice.

Q. Yes. I understand that clearly, Dr. Jones. Now, you then -- sorry, if we can come to I think -- I think there was a -- there was a publication in The Lancet of the White case, if I might refer to it in that way, at page 13 of the book of documents. And this is The Lancet of the 15th of March of 1986, isn't that correct?
A. That is correct.

Q. And this is a publication by Gilbert White and others from the University of North Carolina, Chapel Hill, North Carolina, isn't that correct?
A. Yes.

Q. And essentially it is setting out information about an individual person with haemophilia who seroconverted, isn't that correct?
A. Yes.

Q. I mean, the first is introductory. And just at the same time, since it sets the context for the article: "Patients with haemophilia are at high risk of HTLV-III infection and AIDS from contaminated clotting factor concentrates. Although HTLV-III has not been demonstrated in these concentrates, the prevalence of HTLV-III antibody in haemophilic patients is high. On the basis of the known sensitivity of HTLV-III to heat, and of studies demonstrating inactivation of HTLV-III in spiked concentrates" -- and there are references given then -- "the Centres for Disease Control and the Medical and Scientific Advisory Council of the National Haemophilia Foundation in the United States have recommended the preferential use of heat-treated Factor VIII preparations over cryoprecipitate, plasma or nonheat-treated materials. Preliminary studies have revealed an absence of HTLV-III seroconversion in previously untreated patients receiving heat-treat products. "They give the references for those studies. "However, these studies have been done on small numbers of patients; some have had mild or moderate disease and their infrequent treatment may not have resulted in a sufficiently heavy inoculum of surviving virus to induce seroconversion. We report here a case of HTLV-III seroconversion in a mild haemophiliac after administration of high doses of heat-treated Factor VIII concentrate," isn't that correct?
A. That's correct.

Q. Yes. Now, the actual facts concerning the person involved is set out in the next paragraph: "A 31-year-old man with mild Haemophilia A was transferred to the emergency room at in his left leg and an acute compartment syndrome. He had been treated with cryoprecipitate in his youth, but had not had plasma, cryoprecipitate or other blood products since 1975. He admitted to previous drug abuse, including intravenous drugs, but denied use of intravenous drugs in the previous seven years. He had no other risk factors for AIDS." So, first of all, he had had no blood products since 1975, isn't that correct?
A. That's what they say, yes.

Q. And obviously the relevance of the other references to his drug abuse and to any other risk factor for AIDS was in order to consider the possibility or to exclude the possibility that there was some independent source of his AIDS --
A. Yes.

Q. -- isn't that correct?
A. And the known risk factors in those days were intra -- included intravenous drug abuse.

Q. Yes. That would have been a recognised risk factor --
A. Yes.

Q. -- for HIV?
A. And the other risk factor was of course male homosexuality, and that is referred to in the last sentence.

Q. Yes. Now, they then go on to deal in some scientific detail with the testing which had been carried out in respect of this patient. But in summary, Dr. Jones, would it be correct to say that what their testing showed was: A sample taken on the 5th of August of 1985 was positive on the Western Blot test?
A. I have lost you, excuse me. I have lost the actual reference in the letter.

Q. Well, it's rather dense. If we come down to the -- the page, it's at page 14. And if we go down to the end of the first column, in the text, if we look in the middle of the first column: "Specific antibody was only apparent in the last blood sample (August 8) and this sample showed reactivity to both the recombinant envelope peptide," et cetera. But I mean, I don't think this is a matter of any controversy. The unfortunate patient, it was --
A. Was positive, yes.

Q. And I don't think anything turns on that. So we can sort of skip the scientific detail of how they -- how they ascertained that.
A. Yes.

Q. Now, they do, however, then go on to discuss the seroconversion of the patient in the last two paragraphs of the letter, isn't that correct?
A. They do.

Q. And they say at the bottom of the first column at page 14: "While the seroconversion encountered in this case appears to represent a specific immune response against HTLV-III antigens, the significance of this response is uncertain. Although a single attempt to detect live virus in the patient's lymphocytes at the time he was seropositive, it was unsuccessful, the possibility remains that, in this case, heat treatment failed to inactivate virus and immunity was in response to infectious virus. The finding of an inverted T4/T8 ratio at the time seroconversion was first noted, suggests live virus transmission. Also, the febrile illness 25 days post-operatively could have been acute HTLV-III infection." Now, if we might just stop there. That would in effect be reporting that this unfortunate patient was infected with live HIV virus, isn't that correct?

A. Yes, that is correct.

Q. The possibility referred to there?
A. Yes.

Q. And had developed antibodies and was therefore unfortunately infected with HIV?
A. Yes.

Q. His immune system was showing that infection?
A. Yes.

Q. Then they go on in their article and they refer to that as a possibility in this letter. But then they go on to refer to a number of other hypotheses, isn't that correct, Dr. Jones?
A. Yes.

Q. "Another possibility is that inactive virus or viral fragments provoked the immune response. If viral material is present in concentrates, heat treatment might inactivate virus, but viral antigen might still be present in amounts sufficient to elicit an immune response. Seroconversion in this case would not signify exposure to active virus." I don't quite follow that hypothesis.
A. There was debate continuing at that time about whether all our patients who were proving to be antibody positive had in fact been infected; in other words, whether the antibody test truly reflected a disease process which was active. And that was one of the arguments that led to the suggestion that infection -- or the positive antibody test might not signify a long-term risk of developing AIDS.

Q. I see. But --
A. That's what they are referring to here.

Q. Yes. What they seem to be referring to, though, is the possibility that heat treatment might have inactivated the virus, but that in some way there might still have been a level of antigen which provoked antibodies but not infection?
A. Yes. That was, again, part of the argument. The materials that we were injecting at that time contained far more than the Factor VIII; in fact, Factor VIII was a trace protein within the material.

Q. Yes.
A. And there were a lot of suggestions at the time, and a lot of work was done to try to determine whether the bombardment of people with haemophilia with these materials over a period of time altered their immune systems to the extent that they would eventually develop disease. And there was even debate about whether the disease that we might see as a result of that might be a mimic of AIDS, might be a different condition altogether. So --

Q. But -- I mean, with respect, Dr. Jones: I don't think that -- I'm familiar with that line of discussion, but I don't think that's what is being suggested in the sentence we have just read. It doesn't seem to be suggesting that there might have been a general interference with the immune system of the patient as a result of receiving proteins or

products. But what they seem to be suggesting is that the possibility that although there were antibodies present, that the patient might not have been infected; because in some way the virus had been inactivated by heat treatment?
A. Yes. Sorry. I have taken you on too far I think in my supposition.

Q. Yes.
A. The -- what they are suggesting is that the virus itself, the protein of the virus has stimulated the immune response in the patient, and yet the virus was dead.

Q. Yes. That's what they are suggesting?
A. Yes.

Q. They go on to give another hypothesis: "Another possibility is passive transfer of HTLV-III antibody." So what I would understand by that: The suggestion is that although the concentrate given to the patient didn't contain a virus, it might have contained antibodies?
A. Yes.

Q. And that the transfer of the antibodies into the patient's system then resulted in a positive antibody test, but again, no exposure to infection?
A. Yes, passive transfer.

Q. Yes. That's what is being suggested there. And then: "A final possibility is that the patient acquired HTLV-III through intravenous drug use despite his denial of current activity. More recent specimens are not available. We have lost touch with this patient." They mention that hypothesis again?
A. Yes.

Q. Yes. And then they conclude by saying: "This case illustrates the need for further studies of heat-treated Factor VIII and Factor IX concentrates with the aim of determining, as rapidly as possible, how frequently HTLV-III seroconversion occurs after administration of heat-treated product, and whether seroconversion reflects a response to live or attenuated virus. The urgency of these studies is obvious in view of the need to make reliable recommendations for safe treatment of haemophilic patients."
A. I totally agree.

Q. Yes. The authors do seem to have been at pains to, as it were, avoid the obvious conclusion that this was seroconversion following the use of a heat-treated product; would that be a fair comment?
A. That's a perfectly fair comment. They were conducting whether -- all -- the science of the time and they were trying to apply it and trying to think of the various ways in which this patient could become infected.

Q. Yes. And of course, the article doesn't either mention the product or the protocol of the heat treatment used?
A. That's right.

Q. Now, I think if we return to page 40, Dr. Jones. There was a letter, an individual letter that you wrote to Dr. Evans, who was a colleague, consultant haematologist in the Royal Manchester Children's Hospital on the 20th of March --
A. Yes.

Q. -- isn't that correct?
A. That's correct.

Q. And presumably it refers to his letter of the 25th of February, you having met him at the conference. And you thank him for his kind remarks. You go on to say: "More information about heat treatment and its efficacy is beginning to emerge. The really worrying thing to me is that there is evidence that there are still concentrates being used which have been derived from plasma which has not been individually donor tested. This I know to be true of the Armour product, but I suspect that it might also be true of other commercial concentrates as well. As you know, all the evidence about the safety of heat treatment has, because of the time lag, to depend on in vitro testing of spiked material. The handful of cases in which seroconversion might have occurred may or may not grow. My argument is that we do not have time to wait for this epidemiological evidence and should be making sure that the material we use is covered by the only three methods that we have of trying to screen out the retrovirus. I think that this is particularly important because there is still evidence of non-A non-B Hepatitis despite heat treatment, and there is a school of thought that one of the agents for non-A non-B Hepatitis is a retrovirus. The three precautions are that plasma is only drawn in populations with a low incidence of HTLV-III; the individual donations are tested; and that the best method of heat treatment is employed. Details from the various firms were published in The New Scientist the week after the conference, together with a comment from BPL that they considered the Armour material, which is only heated for 30 hours, as being unsafe." I think that last comment, Dr. Jones, would be to draw two pieces of information together - in that article, rather: I mean, BPL didn't directly comment on the Armour product?
A. Yes, that is drawn together.

Q. "I have sent all the information that I have to the Committee on Safety of Medicines. At present in Newcastle I am prescribing anti-HTLV-III tested cryo for the children, or FFP in the case of Factor IX minor bleeds and NHS 8Y for everybody else. Sparse stocks will allow. The only commercial product I'm using is the Alpha Profilate, and this solely on the basis of their non-A non-B evidence." So at that stage, Dr. Jones, you said that you were prescribing anti-HTLV-III tested cryo for children and FFP?
A. Fresh frozen plasma.

Q. Fresh frozen plasma. Was that a change in your practice or --
A. No, we had been prescribing cryoprecipitate for the children from the first doubts about the infection. And so all the children were on cryo. And the only change that we made from that policy was when children went on to home therapy. And cryoprecipitate, the cryoprecipitate in Newcastle was wet cryoprecipitate. It had to be stored in a deep freeze. I believe in Ireland you had dry, dried cryoprecipitate.

Q. Yes.

A. And so, it was an inconvenient material for home therapy, and we put the children on to concentrates when they went on to home therapy, at the age of about six, usually. But this was policy right from the beginning of the worries there were about AIDS, and indeed, it was policy before that because of the hepatitis problems as well.

Q. I see. Did that survive; did that policy of using cryoprecipitate, did that -- did you use cryoprecipitate for children between the beginning of 1985 and, say, the end of 1985?
A. Yes, I believe we did.

Q. Even though it wouldn't have been individually donor tested; couldn't have been at that time?
A. We were using cryoprecipitate from much further back than that.

Q. I know, I understand that.
A. I can't tell you when we stopped using it. I haven't got that data with me. I could find it out if the Tribunal wished me to. But whilst there was concern about transmission, we preferred to use our individually donor tested cryoprecipitate for the children.

Q. Yes. But what I'm asking you about is that I think the Tribunal would be aware that there wasn't, widely, testing for HIV antibodies in the United Kingdom until October of 1985?
A. We were testing from February, I believe -- no, May of 1985 we got testing in Newcastle.

Q. And so whose -- who is the "we"; I mean, in the sense --
A. In the centre we had individual -- we had the testing available, and I think this has already been referred to in our article: Dr. Codd of the Public Health Laboratory Service --

Q. Yes.
A. -- was setting up the test. The Blood Transfusion Service in Newcastle were capable of testing in May of 1985. The Blood Transfusion Service in the United Kingdom as a whole started in September of 1985.

Q. When you say that the Blood Transfusion Service in Newcastle was capable of testing from May, did it in fact test from May?
A. My memory was that individual testing of cryoprecipitate started in May of 1985.

Q. I see.
A. Whether they tested everybody I can't tell you.

Q. Yes. Well then, therefore, I mean, the point remains the same, though. What I'm asking you about is this, then, Dr. Jones, if you can recall: You mention to us that you changed all your patients to heat-treated product at the beginning -- at the end of 1984/beginning of 1985 --
A. Yes.

