PENROSE INQUIRY

C5

HEPATITIS C LOOK BACK

"…….. no longer a matter of policy but of legal liability"

(Lord Fraser of Carmyllie 22.12.1994)

Witness Statement of

David B. McIntosh

Former General Manager SNBTS (1990 – 1996)

14.11.2011

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Reference the Inquiry's letter of 26th October 2011 (A408152) - Answers to Questions 1 – 10

1 Introduction

1.1 Matters Included

1.1.1 I have tried to restrict my answers here to aspects of the matter in which I was directly involved or of which I remember having knowledge at the time. However, where matters have come to light as a result of the Inquiry team's work that have a direct bearing on a particular question, I have felt it appropriate to use and to quote from the Inquiry team's documents in my answers, even where I had not been aware of the documents at the time.

1.1.2 My answers given here therefore include a good deal of post-facto analysis, on the basis of the facts as I understood them at the time but also applying significant elements of hindsight, made possible

- partly by the more mature perspective lent by the passage of time; and
- partly by insights gained, or stimulated, by the evidence that the Inquiry has amassed and to which I am now privileged to have access.

1.1.3 I hope that this approach to the subject matter is in order and that the Inquiry may find it helpful in formulating its own analyses.

1.2 Witness Statement Numbering and Arrangement

1.2.1 Paragraph numbering throughout is based on the same convention as is used in this introduction. For ease of reference, all paragraph numbers in Section 2 relate directly to the numbering of the questions as asked. (The numbering is restarted over-page to fit in with the question numbers).

1.2.2 Each question is allocated a separate chapter, with a page break at the end of each.

1.3 Supplementary Questions

I am of course available to the Inquiry team if there are any supplementary questions that the Inquiry would like me to address.

David B. McIntosh

14th November 2011

2 Answers to Questions

1. What was Mr McIntosh's involvement in the look-back exercise?

1.1 As General Manager of the SNBTS, I was responsible for the overall performance of the Service and for ensuring that it fulfilled its allotted roles efficiently and effectively, within the budget allocated to it. My involvement in SNBTS activities was mainly as a leader, strategist and director; but did of course also involve some direct management of some of the 1,500 team members for whom I was responsible, from time to time.

1.2 In matters less directly related to SNBTS internal affairs, as for instance in the case of almost entirely medical matters being dealt with by the Medical and Scientific Committee (MSC) and by my Regional Directors working closely with their medical colleagues in local Health Boards, my managerial interventions were less direct and less frequent. It was not normally necessary for me to become involved in matters of this kind.

1.3 The Hepatitis C Look Back programme was an example of this latter kind of subject matter. Almost all of the detailed consideration of the matter, including the planning of the Look Back programme itself, was part of the professional responsibility of the SNBTS Medical and Scientific Committee (MSC). Implementation of Look Back was mainly the direct local responsibility of each Regional Director, in liaison with Health Board colleagues, including haemophilia directors, community medicine specialists, physicians and other professionals.

1.4 It is probably helpful in this context to point out that whereas Hepatitis C testing, as such, was very much an SNBTS activity, conducted and paid for within the SNBTS, the subsequent Look Back exercise was a rather different affair. Look Back activity took place to a great extent outwith the SNBTS and relied upon the consent, co-operation and hard work of a wide range of professionals and other staff in the Health Boards.

1.5 A fuller understanding of this point can be gained by study of the algorithm for the HCV Look Back programme (SGH.008.3098). As I remember it, much of the load of work to be done below the horizontal dotted line (below the words "at relevant hospitals with donation number and date of issue to hospital") fell upon hospital consultants, general practitioners and others whose patients may have been affected.

1.6 The ability of these staff to cope with the added workload and the efficiency with which Health Board and hospital systems could hope to deliver the goals of the Look Back exercise were, as I remember it, significant factors in the consideration given to the commencement of Look Back and to the timing of its wider introduction in Scotland (beyond Edinburgh and the South East) over the years 1992 – 1995.

1.7 At the planning stage and in the run up to the decision to commence universal implementation of the Look Back programme, the key player within the SNBTS was the Medical and Scientific Committee (MSC). The MSC was a sub-committee of the SNBTS Management Board and was therefore part of my overall responsibility as General Manager and Chairman of the Board, but most of its activities related to the professional areas mentioned above, in which I did not often need to get directly involved. Under the chairmanship of the SNBTS Medical Director, Professor John Cash, the MSC fulfilled its responsibilities in liaison with

1.7.1 the various national advisory committees involved, both at Scottish and UK level,

1.7.2 relevant professional bodies and individuals, nationally and at hospital level,

1.7.3 medical and other staff at the Scottish Office Home and Health Department,

1.7.4 medical and other staff at the Department of Health for England and Wales.