Q. -- isn't that correct?
A. Yes.

Q. And what I'm wondering is: So therefore, if we take the -- the tested cryo became available from say May or June of 1985. There is an interregnum between the end of '84 --
A. I understand the difficulty. As we developed a test in Newcastle and started to apply it to my patients and to the blood products, yes, there was a gap.

Q. Yes.
A. But the -- the strong recommendation in the United Kingdom for some years had been that the little children, the ones who couldn't go on home therapy because it was too early for the teaching and all the techniques that were involved, be treated with cryoprecipitate from volunteer donors. And that was still, as this letter shows, what we were doing at this particular time. And we must, by March, as the letter shows, we must have been testing the individual --

Q. This is March of 1986, Dr. Jones, this letter?
A. Oh, I see what you are coming from. Yes.

Q. And perfectly clearly by then tested cryo is available?
A. Yes. We went on with the tested cryo for the children.

Q. All right. What I was asking you, if you can recall, I don't know if you are in a position to assist the Tribunal on this: In the previous year --
A. I'm sorry, Mr. Finlay. I got muddled up.

Q. Just if we look at it again: At the end of 1984 you told us in general you switched from nonheated material to heated material for your patients?
A. Yes.

Q. And you have also told us that by the middle of 1985, by May or June of 1985, individually donor tested cryo was available?
A. Yes.

Q. So, it wasn't available obviously before that?
A. Yes.

Q. So what I'm wondering is if you can recall what you did for patients who would have been receiving cryo between the end of 1984 and the middle of 1985. I don't know whether --
A. I would have to check that. I can check that easily for the Tribunal, but from memory I honestly can't remember at this stage.

Q. That's fine.
A. I understand exactly what you say to me.

Q. Yes. Now, I think if we could return, Dr. Jones, to the documents. And I think there was a further publication then on the 15th of April, which appears at page 41; another letter to The Lancet.
A. Yes. This the Van den Berg letter.

Q. Yes. And exactly. This is the -- the Van Den Berg letter, but it's also the person who had referred this particular case to you; Dr. Breederveld was also a co-author of the letter?
A. Yes, he was.

Q. And so this letter is, in fact, just to identify it, that is a publication in The Lancet in April of 1986 of the Dutch case, if I might put it that way, which was one of the cases you had referred to in your paper in February --
A. It was. It was.

Q. -- isn't that correct?
A. It was.

Q. Yes. And the information in this letter, we can see the particular facts relating to the individual patient are set out at page 41, after the introductory paragraphs, where it says: "A 27-year-old HTVL-III antibody negative man with severe Haemophilia A, less than one percent, who, since 1983, had been on heat-treated Factor VIII home treatment and prophylaxis, presented in January 1985 with fatigue and slight fever. He had an unexplained lymphadenopathy of at least three months' duration. He had no history of other recent illness, drug abuse, homosexuality or recent visits to Africa or the Caribbean." So this particular patient had been receiving heat-treated Factor VIII since 1983, and what they are saying in the article quite clearly is that there was no other possible or likely source of this infection?
A. Yes. The reference to the Caribbean is because of the high incidence in Haiti at the time.

Q. Yes. And it was found on testing in 1985 that he was unfortunately positive for HIV antibodies. And they refer specifically to the fact that previous tests in 1984, I think -- sorry, spring and summer 1984 had been negative, isn't that correct?
A. That's correct.

Q. And at the next page, page 42, they say: "Thus, seroconversion to antiHTLV-III positivity occurred in a patient using exclusively heat-treated intermediate and high purity Factor VIII concentrate of American origin. According to the manufacturers, one of the donors whose plasma was included in one of the individual batches, which was of intermediate purity, has developed AIDS. All other possible routes of infection were excluded." So, there are no alternative hypothesis or suppositions in this letter; it's very clear in the information that it's presenting, isn't that correct?
A. It's very clear indeed.

Q. Yes. And it is saying that in the opinion of the authors there were no other possible reasons why this unfortunate patient might have become positive?
A. Yes, this is the first time there has been a link with a donor of AIDS and a recipient of AIDS after using a heat-treated concentrate.

Q. Yes. And, of course, this letter doesn't identify the product?
A. No, it doesn't.

Q. But presumably at the time you read the letter -- did you read the letter in April of 1986?
A. Yes.

Q. And you would have been aware at that time, Dr. Jones, that that was in fact -- you would have been aware that that was, in fact, the Armour product?
A. Yes.

Q. From the personal communication you would have had from Dr. Breederveld, isn't that correct?
A. Yes. Yes.

Q. Now, I think in respect of those two publications that we have seen, the earlier White one and that letter didn't refer to the product and didn't refer to the protocol of heat treatment involved, isn't that correct?
A. That's correct.

Q. And that was the subject matter itself of correspondence in The Lancet on the 14th of June of 1986. And one sees that at page 43. Isn't that correct?
A. That's correct, the Rousell letter.

Q. Yes. And in effect, the letter is a letter of complaint from Mr. Rousell who was attached to Cutter Laboratories?
A. Yes. That's what it says, yes.

Q. In effect, what he is saying is that people who report seroconversion of people who are using heat treatment should at least indicate the -- the protocol of heat treatment which has been involved?
A. Yes, I would agree.

Q. Yes. Because what he says in the letter is that heat treatment at a higher temperature and for longer periods could be thought to be more effective than at a lower temperature and for a shorter period?
A. Yes.

Q. And therefore, in effect, obviously he, on behalf of Cutter, who have their own product heated at 68 degrees Centigrade for 72 hours, all heat-treated, is given a bad name if the protocol involved isn't specified?
A. Well, that's true; but also, to go with that, the fact that treaters need to know which product is implicating them.

Q. Yes.
A. Dealing at the bottom of the letter is the addendum from the editor of The Lancet where they have gone out and asked both authors of the previous letters what the heat-treated product was. And in both cases, it's 60 degrees for 30 hours.

Q. Yes.

A. In the lyophilised state, in the dry state.

Q. Yes. And that was the Armour protocol?
A. And that was the Armour protocol.

Q. Yes. Dr. Jones, were you aware at the time of the publication by Dr. Prince of his article about the reservations he had about the dry heat treatment method?
A. Yes, I was.

Q. And I think we see that at page 60. The Tribunal is quite familiar with this article, has heard from Dr. Prince. And what was your reaction from reading that article at the time, Dr. Jones?
A. Well, I knew the work of Dr. Prince and Dr. Horowitz, particularly in relation to their development of solvent/detergent, viral inactivation, from New York. And my reaction to this particular letter was that here was yet another piece of evidence which was emerging that the Armour product could have been unsafe.

Q. Yes.
A. And in the last -- if I could continue, the last sentence is exactly what I have been saying: That the proof of the pudding, again --

Q. That "long-term surveillance of recipients of such products for seroconversion to antiHIV is still required"?
A. Yes.

Q. Yes. I can understand that. I think, Dr. Jones, on the 11th of July of 1986, Armour wrote to UK haemophilia centre directors offering to exchange nontested product for tested product. And a copy of such a letter - not a letter sent to you, but a copy of such a letter, which I think was a standard-form letter - appears at page 61 of the book of documents?
A. Yes. I have that.

Q. Do you know, did you receive that letter at the time?A. Yes. It went to all directors I think; that's my memory of it. And there were copies to the person looking after the -- one of the people looking after the Committee of Safety of Medicine material. Dr. Rotblat.

Q. Yes.
A. I have seen this letter before, certainly.

Q. And then I think subsequently, you mention in your statement, Dr. Jones, that there was a release from Armour on the 6th of October, 1986, in which they -- at page eight of your statement, in which Armour announce that in consultation with the UK Government Departments of Health, it was withdrawing factorate from the UK market --
A. Yes.

Q. -- isn't that correct? And refers to the reported seroconversion of two patients in Birmingham, two haemophiliac patients. It doesn't say Birmingham, but in the UK?
A. Yes.

Q. But I think they were, in fact, the Birmingham patients, as we now know, isn't that correct?
A. That is correct.

Q. And obviously, following that, this Armour dry heat-treated product was withdrawn from the UK?
A. Yes.

Q. Yes. Now, was there some information or rumour circulating about those seroconversions before October of 1986?
A. Yes.

Q. And I think is that referred to in the minutes of a meeting of the AIDS group -- of haemophilia centre directors? If we look at page -- first of all, if we look at page 63 of the book of documents. That was a meeting held on Monday the 22nd of September, 1986, so it's very shortly before the withdrawal on the 6th of October. And in fact, perhaps we better identify that you were unable to be present?
A. Yes.

Q. But you would normally have attended such meetings?
A. Yes, I would.

Q. And I presume would have received these minutes --
A. Yes.

Q. -- subsequently.
A. Yes.

Q. But if we just go to page 67 under: "Seroconversion following treatment with commercial concentrates: The Chairman said that the rumours were rife regarding seroconversions following treatment with commercial concentrates, and he was not sure how strong the evidence was. Dr. Kernoff said he thought it was going a little too far to say the seroconversions were undoubtedly due to commercial concentrates as some of the data were not clear-cut." The entry there, Dr. Jones, would suggest that -- first of all that there were rumours obviously at the time. But the way in which it's noted there in the minutes, regarding "seroconversion following treatment with commercial concentrates," it doesn't seem to have been specific to one particular product, to the Armour product?
A. No, that's what the minute says.

Q. And would that accord with your recollection of the time?
A. No, it wouldn't.

Q. I see.
A. Because this was in --

Q. September?
A. -- September of 1986, and I published that -- the paper at the AIDS conference in February of 1986. And as we have shown this morning, there was subsequently the

letters in The Lancet, so I would have put a different -- given connotation on this if I'd been present at the meeting. The other interesting thing in looking at these minutes is that Dr. Hill wasn't present. And he is the director of the -- at the Birmingham Children's Hospital where the two cases of seroconversion were subsequently reported. So the attendance at this meeting was insufficient perhaps to add strength to that particular discussion.

Q. Yes. And is it your recollection then, Dr. Jones, that the -- the rumours and the sort of reports, informal reports of the possibility of seroconversions that obviously were circulated and are referred to in these minutes, is it your recollection that they would have been specific to Armour?
A. Oh, no. No. We were concerned -- we'd been hit, as the Tribunal is well aware, with a new disease.

Q. Yes.
A. We were trying to follow the best guidelines that we possibly could on how to prevent further transmission of this disease. We were also aware that in doing so, we must keep a very strict surveillance on all the patients, and particularly the people who were seronegative, in order to ensure safety of the product. The scientific evidence, the log kill and all the other scientific evidence, was being regularly evaluated by colleagues.

Q. Yes.
A. And what this paragraph is saying is that the evidence is incomplete. We are coming back to conjecture; we are dealing with a situation in which pieces of evidence are being put together, and the final verdict rested on the surveillance of the patients. Now, if they had known at that stage, at this particular meeting, from Dr. Hill, that two boys had seroconverted, the evidence in that paragraph would have been much stronger.

Q. I understand that, Dr. Jones. But I was asking you something slightly different: It's clear from this paragraph, even in its present form, that there was information there that there were possible seroconversions, or there may have been seroconversions, isn't that correct?
A. That is correct, yes.

Q. But what is certainly not recorded there is that those seroconversions were caused by a particular dry heat-treated product, namely the Armour product?
A. No. That's fair comment, yes.

Q. And what I'm wondering is: Can you help us, from your recollection, as to whether the speculation at that time was that there were seroconversions which may have been caused by a dry heat-treated product without knowing which of them it was; or whether there was specific speculation about -- that the Armour dry heat-treated product had caused these seroconversions?
A. There was --

Q. Do you understand?
A. Yes, I do understand. In looking at the evidence that was then available, one looked at the products that were being treated in whatever way less than other

products. And Armour was the bottom of the pile, if you like, in that they were heating for a short period of time at a low temperature.

Q. I understand that clearly, Dr. Jones, and that might be why you would look at Armour in particular. But I'm asking you something slightly different: If there were rumours or speculation or worries that there had been seroconversions, you could have either of two situations: It could either be seroconversions following the use of a heat-treated product without knowing which heat-treated product; or it could be a specific rumour or worry or concern that there had been seroconversions following the use of the Armour heat-treated product. And what I'm wondering is whether you can help us at this stage in your recollection --
A. My recollection is --

Q. -- as to which it was?
A. My recollection is Armour was the one that people were watching specifically.

Q. I see. That's still not quite what I'm asking you, Dr. Jones. I understand, and you have explained the reason why one might have looked at Armour specifically, but what I'm asking you is specifically in relation to the speculation or rumour or information that there may have been seroconversions, whether that was specifically linked to the Armour product. Do you understand?
A. I do understand what you are telling me. And you put me in a difficult position because I wasn't at this meeting, but my recollection is that people were looking specifically at the Armour product.