1.8 In the case of Hepatitis C Look Back, the scope of professional discussion and decision-making included microbiology, immunology, public health (community medicine), health economics, clinical treatment, counselling and care, as well as logistics and information technology. It was the MSC's responsibility to co-ordinate appropriate research on these issues and generate recommendations based on their results and upon the professional opinions of MSC members and those that the MSC and its members had consulted, including the various professional and national advisory bodies involved, both at Scottish and UK level. All of this was then supposed to be fed into formal recommendations made by the MSC to the SNBTS Management Board, to the CSA and to SHHD.

1.9 My role in relation to MSC responsibilities of this kind included:

1.9.1 seeking to help my professional colleagues to come to a clear conclusion on appropriate recommendations for action, in a timely manner;

1.9.2 intervening in the detailed debate if asked to do so by the MSC or one of its members, or if I had reason to believe that my involvement was necessary - either to help resolve conflicts or disagreements or to stimulate accelerated progress where I felt this was necessary; and

1.9.3 ensuring that an appropriate practical plan of action was prepared, authorised and implemented effectively and efficiently.

1.10 As I recall, my personal involvement in the consideration of Hepatitis C Look Back, as also in the planning and implementation of it, was not great. I remember it as one of those matters over which, as far as I could tell, the MSC was doing a good job and in which my personal intervention was not often necessary. (Now, with the benefit of hindsight, I find it hard to understand why I took such a "hands off" approach and this point is touched upon further in Clause 5, below, page 9 et seq).

1.11 In answer to this question 1, I have tried to describe the relevant structure of roles and responsibilities and to indicate my own personal involvement as accurately as possible. I hope that this has served to elucidate the background to the decision making processes that were at work at the time and so to help the Inquiry with its investigations.

1.12 However, I do not of course suggest that Hepatitis C Look Back was not part of my job. I make no attempt here to evade the responsibility that I had for the programme as the Service's General Manager and budget holder. Indeed, I am on record as having urged the commencement of universal Look Back in May 1994, some eight months before it was actually actioned (SNB.008.4779). I think that it is clear from this and other evidence gathered by the Inquiry that I did involve myself in the Look Back process at a strategic level and did try to contribute to its earlier introduction. With hindsight, the fact that I and like-minded colleagues achieved less in this regard than we should have done is a matter of regret (touched upon in Clause 5, below, page 9 et seq).

2 Why was the look-back not commenced earlier given that a screening test for anti-HCV was available from 1991?

2.1 The answer to this question can be dealt with at various levels. I am anxious to ensure as far as possible that I distinguish clearly here between what I regard as fact and what has to be to some extent speculative, even with the benefit of hindsight. In this clause 2, I try to restrict my remarks to the perspective I remember at the time. My deeper and, I hope, more helpful, analysis based on hindsight and the evidence to which I now have access, thanks to the Inquiry, is dealt with in clause 5 (page 9 et seq). I hope that this approach is helpful to the Inquiry.

2.2 It will I think be helpful to break this answer down into three parts, as follows:

2.2.1 Why? - in the most formal mechanistic of terms – as in "not commenced because the order to commence was not given" (covered here below);

2.2.2 Why? - in terms of the official reasons given at the time, which were certainly part of the story but may not have been the whole story (covered here below); and

2.2.3 Why? - in terms of what may actually have been going on behind the scenes and was influencing events, though not specifically stated as a reason for non-commencement at the time. (Covered more fully in clause 5, page 9 et seq).

2.3 At the first, simplest, level, the answer to the question – certainly as put to me as the then General Manager of the Service – is that Look Back was not implemented earlier because it was not authorised earlier. The record is clear (and has already been well documented by the Inquiry) that no formal go-ahead was given until December 1994 for January 1995. This was because the official professional recommendations that we were all getting in 1991, '92, '93 and almost all of '94 were that Look Back was not appropriate (mainly, as I understand it, for the reasons summarised briefly in Lord Fraser's letter of 22nd December 1994 to Tom Sackville MP (SNB.008.4848). Certainly, as I remember it, the instructions given to me by or via the Scottish Office Home and Health Department during that time were that universal Look Back was not the policy that I and my Service should follow.