Q. I see.
A. But not -- not to the exclusion of every other product.

Q. I see. I see.

MR. FINLAY: Thank you very much, Dr. Jones.

THE CHAIRPERSON: Ms. Murphy?

MS. MURPHY: Just a couple of questions, Madam Chairperson.

THE WITNESS WAS THEN EXAMINED AS FOLLOWS BY MS. MURPHY:

Q. Sorry, yes.
A. Good morning.

Q. Morning. Deirdre Murphy from St. James's Hospital. Just want to clarify some small matters that have arisen on your evidence yesterday. The first one is in relation to the specifications and criteria in relation to comprehensive care. It's at page 2 of your statement. You referred -- you can see at the first paragraph under "comprehensive care," you refer to a health circular on haemophilia first issued in 1974. But I think we are all now agreed that was 1976?
A. We are, yes.

Q. And I think we have a copy of that which was referred to yesterday at page 46 of the documents. I'm not going to go into it in detail, I'm just confirming that.
A. Yes.

Q. And you told us it was updated in 1984?
A. Yes.

Q. We don't have a copy of the 1984 document, but presumably it's available if anybody needs it.
A. It is, yes, and it's quoted from.

Q. This is what I'm coming to. In the next paragraph, you refer to the fact that the most recent circular stated, and you set out what it states?
A. Yes. And that indeed is the second one. That is the 1984 document.

Q. And I am just wondering about that: Has it not been updated since 1984 at all?
A. No, not to my knowledge. I retired last year and it hadn't been updated then.

Q. I am just a little surprised, because the specifications refer to haemostatic disorders as well as haemophilia?
A. Yes.

Q. Which would not have been a concern of haemophilia treatment centres in 1984?
A. Oh, yes.

Q. It was?
A. Yes. We were interested in looking at anyone with bleeding problems.

Q. Coagulation disorders?
A. Yes.

Q. Yes. I see. It also refers to HIV, which would not have been a 1984 term; it was more likely to be HTLV-III, isn't that right?
A. I might have used HIV when I typed this. I would have to go back to the original.

Q. I see. Well, perhaps in due course -- not a major amount turns on it. And it refers to the national external -- UK National External Quality Assessment Scheme?
A. Yes, NEQAS.

Q. When was that set up?
A. Oh, I can't answer that I'm afraid. It's been there for years. This was the -- I referred to it yesterday, when we were talking about this, as the way of monitoring laboratory standards and results.

Q. Yes. Yes, I appreciate that.
A. Dr. Eric Preston, who is going to give evidence, I believe, to the Tribunal would be able to answer that question specifically.

Q. I see. Now, the other area I wanted to canvass with you, just briefly, was the -- under the heading in your statement of "regional services" on page five.
A. Yes, I have that.

Q. You were saying that in the late '90s, the cohort of patients at your centre was 550?
A. Yes.

Q. And that would include people with all sorts of disorders, not merely -- coagulation disorders; not merely haemophilia?
A. And it included carriers as well. And if I could just point out: One of the difficulties in retirement is that one loses your secretary.

Q. I see.
A. Which is a terrible thing to do. And I typed this myself and I misled the Tribunal yesterday in letting you -- in thinking that the population for our region was 1.1 million; it should be 3.1 million.

Q. I see.
A. Which is, of course, in accord with the Irish Republic population.

THE CHAIRPERSON: Thank you.
A. It's my fault entirely.

Q. The cohort in Newcastle would be quite similar to the cohort in the Republic of Ireland?
A. Indeed, yes.

Q. And how many of those would have been haemophiliacs, Dr. Jones?
A. There were 143 multitransfused patients: The majority of them would have had Haemophilia A, of the milds and moderates; and the minority, Haemophilia B. And included in that number were people with von Willebrands disease and some of the minor clotting disorders like Factor V and Factor VII and Factor X and the carriers, both the obligate and the putative (?) carriers of Haemophilia A and B.

Q. Out of that, are you able to tell us, out of that 550, how many would have required treatment, we will say, in the form of concentrates?
A. Yes, 143 were specifically multitransfused patients.

Q. Isn't that the same figure that we had in 1984, of the numbers that were tested in 1985 for infection -- had it not changed?
A. Sorry, I missed the year that you were asking about.

Q. In the late 1990s?
A. Oh, 1990s. Right.

Q. You had 550 according to your statement?
A. Yes. Of those 550, as a round number, 200 /250 would have been people with either Haemophilia A, B or von Willebrands disease; and the majority of those would be moderate or mild. Because of the effect of AIDS on our population, the severely

affected Haemophilia A patients were no longer with us. They are now -- we expected -- to put this into another context: We expected two to three births of somebody with severe haemophilia each year. And so the population is building again.

Q. I see.
A. When you ask about treatment, the minority of those patients would now need concentrates - of the total - and we would be using DDAVP, Desmopressin, for the treatment of all our von Willebrands cases - we didn't have a severe case of von Willebrand - and all the mild and most of the moderately affected patients with Haemophilia A. And we would be using concentrates for the treatment of people with Haemophilia B.

Q. So you are still using blood-based plasma in Newcastle up to the time of your retirement?
A. Up to the time of my retirement. Not everybody was able to go on to recombinant Factor VIII and recombinant Factor IX. And there were two reasons for that: The first unfortunately was cost. And in the United Kingdom, we had a situation of prescription by post code. And in Newcastle we were unfortunate that our health authority at that time could not afford the cost for everybody, but they did agree to putting children on to recombinant Factor VIII. And within the last six months they have agreed that everybody should go on to recombinant Factor VIII and IX. The second problem is that there is a failure of supply of the recombinant products, which has worsened in the last year because one of the companies has had to stop supplying them. But now if supply is possible, then everybody will be on recombinant.

Q. So in that respect, you are a little bit behind the haemophilia treatment centre here in Ireland, isn't that correct?
A. We are, yes, definitely.

Q. And perhaps the -- that is reflected, the figure for a similar period here for product would have been 13 million pounds; and that perhaps is reflected in these figures, is that correct?
A. It is, yes.

Q. Yes.

THE WITNESS WAS THEN EXAMINED AS FOLLOWS BY MR. BRADLEY:

Q. Good morning, Dr. Jones.
A. Morning.

Q. In relation to statistics, and we are talking about -- we have established that the population of your region was 3.1 million. The population of patients attending your centre with haemophilia disorders or blood coagulation disorders in or around 1988 -- period '80 to '85, what was the population at that time?
A. The number of patients?

Q. Patients.

A. I think it's been referred to in the document here. I think it was about 300 to 400, perhaps 450, in round terms.

Q. In terms of the number of patients who became infected with HTLV-III, of that population, what number became infected?
A. Seventy-six patients with Haemophilia A became infected; and none with Haemophilia B.

Q. In terms of the breakdown of the persons who became infected, how many people with mild haemophilia became infected?
A. I don't think we had anybody.

Q. How many children under four became infected?
A. None.

Q. And in relation to those patients that unfortunately became infected with HIV, were there persons with severe haemophilia --
A. Severe Haemophilia A?

Q. -- severe Haemophilia A?
A. We tested 99 at that time, and 76 were positive.

Q. And had you any Haemophilia B patients that became infected?
A. None, and we tested 18.

Q. In respect of the dry treatment regime that you promoted in and around the beginning of 1983 for people with haemophilia, could you tell the Tribunal what was that regime?
A. In 1983, we were aware of the impending problem of AIDS, and we were treating the children with cryoprecipitate which was from volunteer donor plasma prepared for us by the Newcastle Blood Transfusion Service. And that policy, as we have said already this morning, continued; that the children should not be exposed to multi-donor treatment. We were using, as far as possible, National Health Service product, but, having said that, there was not a sufficient National Health Service product available; there was a failure to meet demand.

Q. And yesterday when Mr. Finlay was bringing you through the first article in the booklet of articles, was that -- does that explain why patients received both commercial concentrate and National Health Service concentrate?
A. Almost certainly, yes. We were in a situation where, if the United Kingdom as a whole had been self-sufficient in blood products supply with a good quality and efficacious product, then doctors would have used it; but it wasn't, and never has been.

Q. You mentioned earlier on this morning that that policy of using cryoprecipitate evolved prior to the onset of AIDS, why did it evolve at that time?
A. It evolved --

Q. Prior to that date?
A. It evolved because of concern about hepatitis.

Q. And did you publish on that particular issue at any time?
A. Yes, from memory, a number of different articles in different journals and books.

Q. And what was the concern in relation to hepatitis?
A. Well, the concern stemmed from the beginning of modern haemophilia treatment, in the early 1970s. And there is a publication by Dr. Craske which exemplifies this particular problem in that there was an outbreak of Hepatitis B in Bournemouth which was reported in, I think, 1976, and three -- two or three years after the introduction of commercial concentrates. And we also had an outbreak in Newcastle at that time of, from memory, 16 patients who became jaundiced as a result of treatment. So right from the beginning, we were concerned about hepatitis. And then, of course, vaccination for Hepatitis B became possible. But we were very well aware that we were dealing with what is now known as Hepatitis C as well.

Q. Can I stop you there for a moment. You mentioned the vaccination of patients for Hepatitis B; when was that introduced?
A. I'd have to look that up for you.

Q. Okay.
A. I can't remember the exact date. But as soon as it was introduced, we used it. It was first introduced as a plasma-derived product, and again, there were concerns about what else you might be injecting. And I remember evaluating these concerns and, in fact, I was the first person to be injected with that plasma-derived Hepatitis B vaccine in Newcastle. Later on there was a genetic -- a recombinant product which is now in use and is combined with Hepatitis A vaccine, but in those early days, again, there were concerns about plasma-derived product.

Q. Your options in terms of treatment provision leading to the early stage of 1983 were -- what treatment options were there?
A. At the beginning of 1983, cryoprecipitate.

Q. What form of cryoprecipitate?
A. Wet cryoprecipitate, which had to be kept in a deep-freeze and thawed and pooled in order to be given to the patient; fresh frozen plasma, which -- again, a wet product, which had to be stored in a deep-freeze and thawed and then given to the patient; the National Health Service products, prepared from volunteer donor plasma, sent to Elstree; and the various commercial concentrates which had been licensed for use by the Committee of Safety of Medicines.

Q. Were there any publications in and around the beginning of 1983 that would have impacted upon your treatment options within that width or breadth of treatment options?
A. I would have to look at the statement.

Q. Would you have been aware of the MMWR at the time?
A. We were aware of the MMWR from 1981. Prior to 1981, I'd never heard of MMWR. In 1981, the first cases of AIDS were described in MMWR, and all of us knew about MMWR and kept an eye on MMWR. We had it delivered regularly and we were looking at the question of AIDS. The regular delivery, however, started in

1983, which was after the December 1982 issue which described the case of a baby with platelet disorder or who needed platelets in America who had developed AIDS as a result of blood transfusion. 1983, the first haemophiliacs were identified in the United States as having AIDS. But because we were dealing with a new -- we were watching a new disease emerge, we were aware from 1981 of MMWR.

Q. Okay.
A. I'm sorry to be -- it's my mind is -- as I remember the sequence.

Q. You mentioned Desmopressin in your direct evidence. What was Desmopressin and when was it used?
A. Desmopressin, DDAVP, was first described way before the problem with AIDS. It was a synthetic analog of a naturally-occurring hormone in the body which was found to raise Factor VIII level in people who could already make active Factor VIII. And it was suggested that the use of DDAVP was an alternative to blood products. Unfortunately, the initial investigation of DDAVP showed that it didn't work for very long in people who were given it and it did not -- it didn't get the impetus amongst mildly affected people with haemophilia or von Willebrands Disease until AIDS was upon us. So although it was being used in the late 1970s, it wasn't -- it wasn't specifically prescribed for everybody with mild haemophilia or von Willebrand disease, as it is now.

Q. Okay. So it was the advent of AIDS that resulted in the promotion of that particular treatment option?
A. Yes, but another thing was that it wasn't licensed until recently in the United States of America. So it wasn't available.

Q. Okay. But was it used in the United Kingdom?
A. It was used in the United Kingdom.

Q. Yes. In relation to the period of 1983 and the evolving knowledge pertaining to AIDS, what information would you be furnishing to your patients at that time?
A. Everything that we knew. We had a variety of ways of communicating with the patients: We saw them regularly every three months, as a minimum, for followup; those who, for one reason or another, didn't attend, were followed up anyway - one of the nurses or social workers would go visit them at home. We had regular newsletters for our haemophilia society. We were very fortunate in having a very active local group of the haemophilia society - we were careful not to have a member of staff on that committee; we regarded them as a ginger group who should always be aware they could come to us with any problems or suggestions at any time and ask us to act. We met them regularly at their invitation, and there evolved, over this period, the procedure whereby we had this residential weekend every year where people with haemophilia and their families were invited to come free to a residential weekend in one of the University of Durham colleges, and they would be then given a fairly informal series of talks and then would ask any questions that they wanted in open discussion. And at the beginning -- we had the first of these residential meetings at the beginning of the AIDS epidemic and it was a very, very good way of imparting information and of answering questions, and also, it formed a communal spirit where people with problems were able to discuss between themselves and between the

various members of staff, if necessary in private, all the concerns. It taught us an awful lot. And that continues.