2.4 In terms of the official reasons given at the time, I think the answer is also very clear. Put simply, whereas Hep C testing almost certainly began immediately to save (or safeguard) lives from September 1991 onwards – by greatly reducing further transfusion transmitted exposure - it was less clear (it was certainly less clear to me at the time) that a Look Back exercise would have any such clear-cut beneficial effect. This view is summed up well I think in Lord Fraser's letter of December 1994 (SNB.008.4848. paragraph 1). He explains the non-introduction of Look Back prior to that date as having been because of

2.4.1 concerns about the impossibility of finding all the exposed individuals;

2.4.2 doubts about the advisability, even if it were possible, of telling people they might be infected when no beneficial treatment was available to help them; and

2.4.3 fears that it would not be right to inform those few people that one might be able to trace, when all one could do was cause them "stress and anxiety without any benefit".

2.5 Lord Fraser went on to say (SNB.008.4848. paragraph 2) that "a pilot research study" carried out in Edinburgh (the Edinburgh Pilot Study - now well known and already well documented by the Inquiry) had by then established the feasibility and practicability of Look Back and that this had changed the situation.

2.6 Lord Fraser went on to say that because the practicability of Look Back had now been demonstrated, the feeling in Scotland was that it should be implemented Scotland-wide as soon as possible. As we know, this letter was sent to Tom Sackville in December 1994 and the universal introduction of Look Back for the whole of the UK was started almost immediately afterwards, in January 1995. The clear implication in Lord Fraser's letter would seem to be that the coming to light of the Edinburgh "pilot research study" was the trigger that made the commencement of universal Look Back both advisable and urgent in the winter of '94/'95.

2.7 I believe that a case could be made that the right answer to this question 2 is in line with the above. As I remember it, this is the case that was made at the time and the explanation that I myself accepted from 1991 until early 1994. I certainly don't remember feeling uncomfortable with the status quo for the two and a half years from the introduction of testing in September 1991 until Look Back became once again an urgent matter of debate in the second quarter of '94. I did not see Lord Fraser's letter (SNB.008.4848) at the time, but had I done so, I imagine that I would probably have felt that its analysis of the historic reasons why Look Back had not been implemented earlier did faithfully reflect the reality on the ground.

2.8 However, with hindsight, I believe it now to be clear that this official version of events was not in fact accurate. I believe that the full reasons why universal Look Back was not commenced earlier are both more complex and less commendable than those given at the time and repeated above. This is a matter of regret that I go into in more detail in answer to the Inquiry's question 5 (below, page 9 et seq).

3 How useful does Mr McIntosh think the look-back exercise was?

3.1 I do not feel qualified to offer a definitive personal judgement on this. I am not a medical practitioner, nor have I had time to research the records on this point. My further comments here are based almost exclusively on distant memory and hearsay. However, in summary, my understanding of the situation is that the Look Back exercise in Scotland was of significant value and did in fact improve the care and in some cases treatment of patients in Scotland who had been exposed to the Hepatitis C Virus through transfusion.

3.2 I have not been able in the time available since being called as a witness to the Inquiry to remind myself of the full facts of the Look Back programme (eg total numbers exposed to HCV, total still alive at the time of Look Back, total contacted, counselled, treated). However, as I understand it, the numbers of patients affected and the number helped as a result of Look Back are not insignificant.

3.3 It is important I think to emphasise here that the Look Back exercise pioneered by the Edinburgh and South East Scotland Blood Transfusion Service and commenced in the autumn of 1991 (long before the general commencement in Scotland as a whole) was particularly successful and helpful to patients. Clearly, the sooner action was taken on Look Back the more useful it was likely to be. This point is touched upon further in my answer to question 5 below (page 9 et seq).

4 What does he think was achieved?

4.1 As above, I do not feel qualified to help the Inquiry with a definitive answer to this question. However, I am attempting a partial answer here, mainly for three reasons:

4.1.1 I take it that by asking me this question the Inquiry has indicated that it believes that I should be able to throw some light on the subject and I therefore feel obliged to at least try;

4.1.2 I believe that I do have a reasonable layman's understanding of the matter; and

4.1.3 the answer to this question is inter-woven with all the others, particularly with the question as to why Look Back was not implemented earlier.

4.2 My understanding is that the key benefits of Look Back in general and the benefits actually delivered by the Scottish Look Back exercise in particular are:

4.2.1 to fulfil a moral/ethical requirement to inform those who may have been exposed to the risk of a transfusion transmitted disease and to inform also the doctors looking after them, so that the patients' condition can be checked and verified and that they may be made aware of it;

4.2.2 to allow those who are proven to have been exposed and infected (or potentially infected) to be given the right advice, counselling and where possible treatment, so that their quality of life can be made as good as possible under the circumstances;

4.2.3 even in the absence of any possible treatment, at least to allow counselling to take place on life-style choices (alcohol consumption, etc) that could affect their quality of life (by helping to improve, or to avoid unnecessarily rapid deterioration in, the patient's condition.)