Q. More particularly in relation to treatment options for people with haemophilia who attended your centre, what information would you give a patient in such circumstances in or around 1983?
A. Everything; we always have.

Q. What do you mean by "everything," in relation to treatment options?
A. Everybody was aware of hepatitis and the problems with hepatitis right from the early 1970s. Everybody was aware of how concentrates were chosen for treatment. Everybody was aware that they could read the data sheets that were included with the various products that were available. Everybody was aware why they were being followed up and of the blood tests that were being taken from them. So the patient population, as again we said yesterday, had input at every stage of the choice of product.

Q. Would you sit down and discuss the merits of National Health Service concentrate versus commercial concentrate?
A. Yes.

Q. And what would be the merits -- what would be the likely discussions in such circumstances?
A. Well, before AIDS, the safety of the products was in debate: Whereas self-sufficiency with volunteer donor products sounded as though it would be the best possible option, it was not. And it was promised to us in the early 1970s by the then Secretary of State for Health; it never appeared. So when we looked at the various options, we had to choose licensed products - that is number one - because they had been looked at by the Committee of Safety of Medicines in knowledge which wasn't available to us and still isn't available to us. In other words, they talked directly to manufacturers and saw all the information that the manufacturers saw. So if we ever used products that weren't licensed, that was done on a named patient basis. So our patients were assured, to start off with, that it wasn't simply what we thought, these were products that had been looked at by people who were treating people with haemophilia. And secondly, they were also aware, from the early 1970s, of the problems of commercial products and of commercial donors. And that was exemplified in our particular centre in an early television programme by the World In Action, which looked at donor populations in the United States. They were also very much aware of the impetus that we'd helped with to treat haemophilia. When I started with haemophilia, the morbidity was horrific - every single severely affected patient with haemophilia had gross painful arthritis. The incidence of really nasty bleeds was also high. If we wished to operate on a patient, when I started haemophilia work, we used all the concentrate available in the United Kingdom for the treatment of that one patient, leaving everybody else without treatment, except fresh frozen plasma. So there was a tremendous impetus to control haemophilia, and that's how home therapy and prophylaxis came in. So all the patients were aware that this balance had to take place between controlling bleeding and the effects of bleeding, sometimes -- on average, 35 times a year, and the possible side effects of blood products.

Q. That balance was different depending upon the severity of haemophilia?

A. It was very different depending on the severity of haemophilia. The sequelae which I'm referring to were severe haemophilia. And as an example of this balance and how it was viewed by patients: It was very salutary that, when AIDS was upon us and people were dying before we knew how to treat AIDS, people with AIDS, the old generation of people with haemophilia were telling us and our staff that they were - "pleased" is perhaps too strong a term, but they were sick but they realised the enormous change that had taken place with their treatment and they were glad to have lived through that period. That is -- sounds terrible in the context of what happened, but was salutary to realise how awful haemophilia in its natural state is in most of the world today.

Q. In relation to when it came to informing patients of their HIV diagnosis - and you discussed in some detail with Mr. Finlay yesterday the process that you went through - within what period did you complete that process of informing your patients?
A. They were all informed by May of 1985.

Q. And how did you manage to inform your patients within such a short time period?
A. We started to test in December of 1984. We simply put it as the priority, that people should -- who wanted to be tested, were tested, and that the results must be given to them as soon as they were available. As I said yesterday, the long-stop was the three-month follow-up, but that was the long-stop; the majority of people were told as soon as we had the test -- the test results came in batches, they didn't trickle in one by one, and we would then tell the patients the result. And we would tell them in precisely the way that I detailed yesterday.

Q. In relation to confirmatory testing, did you undertake any confirmatory testing?
A. Yes, we did; and indeed, we still do do confirmatory testing.

Q. How did that process operate?
A. To start off with, we didn't have the test available in Newcastle, and we used the services of Dr. Richard Tedder in London. And as we were using those services, Dr. Arthur Codd of the Public Health Laboratory in Newcastle was setting up his test. We were lucky enough to receive the cell lines needed for those tests both from Dr. Gallo in the United States and from Dr. Weiss in London. As Dr. Codd became proficient with the test, so we needed to call on Dr. Tedder's services less often, but we always called on his services when there was a question mark about the validity of a particular test. And that took place in those months before May of 1985.

Q. In terms of monitoring, informing patients, did you keep records, or how was that operated?
A. We have always kept very strict records. Every single patient attending the centre who needed treatment was recorded initially in written form, in what we call the haemophilia register, and that would be a big register like a folder like this, which was confidential, but was kept in the centre itself. And for when the centre was closed, out of hours, a copy would be kept on each of the two wards to which the patients were able to go for treatment or help.

Q. What would be contained in that register?

A. Within the register there would be a sheet for every patient; with the details of that patient, the relatives, the factor level, the -- if there was an inhibitor, the blood group, and the specific recommendation for treatment.

Q. When you say "the specific recommendation for treatment," what do you mean?
A. If it was a patient with Haemophilia A, which product that patient should receive treatment with; similarly for Haemophilia B, von Willebrands. It would say, for instance, for a hypothetical patient, 'this patient should only receive Factor VIII concentrate,' and it would give the name of that concentrate. And it would give the dosage, the recommended dosage.

Q. And if it was a person with mild haemophilia, what would be the situation in such circumstances?
A. The situation would be DDAVP. Or before we were using DDAVP, cryoprecipitate or one of the products less likely to cause problems.

Q. Okay. When you came along to testing people with haemophilia for HIV, what system operated in those circumstances?
A. The system of telling them or the system --

Q. Management of data administration?
A. We added the knowledge we then had about HIV to the patient record and to the register. But we only added it in a way that was confidential; in other words, we specifically did not mark the outside of a record with the HIV -- or the HTLV-III status, because of the stigma attached to that diagnosis. We did, however -- every patient hospital record had it within it, so if a doctor opened the record, the result was in it. So there was no mistake, the result was always there when the patient was seen. It was also in the register. So the hepatitis status and the HIV status was available to any doctor who was involved with the patient.

Q. Was there a procedure for checking to see whether patients had been informed of their diagnosis?
A. Yes. The nursing staff in particular kept a very careful diary record of the patients, and -- who had been told or who had not been told.

Q. In relation to provision of treatment for haemophilia, is there a method whereby one can check the treatment prescribed to a patient in terms of batch numbers, in terms of type of concentrate?
A. Yes, right from the beginning. Every single treatment had a specific card called the 'green card', which, before computerisation, was accessed through the needle, needling method, through holes along the edges of it - I'm old enough to remember that - and now can be fed into a computer. But all those cards have been kept. And when I left last year, they were being put on CD ROM, the information on them. The card recorded the patient's name, the date of the treatment, the reason for the treatment, the batch number and the amount of units, or whatever it was, given at that particular time.

Q. When was that system implemented?
A. 1970s.

Q. Why was it implemented?
A. It was implemented because of the need for constant surveillance of any patient receiving blood products.

Q. If a patient presented after hours for treatment, what supervisory methods were in place to ensure that appropriate treatment was afforded?
A. Well, first of all, we had these designated wards for patients, they were actually Wards 8 and 13; 13 was for adults and 8 was for children. And as the children grew into teenagers, they were given the choice of which ward they'd like to go to. The staff on those two wards were trained in what to do. The nursing staff were comfortable with seeing people with haemophilia and there were frequent interchange of views between members of the haemophilia team and the wards. In the days before home therapy, the wards were used quite extensively; inpatient treatment was the norm and, not unexpectedly, a lot of patients didn't like it at all. Following home therapy, we still kept this specific ward for the adults and the children. The register was on the ward with the recommended treatment and the details of each patient, and that was -- it was the responsibility of the secretarial staff in the haemophilia centre to update those files regularly. Every day they were updated with the latest information - any change that was necessary; from simple things like change of name in a lady with von Willebrands disease who got married, to a side effect of treatment or a change in treatment. In addition to that, the junior hospital doctors who were attached to Haematology and Haemophilia also worked on the wards, so they visited patients, our patients on the ward. And there was a regime in place that every morning when sister came in - it was common for the nursing sister to start work at 8:00 in the morning - she would be notified by the wards of any patients that had come in overnight. If she wasn't notified, if nothing was heard, she would actually ring the ward and check that there was no -- nothing happening. And then when we came in, we'd go and see the patient on the ward.

Q. And in relation to training for junior doctors when they became involved in haematology, what training was available?
A. They were -- there wasn't sufficient workload from haemophilia for a specific junior doctor, so all our junior doctors were appointed to haematology. And part of haematology was the haemophilia centre, so they all got training in haemophilia care. There were written protocols for them, and the nursing staff, again, did a lot of training on venepuncture and the administration of blood products. One of our major problems was the -- for the junior doctors, was the treatment of children, because, going into haematology, they hadn't necessarily had any pediatric experience. So that was one of the areas that was targeted by the nursing staff in particular in order to train these junior doctors, how to treat haemophilic children.

Q. You mentioned earlier that children under four were prescribed cryoprecipitate; was there any difficulties in administration of that product?
A. No. It's less convenient, but we were using the wet cryoprecipitate, which means that you have got to go to a deep-freeze, take the pack out, thaw it, and then in some way pool it with other packs of cryoprecipitate, depending on the age and weight of the patient. In the old days we used to give it by drip, which is inconvenient, and patients, of course, didn't like it because they had got to lie on their bed having a drip for a long period of time. We answered that by giving it by syringe. So the inconvenience there is you have got to get several syringe-fulls, whereas with the

concentrate it's usually with a very small syringe. With dried cryoprecipitate, as I believe that you have in the Republic, it's much easier because you don't have to defrost it. And dried cryoprecipitate was one of the options for home therapy and was, I think, extensively used in Finland, for instance, for home therapy.

THE CHAIRPERSON: We will adjourn for lunch and resume again at 2 p.m..

THE TRIBUNAL THEN ADJOURNED FOR LUNCH.

THE TRIBUNAL RESUMED AFTER LUNCH AS FOLLOWS:

CONTINUATION OF EXAMINATION OF DR. PETER JONES BY MR. BRADLEY AS FOLLOWS:

THE CHAIRPERSON: Good afternoon.

MR. BRADLEY: Good afternoon, Madam Chairperson. Good afternoon, Dr. Jones.
A. Good afternoon, Mr. Bradley.

Q. Now, in relation to -- we're talking about treatment options for the period 1980-'85, and we mentioned the various treatment options that were available to you in Newcastle for that period. In priority, in terms of safety, what particular treatment options were pursued?
A. We considered that the safest material available to us locally was our cryoprecipitate. That was certainly before AIDS. It was less likely to be associated with hepatitis than the pooled products, for reasons that have already been discussed at length. It was also thought to be safer because of the population from the northern region that it was drawn from. Secondly, the National Health Service product was considered to be safe really for the same reasons; because of the population of our voluntary donors. But we were not given the luxury of being able to use that because there was insufficient material. Now, thirdly, the licensed commercial products, which had been first licensed in 1973. And of those, there was very little to choose between them. They were all drawn from commercial donors. We had looked, by way of completeness, at getting volunteer donor plasma products from other sources, but again, that was impossible because of the paucities of supply. So those were the treatment options open to us prior to HIV. The question of heat treatment and other treatments of products were under clinical trial. And in respect of hepatitis, we were aware, by the time that AIDS was with us, that the early heat treatment drought had not succeeded in removing what was then known as non-A non-B Hepatitis. And that's why they weren't more generally in use by the time AIDS came along.

Q. In terms of safety in respect of hepatitis, your concern was that in relation to treatment for people with haemophilia prior to the AIDS epidemic?
A. It was very significant and all the patients knew about it and were regularly tested - their liver function was tested; their antigen and antibody status was tested; and they were told the results. And when a vaccine became available, then that was, of course, offered to them. And it's worth noting that it wasn't just offered to the patients, it was offered to relatives and members of staff as well. So there was a general concern that there was a pathogen there. There was also the knowledge that that pathogen could, in terms of serum hepatitis, Hepatitis B, in a minority of cases

lead to severe liver disease in later life; and in some of those patients, the severe liver disease to liver cancer. But that was a minority. And again, we come back to this balance between being able to treat haemophilia and the possible risks of transfusion. Underlying everything else, once Hepatitis B had been thought of was the question of what else was in that, what other pathogens were there? And that's where the term 'non-A non-B Hepatitis' came on. At the time before AIDS, we thought that Hepatitis A was not transmitted by blood products.

Q. Had you any limiting factors in relation to availability of product of choice, such as NHS factor concentrate?
A. Oh, yes. NHS concentrate in England and Wales at least was always in short supply and we were never self-sufficient.

Q. And would that have changed your regime of treatment in any manner if it had have been available?
A. I think at that time, yes, it would have done. In fact, I think it's probably not sufficiently aggressive. If we had had enough National Health Service concentrate in the early days, we would not have had to import commercial concentrates.

Q. And would that have been a factor that you would have taken into account pre-advent of AIDS, in or around the beginning of 1983?
A. Oh, yes, because we knew about the commercial donors. This was well-known, public knowledge and -- about the high incidence or higher incidence of disease that was likely to be transmitted from products prepared from paid donors.

Q. I'd like you to turn to page 70, Dr. Jones, and it's an article that you published in The Lancet on January the 15th, 1983?
A. I'm sorry, Mr. Bradley, could you repeat the number?

Q. Page 70.
A. Thank you.

Q. We'll look at the third paragraph: "We know the transfusion of patients undergoing renal transplantation is associated with improved graft survival and it has been suggested that transfusion is immunosupressive in an, as yet, unidentified way. Until recently there has been no suggestion of a similar immunosuppression in the haemophilic population. However, an immunosupressive syndrome associated with T-cell subset reversal has now been noted in a small population of multitransfused heterosexual haemophiliacs in New York. (Mark Hilgartner). The syndrome shows similarity with that affecting homosexual males in the United States and named Acquired Immune Deficiency Syndrome (AIDS). Clinically AIDS presents with lymphadenopathy, weight loss, chronic diarrhoea and sometimes with overwhelming infection or malignancy. The six haemophiliacs we know of had pneumocystis carinii pneumonia."Was that a concern of your centre in or around the beginning of 1983, monitoring patients for T-cell subsets for adverse consequences associated with lymph glands? Was that an issue you were addressing at that time?
A. Yes, it was. We were doing physical examinations regularly and we were using all the technologies that were emerging that we hadn't really appreciated before to monitor the patients and see what effect transfusion was having on them.

Q. And what particular symptoms were you looking for, what was the purpose of the exercise?
A. Well, we knew -- the clinical symptoms of AIDS were emerging and the question was whether or not what we were seeing in the changed immunology in our haemophilic patients was a different disease to that that was being described principally in the United States as AIDS; in other words, was this an infectious thing or was it something -- another response to something else in the blood product.

Q. Did the results of those investigations cause additional concern?
A. Yes. If you read down to the end of the letter, I think it will tell you that there were changes in our subsets. So whatever was happening wasn't normal, there was something going wrong in the patients. And the real question was, was that going to lead to significant deterioration in health in one way or another, or was it simply a reflection of the amount of material that they were having? Was it a -- it says in the penultimate paragraph: "Was this a normal defence mechanism to antigenic load?" We didn't know but we thought it worth following these patients up. From that day, every patient, when they came to follow-up, had their CD4 T-cells measured.

Q. And did that have any impact in relation to treatment options arising from your studies of the patients?
A. Well, we looked more carefully at how we should be treating the new patients, the children in particular, and the mildly affected patients. And it strengthened our view that, as far as possible, we shouldn't be using multidonor products on people who had not been subjected to treatment before.

Q. In relation to Hepatitis non-A non-B - now known as Hepatitis C - in respect of the provision of treatment, what particular products were used from 1985 onwards in terms of viral inactivation processes at your centre?
A. We started to use the solvent/detergent products. All -- initially I think we -- sorry?

Q. From 1985 onwards, sorry. From the advent of heat-treated products?
A. Yeah, we didn't use the Armour product for reasons we've already discussed. We started to use the - I think what has been referred to, to the Tribunal, as pasteurised product. And Alpha 8 and Alpha 9 were the two that were being used at that time, and later we changed to the solvent/detergent.

Q. Okay. Look at page 40, and it's a letter from yourself to Dr. Evans, consultant haematologist in Manchester. Look at the last paragraph: "The only commercial product namely I'm using is the Alpha Profilate and this solely on the basis of their non-A non-B evidence." What evidence was available to you, as a treating physician, in respect of the efficacy of pasteurisation in respect of non-A non-B at that time?
A. We had the evidence before AIDS that would break through that non-A non-B in the early heat treatment trials. And the one that I can specifically remember was the Travenol product. And later, all these products were under increased surveillance. And I remember that the Alpha Profilate, we thought their evidence was good; that there wasn't a transmission of non-A non-B. And so obviously we would go for something where the evidence was available. And also, if one thinks of non-A non-B as a surrogate for other possible pathogens, it seemed a sensible choice.

Q. And were you aware, at that point in time, of the consequences of non-A non-B, that they could be serious?
A. We were aware that non-A non-B, what we used to call transaminitis because of the fluctuating liver function tests, could lead to disease. We were not aware of how long it would take for that disease to become manifest, and we were not aware that the proportion of patients who were likely to become seriously ill was going to be significantly higher.

Q. If we look at the Newcastle conference, more particularly to page 21 of the booklet, what you said there was: "The greater the likelihood of viral contamination. The commonest complication of this massive exposure is viral hepatitis and abnormal liver function tests and cases of cirrhosis are seen in every hemophilic population studied." Was that your perception at that particular time of the situation?
A. Yes. If I can exemplify that, though: There was this long drawn-out incubation period between a disease becoming manifest after a presumptive infection, because at that time we didn't have a test for hepatitis - what then became Hepatitis C. And we'd known, from the early 1970s, that there had been physical symptoms which were attributed to possible hepatitis, and in particular, a paper by Dr. Peter Levine, pointing out splenomegaly and lymphadenopathy in patients who had been multitransfused. That was the beginning of the 1970s. But even those patients hadn't gone on to produce overt signs of liver disease by the time that this paper was written in a -- in quantity. Yes, cirrhosis occurred in some patients, but the majority of patients continued to be well, albeit that their liver function tests fluctuated.

Q. Did the concern in relation to liver function test results impact upon your selection of treatment?
A. Yes, it did. We would not choose anything that was likely, in our opinion, to transmit disease, obviously.

Q. And in that regard, would you prefer low or smaller donor-pooled products?
A. If small donor-pooled products were feasible and obtainable, then undoubtedly we would have preferred them.

Q. And in relation to pasteurised product in 1986, would that be a preferable option for the same reasons?
A. We thought so, and that's why we went for Alpha 8 and Alpha 9, because they were pasteurised.

Q. So did you move from fresh frozen plasma to Alpha 9?
A. Fresh frozen plasma had already been superceded by that time for treatment of Hepatitis B patients. And we'd used just the National Health Service product and had no cases of HIV infections as a result. The alternative for Haemophilia A was cryoprecipitate, and one definition of cryoprecipitate is a small pooled product. And we continued to use that for the children. And my memory from Mr. Finlay's question this morning was that we did keep the children on cryoprecipitate for that reason, even during this period. And the references to heat-treated concentrate in December 1984 /January 1985 were for the patients who were already on concentrates.

Q. What I'm seeking to ascertain is in or around the period of February/March '86, you moved back to using cryoprecipitate for children, fresh frozen plasma for Factor IX deficient children. Did you move towards Alpha 9 after that period of time?
A. Yes, we did, because there was no National Health Service product. When we could -- when we could get away with treatment with one of our volunteer donor sources for cryoprecipitate or fresh frozen plasma, then we'd use it. But the difficulty with fresh frozen plasma is that there are other hazards of transfusion in small children in particular. So sometimes that decision was not possible.

Q. How readily available was the Alpha Profilate and the Alpha 9 product?
A. We had no difficulty in obtaining it at all.

Q. And were they licensed in the United Kingdom?
A. To my knowledge, it was licensed. I'm not sure about that at the time, because I think the licensing might have come later. And we were prescribing the product on named patient basis. But if I could just add to that: The decision also went through our pharmacology committee at that time, and that was referred to later in the literature.

Q. Mr. Finlay this morning discussed log kill with you and your concerns in relation to log kill and the efficacy of that process in determining the safety of a product. In that regard, did the fact that there was epidemiological evidence of patients seroconverting cause you to have concerns in relation to the propositions that were proposed pertaining to five log kills or in excess of five log kills?
A. Yes, it did, because I would regard epidemiological evidence as concrete; whereas the log kill was, in my opinion, theory.

Q. Scientific evidence?
A. It was scientific evidence; but it's the portcullis: How far did the portcullis have to come down to stop the pathogen getting through?

Q. If you reverse the issue and say the product has a log kill of ten to the power of five, what is the situation where the product is infected with a virus to the extent of log to ten -- to the power of seven?
A. Well, if you're comparing within the method?

Q. Within the method?
A. Within the method, then clearly lower log kills are less likely to be efficacious in whatever you're hoping to do with the virus; in other words, the portcullis isn't coming down very much.

Q. Very much. So that would explain a rationale why you would have concerns in relation to the use of log kill?
A. Yes.

Q. Okay. When -- in relation to HIV, when did you realise that HTLV-III infection could have serious consequences for people with haemophilia? What particular events determined a view that this particular condition was serious?
A. Well, first of all there was the -- it was a 1982 report - I think I said 1983 this morning - of people with haemophilia in the United States becoming infected. And

that was reported in MMWR. And that was a real trigger to the thought that something was happening. And of course, there were all sorts of theories about why it was happening - whether there was an infectious agent present in the blood supply. The next trigger, which was not unexpected but was horrifying when it occurred, was the baby in America who developed AIDS after transfusion. And that was December of that year. And then in 1983, it was evident that the disease was not confined to the United States of America and was with us in the United Kingdom. And the first case of AIDS in haemophilia, from memory, again, I think was that year. And that was, I think, published by Dr. Daly, if my memory serves me correctly.

Q. But in terms of the consequences of HTLV-III infection, when did those consequences become apparent to you as being serious?
A. Well, I think right from the beginning, because although it was a very small number of patients, and although the general opinion was that if there was an infectious agent present, it may only go on to cause overt disease in a minority of people; we have no idea what minority. So in other words, it was -- there was a -- a harmful agent out there, which, if it did cause disease, it was a deadly disease, and these people were going to die extremely quickly. That was the feeling at the beginning of the AIDS epidemic.

Q. During the course of '83 and '84, what physical symptomology did you say; lymphoma?
A. We were looking at lymphadenopathy and large lymph nodes in all the patients as a regular occurrence. And the general physical examination, which occurred at least every three months in everybody, included that; it included looking for signs of other disease, including lymphoma cancer. And early in the course of the epidemic, we had a young man with lymphoma of the jaw, and we saw two other patients with presumed lymphoma with haemophilia. So by 1985, we had those three patients with lymphoma. And my colleagues were looking for lymphoma in other parts of the United Kingdom as well. And it was coming to light in more patients.

Q. When did the evidence, the unfolding evidence in relation to lymphoma become apparent? When did people start to realise this was a consequence associated with the infection?
A. I think certainly by 1986, and I think probably about 1984 that there were real concerns. The presumption was, at that time, that everybody would -- could possibly develop malignancy as their immunity failed. The reason why, in the general population, malignancy is commoner in older people as their immunity failed. And it was thought that this was an accelerated process in AIDS. So again, I have to rely on memory; by 1986 definitely, and I think probably from about 1984.

Q. In relation to your own three patients, can you recollect when the first lymphoma patient became apparent to you?
A. I can't recall that without looking at records, I'm afraid.

Q. Was that a matter that was discussed on a frequent basis between you and your colleagues in respect of the onset of lymphoma?
A. Oh, yes, certainly. But with the haemophilia centre directors, two topics were discussed regularly with a view to finding out more about the disease: One was postmortem examination, which, at that time, was an extremely difficult topic, for

obvious reasons; and the second was regular examinations for lymphoma in the collection of cases. And I think, from memory, that was undertaken by Dr. Christopher Ludlum in Edinburgh.

Q. Before we move on to the Armour topic, in relation to Hepatitis C, had you any incidences of Hepatitis C infections after 1986?
A. After 1985 we had no further infection.