4.2.4 allow also counselling of those infected to enable them and their sexual partners to take appropriate precautions to guard against the possibility of onward transmission.

4.3 I believe that some of these points were somewhat controversial in the early days following the discovery of the Hepatitis C Virus and I believe that some of them remain so, particularly the last (in relation to sexual transmission). However, it is my understanding that the professionals directly involved in Look Back do regard these as key benefits.

4.4 I think that all of these useful results (4.2.1 – 4.2.4 above) were eventually achieved to some extent throughout Scotland. However I believe that particularly valuable results were almost certainly achieved by the Look Back exercise commenced in Edinburgh and South East Scotland in 1991. As I understand it, the principal reasons why this was so are rooted

4.4.1 partly in the unusually advanced information technology available in the Edinburgh and South East Scotland RTC and in the hospitals in that region at the time (in contrast for instance to the Glasgow and West of Scotland region); and

4.4.2 partly of course in the start date chosen. Being started so soon after the introduction of HCV testing (and over three years before the last Scottish region followed suit) the Edinburgh exercise would always I think have had a better chance of making a significant beneficial impact than programmes started later.

5 What, if anything, would he have done differently in hindsight?

5.1 Armed with the documents that the Inquiry has gathered together, many of which I do not recall seeing at the time; and having given the whole matter a good deal of thought in the context of the Inquiry's work, with the benefit of hindsight, I think we should have taken a different approach to the whole issue of Look Back in Scotland from September 1991 onwards.

5.2 I feel that with the commendable exception of the Edinburgh and South East Region, Scotland did not handle the Look Back issue very well at all. I would certainly do things differently if I were able to re-visit the situation as it was in 1991/'92. I try here below to explain what I mean by this, through a "with hindsight" analysis of what I believe were some of the main imperfections and failings in what was done at the time.

5.3 With sincere apologies to Lord Fraser, of whom I imply here no criticism at all, I would like to use his letter of 22nd December 1994 to Tom Sackville MP (SNB.008.4848) as the centre-piece of evidence to illustrate the main points that I'm trying to elucidate.

5.4 By way of an introductory summary:

5.4.1 I believe that the facts show that when Lord Fraser wrote his letter of 22nd December 1994 he had been very badly advised and that one can only conclude from this that Ministers had been repeatedly badly advised throughout 1992, '93 and '94.

5.4.2 One assumes that Lord Fraser's letter must surely have reflected the collective wisdom of those advising him at the time, presumably based, in turn, on the advice his advisors had received from expert committees, professional bodies, individuals, etc. However, this being so, one finds it very hard to understand why his letter (SNB.008.4848) was worded as it was.

5.5 For instance, one inevitably finds oneself asking –

5.5.1 Why did Lord Fraser's letter refer to the Edinburgh initiative as a "pilot research study" when it had not in fact been a pilot since as long ago as 1991; had long since ceased to be a research study at all; and was in fact a well-established permanent Look Back programme – already working to the benefit of patients in Edinburgh and throughout the South East of Scotland?

5.5.2 Why did the letter state that the pilot study had been "carried out last year" (1993) when in fact it had been carried out in 1991?

5.5.3 Why did the letter go on to say that the practicability of a Look Back exercise created a duty upon Lord Fraser and his Secretary of State to "undertake the exercise as soon as possible" (in December 1994), when in fact the practicability had been proven years earlier and he could and should have been advised in exactly the same terms in December 1991, if not before?

5.6 Taking the three main reasons mentioned in Lord Fraser's letter (SNB.008.4848) for delay in the implementation of Look Back (from September 1991 to the date of his letter in December 1994, we have:

5.6.1 *Concerns about the impossibility of finding all the exposed individuals*

5.6.1..1 It must surely be true that not ALL of the exposed individuals could be found. Many would have already died; others, probably asymptomatic, would have melted out of sight, moved

house, moved GP, even moved to another country. Some (many) would be lost due to poor hospital record keeping or loss of records in fire or flood.

5.6.1..2 However, as I understand it, by as early as August/September 1991, and certainly long before December 1994, all serious doubts about the practicability of finding a significant and useful proportion of these individuals had been completely dispelled. The reports from the Edinburgh RTC are already well documented by the Inquiry. It is my understanding that by early 1992, if not before, the evidence had categorically refuted any residual argument that the difficulty of finding people was a valid excuse for further delays in the implementation of Look Back.

5.6.1..3 This is a statement of opinion of course, no more than that; but I would suggest that the Inquiry already has, or can easily obtain, sufficient corroborative evidence to support this assertion.