Q. Both in Factor VIII or Factor IX?
A. Both in Factor VIII and Factor IX.

Q. Dr. Jones, can we look at page ten of the booklet. This is a letter from Mr. Bishop, manager of plasma division, northern Europe, to yourself, dated the 10th of May, 1985. It relates to batch Y 69402. Mr. Finlay has opened it to you."When this donor was giving plasma, we exerted our strict routine screening, the donor showed no indications of ill health, stated he was not a member of any risk group associated with AIDS, and was on active military duty. "Only one batch in the United Kingdom is implicated; fortunately this is a heat-treated batch number Y 69402. This small, heat-treated batch was distributed in December 1984 and January 1985 to a few centres only, of which yours is one, and we anticipate that the product has already been used." On receipt of that particular letter, did that letter cause you to have any concerns?
A. Yes.

Q. What were the nature of your concerns?
A. Firstly, that this particular company, as part of its advertising and marketing strategy, used the fact that their plasma was very unlikely to transmit any disease because of their collection facilities within the United States of America. And yet here was a donor who had developed AIDS and donated into a substantial quantity of material which was later converted into Factor VIII.Secondly, that if their heat treatment was efficacious, then perhaps there was no need to alarm people by starting to withdraw batches. So those were the two question marks that this letter alerted in me.

Q. Were you aware, in or around that time, of any possible seroconversion in the United Kingdom?
A. This is May 1985, and again I rely on memory and not record, but it was about this time that the Lewisham case was being discussed in the United Kingdom. That's Dr. Whitmore's case at Lewisham.

Q. So the two events were pretty contemporaneous?
A. Yes, from memory they were. It was around the same time.

Q. If we move on to page -- the following page, page eleven, a letter of the 4th of June, 1985, from Mr. Christie, director of clinical sciences, to yourself. And I'll open a certain portion of it: "Further to Mr. Bishop's letter of the 10th of May, we have been advised by the Department of Health that they would be very interested if all patients who have received this batch of material could be followed up for HTLV-III antibody conversion and/or any clinical or haematological signs of AIDS or pre-AIDS symptomology."Then he sets out a number of criteria in terms of information that he

requires. And the following page, page 12 he says: "I realise that this request imposes an additional burden on your unit, but it is an unusual opportunity to assess the effectiveness of heat treatment in rendering a batch of Factor VIII safe which was known to contain plasma from a donor who has developed AIDS." Arising from receipt of that letter, did that cause you to have any concern to consider the content of the letter? What was your reaction upon receipt of it?

A. My reaction -- well, our reaction, as a team, was that here was a company rightly asking for epidemiological evidence, but riding on marketing which said that their product was safe as a result of their heat treatment.

Q. And the only epidemiological evidence was your patients?
A. Only epidemiological evidence was our patients, yeah, and the development of HIV infection.

Q. Did you ever hear from Armour in relation -- in or around that time, as to the results of any studies that would have resulted from that request for information?
A. No.

Q. If we move on to page 46, this is a further letter, it's a letter from Mr. Rodell, who's vice-president of regulatory and technical affairs and responsible head. It's from Armour, again, to yourself, and dated the 14th of August. It's quite a long letter, but I'll open some of the portions.First paragraph: "I've been requested by Mr. Duane Miller to respond to your letter of the 19th July, 1985. In my capacity as designated responsible head of Armour Pharmaceutical Company to the USA FDA, I am directly involved in issues associated with plasma collection and processing, as well as manufacture of anti-haemophilic factor (human)."Then he goes on to discuss AIDS in the next paragraph: "In 1983, Armour Pharmaceutical submitted supportive data and a license amendment request to the FDA in order to incorporate a heat treatment step in the manufacturing process for our factorate anti-haemophilic factor (human) products. This heat treatment step, which was intended to reduce the risk of transmission of hepatitis viruses, was approved by the agency. Subsequently, the causative agent of AIDS was identified, isolated and shown to be extremely sensitive to heat by scientists in several countries. All factorate concentrates manufactured and distributed by Armour Pharmaceutical Company now undergo heat treatment." Following paragraph: "Within the past several months, the FDA granted product licenses to three manufacturers for the production and distribution of reagents intended for use in determining the presence of antibody to HTLV-III in blood, plasma or serum. Although testing for antiHTLV-III is not mandatory in the US, our Plasma Alliance subsidiary implemented system-wide testing of each donation of plasma very shortly after the availability of the test. Units of plasma found to be positive for antiHTLV-III are not used in the manufacture of clotting factor concentrates, and donors of these units are permanently deferred from further participation in our plasma programmes." Now, in relation to HTLV-III testing, what was your interpretation, upon receipt of that particular letter, in respect of the provision of Armour products?
A. Well, firstly, that we're talking about a period of time shortly after the test was introduced. Secondly, it seems totally self-evident that you're going to exclude positive donors from the plasma pool; otherwise, why bother in the first place. Thirdly, that they're putting emphasis, within this paragraph, on the timing of the

testing. But we knew around this time that not all the products going through were individually donor tested.

Q. But were you under the impression that the provision of Armour factorate concentrates would, in the near future, have been from screened plasma?
A. Yes.

Q. Look at the second last paragraph: "Additionally, for the manufacture of clotting factor concentrates Armour has not used plasma collected from cities in the United States designated by the CDC as "high-risk AIDS areas." A listing of the centre location of our subsidiary plasma alliance is attached." Would that convey the impression that the donor exclusion processes operated by Armour were safe?
A. No.

Q. Why not?
A. Because we already knew, by then, that AIDS was not confined to the so-called early high-risk groups. We knew that it could appear anywhere and in a population where there was frequent travel. There was a risk anywhere.

Q. In such circumstances, then, what methodology were you relying upon to ensure the safety of the product?
A. Their heat treatment.

Q. Did anyone raise any concerns in relation to the safety of the heat treatment process to you in or around that time?
A. There was continuing debate about all the methods of trying to render product.

Q. Did anyone from Armour raise any concerns?
A. None whatsoever.

Q. If you turn over the page and look at the conference on the 15th, at page 15, in Newcastle. Were Armour aware, in advance of that particular conference, that you were going to give -- deliver the talk that we -- that was discussed this morning?
A. Not in advance of the conference itself, but during the conference, yes.

Q. And did any actions occur that may have impacted upon the content of the discussion or -- and the delivery of the presentation?
A. Yes. We worked very closely with a team of organisers, together; we were in constant communication. And one of that team was a Mr. Joe Kirkley. He had been the head of our blood bank in the hospital for many years. He was a colleague and a friend and he came to me on the morning of my paper and he told me that Mr. Chris Bishop of Armour was organising a petition amongst the exhibitors to try to prevent any discussion that heat treatment may not be guaranteed in the safety of blood products.

Q. In relation to the content of the presentation, did that gentleman's approach have any impact upon the manner in which you presented the data?
A. No, it didn't. I debated whether to specifically mention an individual product, Armour; and I thought that that would be quite wrong in the delivery of a paper which had already been written. So I didn't mention them. But it certainly had an impact on

my thinking; and that impact was that if they had evidence that their product was safe, then there was no need to do something quite so extraordinary.

Q. Did that reaction by Armour Pharmaceutical Company promote the plethora of correspondence that superceded that conference?
A. No. I -- I gave the paper and raised the doubt, and was criticised, as you have already heard, by Donald Acheson for raising doubt. And I raised the doubt on the evidence that we've already discussed. The alleged petition that was being got up, I never mentioned either to him or to anybody else, including the media, who, by that time, were asking all sorts of questions about what was going on, including the New Scientist journalist. So that piece of information has never been made public.

Q. On the 17th of February, 1986, you wrote to your colleagues, the Haemophilia Reference Centre directors, and copied it to regional centre directors in your own region. And if you look at the second paragraph of that letter, at page 32: "I thought a great deal about whether such soft data should be presented at the conference. My view was that, because of the paucity of seronegative cases on a variety of heat-treated materials and the time lag involved, that we could not afford to wait until sufficient scientific 'evidence' was available. My decision to include the four cases in the paper was based on this view, on the strength of the personal reports I had received from reliable doctors and on evidence that I was given in California that live virus had been found in concentrates dry heated for short periods. The argument had been put to me that, because of the extremely low incidence of seropositivity in blood donors tested in this country, together with heat treatment, that there is no longer any threat to haemophiliacs. I do not think that this is true and felt the warning justified." And next paragraph: "I have taken this step in order to try and establish where we appeared to be so vulnerable compared to the rest of the country, in the hope that the answer could prevent further cases both here and abroad in the future." That is a very strong letter to your colleagues. Did that promote discussion with your colleagues, did that promote concerns? What reaction did you -- and feedback did you receive from the content of that letter?
A. It certainly provoked reaction. But my colleagues felt, as a Committee of Safety of Medicines, felt that there was insufficient evidence at that time to withdraw or to ask Armour to withdraw their product. We did not have the in-house evidence of the efficacy of heat treatment with relation to the AIDS virus at that time.

Q. And that was because you weren't in a position to undertake the appropriate studies?
A. Yes.

Q. Would you have expected that Armour, rising out of the information that was in the public domain, would have undertaken such studies?
A. Oh, most certainly.

Q. If we look at page 33, letter of the following day. We look at -- Mr. Finlay has brought you through the information that was enclosed with that particular letter. Look at the final paragraph: "In this centre, in addition to available National Health Service concentrate which is at least heated for 72 hours, we have changed our patients to the Alpha material because of a report to me by Dr. Koerper that it was free of virus after testing by Dr. Levy in San Francisco. It is my personal opinion

that, unless there is irrefutable evidence to the contrary, the Armour material should be withheld until its safety can be endorsed by the CSM." Had you ever written to a regulatory authority prior to that date requesting that the distribution of a blood product would be withheld?
A. No.

Q. Seven days later you wrote to Dr. Harris, who is the medical and technical director of Revlon, the parent company of Armour Pharmaceuticals. That letter is page 34: "Dear Dr. Harris" -- won't go through this letter in detail -- "thank you for your letter of the 19th of February relating to question of heat inactivation of HTLV-III/LAV. With this letter, I enclose a copy of the paper I gave in Newcastle which refers to possible seroconversion in four cases. You will see from this paper and from subsequent publication in New Scientist of the 20th of February that it is the Dutch case that I am particularly concerned about. In my original paper, I did not think it proper to refer to the product used in this case, although now you have confirmed that it was, in fact, Armour factorate heat-treated." It appears you received confirmation from Armour Pharmaceutical in respect of the Dutch case that it was caused by heat-treated factorate concentrate, is that correct?
A. That's correct.

Q. Did Armour furnish you with an explanation, when you received that confirmation, as to what had occurred?
A. I believe that the Dutch case was directly related to an AIDS donor. And I think at that time that information was afforded to me.

Q. So therefore, correct me if I'm wrong, the situation that prevailed was that the donor had been identified and the recipient had been identified and the product was heat-treated?
A. Yes.

Q. Yet it had transmitted --
A. Yes.

Q. -- HTLV-III?
A. Yes.

Q. Arising from that information being in the domain of Armour, did you expect that there would be some reaction on their part in relation to the product?
A. Yes.

Q. What reaction would you have expected?
A. I would have expected, at the very least, that the product be withheld from the previously untreated patients.

Q. I'll go on and finish the letter: "The information about the American cases was given to me by Dr. Peter Levine, and I subsequently discussed them with CDC. I am afraid that I am not party to the products involved in these cases, although it is possible that one of them, which has been reported to Professor Mannucci, was on the Travenol material. Given that most transfusion-transmitted Hepatitis B that we have seen appears to have arisen since screening was introduced, probably as a result of

blood being drawn from people in the early stages of the disease before they became reactive to the laboratory test, I am very concerned that everything possible should be done to address any doubts that we have about our present practice with regard to AIDS. I understand --"Now, it mentioned Hepatitis B there. Why would the increasing incidence of Hepatitis B have raised concerns in relation to the safety of blood products pertaining to AIDS?
A. Because any viral material, any pathogen that was coming through or was thought to be coming through meant that anything else could go through, and the AIDS virus in particular.

Q. I'll proceed. "I understand that the Armour material is" -- blanked out -- "lyophilised Factor VIII which was not subjected to individual HTLV-III/LAV testing and that it was subsequently heat-treated in the dry state for 30 hours at 60 degrees." Then you go on to say: "I am unhappy about this procedure because of the work by Jay A. Levy which because suggests that heating should be at least for 72 hours in the dry state in order to be sure that infectivity has been removed." You've indicated your concerns in relation to the heat treatment process used by Armour in that sentence. Do you believe at that time that you could have indicated any greater concerns to Armour Pharmaceutical in relation to their product?
A. No, because I was not party to any investigation that had been done.

Q. Then you proceed: "From the clinician's point of view, I do not think that we can afford to take a less pragmatic approach of waiting for epidemiological studies to confirm or deny seroconversion in previously untreated patients. I do not think that the Armour material should be prescribed to previously untreated seronegative patients and am particularly aware (sic) of its prescription -- "
A. "Averse".

Q. "Averse to its prescription for children." Had you ever written to a pharmaceutical company itself and indicated such concerns prior to that date?
A. No.

Q. Would you expect, as a treating physician, having referred such concerns to a pharmaceutical company, that some action would have occurred?
A. Yes.

Q. What response did you receive?
A. Again, very little. I would have expected at least a meeting with the people concerned and I would have expected them to open the evidence that they had as to the efficacy of their product. That is common practice with pharmaceutical companies where there is a debate about patient safety.

Q. You copied this letter to two individuals. Those individuals are Dr. Smith of the PHLS --
A. Public Health Laboratory Service.

Q. -- and Dr. Bruce Evatt of CDC?
A. Yes.

Q. Why did you copy the content of that letter to those two individuals?

A. Because the Public Health Laboratory Service was in the position for the surveillance of all patients who were at risk of HIV infection, and Bruce Evatt was a colleague at Centre for Disease Control with responsibility in particular for AIDS and haemophilia.

Q. Mr. Finlay yesterday referred you to an article by Dr. Evatt, in relation to the efficacy of heat treatment, and co-authored by Dr. McDougal. If we look at page 69, letter from Dr. Evatt to yourself dated 11th of March, 1986. If you look at the first paragraph: "We are anxious to document any cases of seroconversion while patients are taking heat-treated material so that the FDA could consider setting minimal standards for heat treatment. To date, the most probable case in the US was the one in North Carolina, although it is not a clean case. I am anxious to hear any information that may develop in your country and would definitely appreciate your keeping us informed of any such possibilities." Did that particular letter from -- first of all, who is Dr. Bruce Evatt?
A. Bruce is a member of the -- executive of the World Federation of Haemophilia, and is particularly active in developing countries now. He remains at the Centre for Disease Control in the United States. And he was, from the very beginning of AIDS, the person who probably did more than any other single individual to explore the epidemiology of AIDS and its impact as a transfusion-transmitted disease.

Q. Would it be fair to say that he was the person who monitored the course of AIDS in the haemophilia community on behalf of the Centre for Disease Control?
A. Certainly.

Q. Here he was saying to you that: "We are anxious to document any cases of seroconversions while patients are taking heat-treated material so that the FDA could consider setting minimal standards for heat treatment." Would that cause you to have concerns in relation to the methodology of heat treatment?
A. The concerns to the effect that here was a very much respected man who was maintaining an open mind about the efficacy of heat treatment.

Q. Two days later on the 13th of March, at page 37, you got a letter, further letter from Armour. And second paragraph: "It is now generally accepted that the maximum HTLV-III contamination that could be expected in any coagulation factor concentrate before processing would be of the order of five logs. Processes that can be shown to inactivate in excess of this virus challenge are therefore likely, successfully, to effect viral elimination ."The recently completed study by our US research laboratories using a highly sensitive assay method gave the following results after seeding of a factorate solution with 6.3 logs of HTLV-III. The solution was lyophilised and the resulting dried product heated at the Armour standard of 60 degrees Centigrade for 30 hours. A reduction of 2.3 logs was shown on lyophilisation and a further 3.2 logs on heating, giving a total elimination of 5.5 logs of virus particles. A more complete synopsis of this study is attached to this letter".Now, you've indicated your views in relation to log kill and we've gone through that already. But do you believe that this particular letter was designed to assuage concerns of treating physicians such as yourself?
A. Yes.

Q. Then it goes on to state: "As you may already know, all our plasma collection centres are situated in the American midwest, away from the known areas of high risk for AIDS." Have you any comment in relation to that particular assertion?
A. Yes. As I've already said, AIDS, we knew then, was not a respecter of your suburban housewife who might be giving plasma in the mid-United States. It's certainly true that, overall, the centres for plasma reliance which supplied the Armour Pharmaceutical Company with their plasma weren't in the high risk connurbations in regard to hepatitis like New York and Los Angeles. But it didn't fill me with great confidence that they could claim that there was little risk of the AIDS virus getting through.

Q. Goes on to say: "Each donation is now specifically screened for HTLV-III antibody and all product being supplied is donor tested." Following page, page 38: "However, it should not be overlooked that there may be material in centres or in the home that is not derived from donors tested for antiHTLV-III. We do appreciate that this information would aggravate the potential for distress to the haemophiliac because of the patient's inference that nondonor-tested material may be less safe with regards to the AIDS risk." Now, considering the concerns that you had raised in the previous month, Armour were raising issues pertaining to product that was out there that was antiHTLV-III -- non-antiHTLV-III tested. Upon receipt of that information, what was your reaction?
A. My reaction was that the -- they were questioning their heat treatment method themselves, because if their heat treatment method was efficacious, was safe, then why was there such a concern about the donor and the individual testing? And I also thought that that paragraph contained a sideswipe at me personally, because one of the arguments that was put to me after I raised the question about that product was that I was frightening the patients unnecessarily.

Q. And on four days later, 17th March, 1986, at page 39, you wrote to the regulatory authority in the UK. And you state: "I have now received a confidential reply from Dr. Harris, the medical and technical director of Revlon Healthcare, to my letter of the 25th of February. It would appear from Dr. Harris's letter that, contrary to an earlier statement made by a representative of the company, Factor VIII concentrate which has not been individually donor tested for antiHTLV-III is still in circulation in the United Kingdom." Is that particular statement factually correct in accordance with your recollection at that time?
A. Yes, it is. And my colleagues were -- I think subsequently wrote to the regulatory authorities asking for specific information about individual donor testing.

Q. So the assurances you had received in relation to provision of donor tested Factor VIII concentrates weren't adhered to?
A. They were a lie.

Q. Next paragraph: "Dr. Harris has kindly given details of the heat inactivation process and its efficiency in-vitro but the fact that he is now looking to recall material that has not been individually donor tested implies that he, too, is aware there may still be in-vivo risk of seroconversion." Did anyone at any time in or around March 1986 indicate to you that -- from Armour, that there was a problem with the heat treatment process?
A. No. To the contrary.

Q. You -- in this instance, you've copied the letter to Dr. Smith, Dr. Smithies?
A. Dr. Smithies was employed at the Department of Health and Social Security with a specific remit to look after the provision of haemophilia care.

Q. "Dr. Evatt had discussed and Professor Rawlins" -- who's Professor Rawlins?
A. Now, Professor -- Sir Michael Rawlins is in charge of the National Institute for Clinical Excellence, NICE in the United Kingdom. At that stage he was our professor of clinical pharmacology and was in charge of the Wolfson (?) unit in Newcastle-upon-Tyne. And his remit, specifically with regard to our practice, was to look at our prescription of blood products. And it was Professor Rawlins and his team who looked at the provision of heat-treated concentrate with me in 1984/1985, and gave clearance for us to start treating all our patients on heat-treated material.

Q. Is there anything more that you could have done in that period of -- we've gone through to date, in notifying the authorities and notifying Armour of your concerns pertaining to the Armour product?
A. No.

Q. Now, if we go to page 61, letter from Dr. Harris to various treating physicians, and it's copied to different people in Armour. And if you look at the second paragraph: "On the 23rd of June, 1986, however, our American parent company wrote to all US-based blood bank directors and/or haemophilia treatment coordinators recommending to them the return for exchange any nondonor tested materials. In line with our corporate policy, and having obtained the agreement of the DHSS, I am now recommending the return of all donor tested (sic) factorate so that we can exchange this for material manufactured from screened donations." And would you please –

MR. FINLAY: Sorry, Madam Chairperson, sorry, he referred to "all donor tested." It's obviously "all nondonor-tested Factor VIII".

Q. MR. BRADLEY: "Would you please review your stocks of heat-treated factorate, including that used for home treatment, and if you have any from the batches listed overleaf, please return these to Armour Pharmaceutical," and the address. Upon receipt of that letter, did that cause you -- would that cause a treating physician, without having had the investigative experience of yourself at that time, to have concerns in relation to the safety of the Armour heat treatment process?

MR. FINLAY: I think, Madam Chairperson, that's not a question for Dr. Jones. He can certainly tell us about his own -- first of all, he can tell us whether he got this letter; and secondly, what his own response to it was.

THE CHAIRPERSON: I think we'll leave it at that, Mr. Bradley: A, did Dr. Jones get this letter; and B, what was his response?

MR. BRADLEY: All right.

Q. Dr. Jones, in relation to that particular letter, did you receive it?
A. I believe, from memory, that I did receive it, yes.

Q. In such circumstances, and in the circumstances of your experience at that time, what was your reaction to the content of that letter?
A. It underlined what I've already said, that there was, A, none individually donor tested material in circulation still; and B, that despite all the protestations of the safety of their product, there was still a question mark about the efficacy of their heat treatment.

Q. And if we look at page 44 and page 45, which is the withdrawal letters: "The action is a result" -- second paragraph -- "the action is a result of the antibody to AIDS virus being detected in two haemophiliac patients' blood in the UK who had used an earlier form of factorate not currently on the market. Detection of this antibody does not mean that these patients have or will contract AIDS, but rather that they have been exposed to the AIDS virus resulting in seroconversions." "Who now used an earlier form of factorate not currently on the market," what -- do you know at that time what was meant by that particular statement?
A. No.

Q. Did you ever discuss the seroconversion of the two Birmingham boys with Dr. Frank Hill?
A. Yes.

Q. And did he indicate anything of that nature to you in relation to the product used by those patients at that time?

MR. FINLAY: I think now, Madam Chairperson, we're going beyond what Dr. Jones knew at the time about Armour and informed other people about Armour.

MR. BRADLEY: That's the difficulty with the constraints we have to operate under.

THE CHAIRPERSON: I don't think that's actually true, Mr. Bradley, given it is quite clear that those risks -- if you want to go with restraints, there aren't restraints; just parameters within a limit you have to work. Just what his state of knowledge was at the time and who he communicated that knowledge to.

MR. BRADLEY: I accept, Madam Chairperson, Dr. Jones has acquired a significant amount of detail since that time. Okay.

Q. In relation to the withdrawal notice and -- that you received, did that indicate any concerns in relation to the heat treatment process?
A. Almost certainly.

MR. FINLAY: Sorry, Madam Chairperson, I'm just not quite clear what we're talking about now.

MR. BRADLEY: The last one of October --

THE CHAIRPERSON: The 44? Which one was it?

MR. BRADLEY: Page 44.

MR. FINLAY: So far as I can see from that, Madam Chairperson, this seems to have been a press release in the United States of America.

THE CHAIRPERSON: Yes.

MR. FINLAY: I'm not clear whether this was sent in some way to Dr. Jones or --

THE CHAIRPERSON: I actually don't think this was the one -- was this the one --

MR. BRADLEY: Wasn't the UK one.

Q. Dr. Jones, did you receive a similar -- or did you become aware of a similar withdrawal notice in the United Kingdom in or around that time?
A. I did, and I was phoned by a member of the Committee of Safety of Medicines to tell me what had happened.

Q. And what was the content of the phone call you received at that time from the particular entity or institution?
A. That Armour had withdrawn their product; that they had not been forced to withdraw their product, that they had taken voluntary action to withdraw it as a direct result of the seroconversion of two boys in Birmingham.

Q. And was there any indication at that time in relation to the efficacy of their heat treatment process --
A. Yes.

Q. -- by Armour?
A. I was told that these boys had been on heat-treated factorate manufactured by Armour.

MR. BRADLEY: Thank you very much, Dr. Jones.

THE CHAIRPERSON: Now, as you've heard from Dr. Jones' evidence and particularly from Mr. Bradley's questioning, that has gone outside the limits of the statements, so if -- and he went particularly into particular aspects of treatment and what Dr. Jones did in Newcastle, which weren't in his -- which wasn't in his statement. So I'm giving everybody an opportunity here now to cross-examine Dr. Jones on that aspect of his treatment in Newcastle. And if anybody would like a few minutes -- perhaps I might rise for a few minutes and I'll come back then, and anyone who wishes to cross-examine Dr. Jones on that particular aspect may do so. Thank you.

AFTER A BRIEF ADJOURNMENT, THE TRIBUNAL RESUMED AS FOLLOWS:THE CHAIRPERSON: All right. Well, I take it the silence is that nobody wishes to ask anything? Well, then, I'll go to you, Mr. Finlay, for further re-examination.

MR. FINLAY: May it please you, Madam Chairperson. There are one or two things.

THE WITNESS WAS FURTHER EXAMINED BY MR. FINLAY AS FOLLOWS:

Q. MR. FINLAY: Dr. Jones, can I ask you about the question of the treatment of children, the treatment which you prescribed for children. And I think you described yesterday that for very young children you would have prescribed cryoprecipitate?
A. That's correct, yes.

Q. And then I think, correct me if I'm wrong about this, did you say that at the age of six approximately, that children would have been changed from cryoprecipitate - which had to be administered in hospital - to home treatment, which would have been on concentrate?
A. Yes.

Q. And would that have been either NHS concentrate or commercial concentrate, with a preference for NHS concentrate if available?
A. If available, yes.

Q. And from what time would that have been your policy; when would that policy have first been adopted by you in the centre?
A. In the 1970s.

Q. Yes. And would that policy have continued up until, say, 1985?
A. Yes.

Q. And so, even after 1983, would children, as they came to the age of approximately six, have continued to be transferred from cryoprecipitate to concentrate?
A. Yes, of course, with the permission of the parents.

Q. Yes, I understand that.
A. But our cryoprecipitate, you see, was wet cryoprecipitate.

Q. Yes?
A. So the logistics of keeping it in deep-freezes and pooling it in the home situation was really not feasible. And so we had to go to a concentrated form of the material in order to allow the injection of the children at home.

Q. Yes. But from 1983 onwards, Dr. Jones, when the risk of AIDS -- I think certainly by the middle to the end of 1983 it was something which would have been causing concern to you, isn't that correct?
A. It was, yes.

Q. And from that time onwards, did you consider keeping the children who were -- who had been treated with cryoprecipitate, maintaining them on cryoprecipitate in order to avoid the risks which would come from home treatment and concentrates?
A. Indeed; we discussed that very carefully, yes. And the youngest child who became infected in my centre was seven years old. We had none, as Mr. Bradley pointed out earlier, below the age of four -- we had none below the age of seven actually. And the reason that he was infected was that he had particular bleeds and severity of bleeds and we started him on home therapy early.

Q. I see. So, the policy remained in place that a child would start on cryo, but at the age of six, approximately, would move to concentrates?
A. Yes, if he was starting on home therapy.

Q. Yes. And that remained in place even after 1983?
A. Yes, it did. You asked me to -- this morning about the heat treatment and the cryoprecipitate. And my memory is that we still kept the children on cryo at that time because we thought it was a safer material, and we changed to the heat-treated concentrates for the patients who were receiving concentrate.

Q. I see. I see. And then what you've mentioned is that even within that policy of having children on cryo up to approximately the age of six, there might be clinical reasons why it would be necessary to depart from that in particular instances?
A. Yes.

Q. And the one you mention, of a child who required concentrate for a particularly severe condition prior to that?
A. Yes. And, for instance, an obvious one is major trauma --

Q. Yes.
A. -- where the volume and the difficulty of giving frequent cryoprecipitate was super -- was overwhelmed by the ease with which a concentrate could be given.

Q. And perhaps surgery would be --
A. Major surgery, yes; and inhibitors was the third.

Q. Yes. And after testing becomes available and after heat-treated product becomes available, do I understand you to say that you continued to use cryoprecipitate for children and for mildly affected people?
A. The recommendations at that time were that if you had access to volunteer donor cryoprecipitate, then the younger children should be kept on that. And because it was our policy in Newcastle to start home therapy, in contrast to some other centres, particularly the United States, relatively late - the reasons for that I can go into if you wish - most of the children were kept on until they started home therapy. So it was six years old.

Q. Yes. But as time went on, Dr. Jones, did -- was there not a risk attached to even donor-tested cryo?
A. Oh, yes. The incidence of HIV infection in our donor population was extremely small. We realised that when testing started.

Q. Yes.
A. Within the United Kingdom, the risk was substantially higher in London and Edinburgh, and the reason for that was the intravenous drug abuse in those two places. So within Newcastle, thankfully we didn't have that particular problem. And within the catchment area for our donors we didn't have that problem. So it was a question of weighing risk all the time. And eventually, of course, we moved away from cryo altogether.

Q. Sorry, the risk attached to even tested -- individually donor tested cryo would obviously be that a donor would donate within what's called the window period, isn't that right?
A. Absolutely.

Q. Isn't that so, Doctor?
A. Oh, yes.

Q. Now, can we turn to Haemophilia B patients for a moment. What was the policy for children who had Haemophilia B? Were they given fresh frozen plasma or Factor IX concentrate; if we take the period, say, from 1978 to 1985, what would have been the policy?
A. Fresh frozen plasma is a very difficult material.

Q. Yes.
A. And it's difficult because whereas with cryoprecipitate, which contains Factor VIII, you can achieve a very good level of Factor VIII after a relatively small volume of cryoprecipitate; with fresh frozen plasma you have to give a big volume of the material in order to raise the Factor IX level. And what that means is that in anything other than a relatively minor bleed, you are in danger of driving -- of overloading the recipient and driving him into heart failure. So you're dealing with the haemophilia and you're dealing with the consequences of heart failure. So quite apart from questions of contamination, there are very real medical reasons for trying to avoid the use of fresh frozen plasma as much as possible in Haemophilia B patients.

Q. Yes.
A. So we -- and the second reason for us adopting Factor IX concentrate was that the United Kingdom was self-sufficient in Factor IX concentrate.

Q. Yes.
A. And therefore, we were able, throughout, to use National Health Service Factor IX, and that, in retrospect, is why we didn't have any infection.

Q. Yes. So would I understand from that, that, in fact, during the period I'm asking about, from 1975 to, say, 1985, you would have been using NHS Factor IX concentrate for all your patients, including children?
A. Yes. We -- for all the Factor IX patients, yes.

Q. Of course, Doctor. I should have said that.
A. If we had a child with a relatively minor bleed and we had fresh frozen plasma available in the 1970s, then we'd use it. But we changed to the concentrate.

Q. Yes. Because you see -- and that, I think, would be borne out if we look at paragraph two in your article -- page two, sorry, of the book of documents, in the article -- the table that we looked at in some detail yesterday --
A. Yes.

Q. -- dealing with the HIV antibody rate amongst your patients, in the various categories of treatment regime. I mean, there's no reference there at all to fresh frozen plasma, isn't that correct?

A. That's correct.

Q. And indeed, there's no reference to anybody receiving cryoprecipitate only in that list?
A. In that list, right. This is the multitransfused.

Q. Yes. So, you see, that's why, Dr. Jones, I'm just wondering -- if we could return then for a moment to the document at page 40 in the book of documents. This is your letter to Dr. Evans in March of 1986. And the last paragraph: "At present in Newcastle I am prescribing antiHTLV-III-tested cryo for the children (or fresh frozen plasma in the case of Factor IX minor bleeds) and NHS 8Y for everybody else, as far as stocks will allow. The only commercial product I'm using is the Alpha Profilate, and this solely on the basis of their non-A non-B evidence." So would that use of fresh frozen plasma, would that have been a change of policy there?
A. It was for minor bleeds where you're not going to overload the circulation.

Q. I see. And what would you have been prescribing for Factor IX patients at this stage in March of 1986?
A. From memory, we were prescribing the order NHS 9.

Q. Heat-treated?
A. No, because the heat-treated Factor IX didn't come in, there was a gap.

Q. Ah, yes, but it was well there I think, Doctor, by then?
A. We would be using that, yes.

Q. Because I think we've had evidence from Dr. Snape that it would have been generally available and, in fact, they were in a position to do a recall and replace nonheat-treated product by October of '85?
A. Yes, that's true. Yes.

Q. Yes. And you mentioned that you had no incidence of an infection of a patient with Hepatitis C after 1985?
A. That's correct.

Q. So, we'll just look at what products would you have been prescribing for your patients after -- say from 1986 onwards: Would I be correct in understanding from this letter that it would have been either NHS heat-treated product, Factor VIII and Factor IX; or the Alpha product, which would have been heated in solution?
A. We come back to how we looked at blood products and procured blood products within the Newcastle Centre, and number one was safety.

Q. Yes.
A. Now, as we go through the evolution of blood products, we moved into solvent/detergent and monoclonal antibody; all these technologies with the ultimate technology at that time of recombinant Factor VIII and Factor IX. And so we were looking both at that evolving technology and at the evidence of the -- particularly the epidemiological evidence for products as they came through into the marketplace.

Q. Yes.

A. So decisions were based on that, and, provided that these products were -- worked in haemophilia, the third of the criteria was cost.

Q. Yes.
A. So the bidding process did not differentiate between the National Health Service product, in particular 8Y at that time, and the commercial products. In terms of safety they were both -- the safety records were extremely good following the early heat treatment problems. And it really came down to cost, and the National Health Service product was not free.

Q. Yes. Well, that's what I just want to understand: What were the commercial products which you were using after -- say from 1986 onwards?
A. Again, I have to rely on memory because I don't have the record with me, but we would have been using the Alpha product, certainly Alpha 8.

Q. And was that heated in solution, wet heated?
A. That is the pasteurised product, yeah. And then solvent/detergent products came on the market and they were particularly Travenol, and the blood -- and the NHS adopted the Travenol method for solvent/detergent under license; Hyland, Travenol, the same. So we used that. There was a product called Monoclate P which was developed by the Armour Pharmaceutical Company.

Q. Yes. These I think would all have been much later, Dr. Jones, is that right; the Travenol solvent/detergent would have been certainly after '88, '89, '90?
A. I mean, I'd have to rely on the records to answer your question intelligently.

Q. Perhaps can I ask you this, Dr. Jones: Would you have used, after 1986, any dry heat-treated product other than the National Health Service dry heat-treated product?
A. To my memory, no, we didn't use the Cutter product.

Q. I see.
A. And we certainly didn't use the Armour product.

Q. I see. I see. So it would seem then, in summary, that from 1986 onwards you would have been using either the National Health Service product --
A. 8Y.

Q. -- yes -- or its equivalent, for Haemophilia B?
A. Yes.

Q. Which we know was safe against the transmission of non-A non-B?
A. Certainly.

Q. Yes. Or product which was pasteurised, or treated with solvent/detergent method, or in later times, perhaps, monoclonal with some other means of viral inactivation with it?
A. Yes.

Q. And therefore, all of those products would, in fact, have been safe against the transmission of non-A non-B?

A. Yes, certainly from 1985 onwards we didn't have any seroconversions.

Q. Yes, I understand. Now, just one other thing maybe, partly a point of detail, Dr. Jones. Mr. Bradley referred you to an article that appears at page 70, or a letter which you wrote to The Lancet in January of 1983. And I think it's clear from the terms of the article -- if we look at the first paragraph of it, what was the purpose of the examination which you carried out of 16 patients of their T-cell status?
A. Well, as stated in the letter, the initial purpose was to look at the question of inhibitors, antibodies to Factor VIII.

Q. What you were looking for was to see whether there was some association between the T-cell status of the patients and the development of inhibitors?
A. Initially, yes.

Q. Isn't that correct?
A. Initially, yes.

Q. Yes. And then, having done so, you found that there were some changes in the T-cell status of the patients?
A. Yes.

Q. Which didn't seem to be related to their inhibitor status?
A. That is correct, yeah.

Q. And you then looked at a study which had been done in America, of the T-cell status of patients?
A. Yes. Yes.

Q. Isn't that correct?
A. Yes.

Q. But the initial -- at this time, in January of 1983, your reason for looking at 16 of your patients, at their T-cell status, wasn't anything to do with their immune status; it was to do with whether or not they were developing antibodies?
A. Well, that is to do with their immune status, forgive me.

Q. I'm sorry, but the particular version of the immune status that we're concerned with, namely that which might be related to HIV, as it was subsequently called?
A. By 1983 we were looking at any clues, so that came into it. I understand the thrust of your question, Mr. Finlay, and I'm not trying to be difficult, because the letter does state why initially we did the work.

Q. Yes.
A. And that was to look at the inhibitors.

Q. Yes. And having done so, you found that there were some changes in the T-cell status of those 16 patients?
A. Yes.

Q. And what you're now doing is that you're reporting this in The Lancet?

A. Yes.

Q. Obviously in response, and you're referring to two possibilities in relation to that, isn't that correct?
A. Yes, that is correct.

Q. One is that this may be related simply to the amount of product which they have received?
A. Yes.

Q. And the way in which the protein I think in the product - wasn't that the theory at the time --
A. That's correct.

Q. -- may have interfered with their immune system?
A. Yes.

Q. And the second is the possibility that it has some relationship to the new condition, which was being called AIDS?
A. Yes.

Q. Isn't that correct?
A. Yes, because it's immune deficiency, abnormality within the immune system.

Q. Yes.

MR. FINLAY: Thank you, Dr. Jones.
A. Thank you.

THE CHAIRPERSON: Thank you, Mr. Finlay.

Thank you, Dr. Jones. That's completes your testimony.

THE WITNESS THEN WITHDREW.

THE CHAIRPERSON: We'll adjourn until tomorrow morning at 10:30. Thank you.

THE TRIBUNAL THEN ADJOURNED TO FRIDAY, JULY 12, 2001, AT 10:30 A.M.