5.6.1..4 I believe therefore that Ministers should have been properly briefed about the Edinburgh work and its implications at a much earlier date (than December '94); and that, had this been done, full Scottish implementation of Look Back would almost certainly have been achieved in January 1992, not January '95. (Some possible reasons why this may not have been done are touched upon below.)

5.6.2 *Doubts about the advisability of telling people they might be infected when no beneficial treatment was available to help them.*

5.6.2..1 I believe that this was indeed a valid concern for many for quite a long time, and may indeed have continued to affect the thinking of opinion formers and decision makers well beyond September 1991. Indeed, I myself recall holding this view, or at least accepting it without question when it was put to me in these terms by my medical and scientific colleagues at the time. However, with hindsight, I simply don't believe that it stands up.

5.6.2..2 To take just one example, from the Inquiry's Preliminary Report (Chapter 9, page 258, para 9.39 and footnote 39), the report by Hoofnagle at al , published as early as 1986, suggested that chronic NANB Hepatitis might be controlled somewhat by interferon treatment. As I now understand it, from 1986 onwards there was an increasing body of evidence that there were in fact treatments such as interferon and other regimes by which patients exposed to Hepatitis C could be helped. Not "cured" probably, but certainly in many cases helped significantly. This should I believe have been made clearer to Ministers earlier, and would have had a significant influence on opinion forming and decision making with reference to Look Back in the "gap years" in question ('92-'94).

5.6.2..3 Furthermore – and I feel personally very unhappy that this point was not much clearer to me at the time (as I believe it should have been, if only on the grounds of common sense) – caring for people infected with Hepatitis C does not consist simply of looking for a cure for them, or ways of controlling the disease. It also involves life-style counselling (in relation for instance to alcohol consumption and other aspects of fitness and health) as well as psychological support and arguably also advice to help avoid the spread of exposure to partners and family. In any event, I believe that by December 1994, those charged with advising Lord Fraser on these important matters did not do well to still be giving him "no available treatment" as an excuse for delays throughout the early '90s in the implementation of full look-back in Scotland. In that context, it may for instance be useful to enquire of the professionals concerned why Look Back was actioned

immediately when HIV testing was introduced, but the same approach was not adopted in the case of HCV testing.

5.6.3 Again, my assertions here are my own personal and non-medical opinions; but I would suggest that the Inquiry already has, or can easily obtain, sufficient corroborative evidence to support them.

5.6.4 *Fears that it would not be right to inform people when all one could do was cause them "further distress and anxiety without any benefit".*

5.6.4..1 The fear of unnecessarily distressing people had of course been a significant factor in the early days of the debate about Look Back. It was I believe a valid concern, and indeed remains so to some extent. However, when one removes the phrase "without any benefit" (which I believe one now must) the point becomes much weaker.

5.6.4..2 In my view, if there are indeed some potential benefits to be gained, possibly including some really useful controlling regimes, then these need to be balanced against the degree of distress caused; and hard but necessary decisions then taken as to the appropriate action to take or to refrain from in individual cases. The idea that this argument can constitute a valid reason for an across-the-board postponement of Look Back for three years or more is surely a complete nonsense – and always was, if we'd only looked at it clearly.

5.7 With hindsight therefore I think one would have to say that the advice given to Lord Fraser as he composed his letter of December 1994 (or the drafting of that letter done for him by civil servants) did not accurately represent the facts. Looking back, I believe that one has to come to the conclusion that Lord Fraser was badly informed and badly advised, then and throughout the three years '92, '93 and '94.

5.8 I believe this (5.7) to be true, but of course the specific advice that civil servants gave to Lord Fraser on the occasion of his letter to Tom Sackville MP is not my point; and I certainly have no intention of implying any criticism of Lord Fraser himself. My point is that Lord Fraser's letter affords us now with an excellent window of insight into the "body of opinion" that was controlling events at the time – and had been doing so since 1991.

5.9 I do not attempt here anything close to a thorough examination of how far the professional bodies and individuals advising Ministers at the time did in fact wholly believe in the three reasons for delay cited in Lord Fraser's letter and how far they were swayed by other considerations. A comprehensive analysis of these matters will no doubt emerge from the Inquiry's wider investigations. However, some of the possible considerations of which I am aware are mentioned here below in the hope that this may be of some value to the Inquiry.

5.10 As I understand it, the reasons why Scottish Ministers were not properly briefed and not advised to implement Look Back earlier were mainly rooted in a damaging lack of focus and clarity in the systems in place to provide them with professional advice. This belief is expanded upon below (5.13 to 5.28).

5.11 However, I believe that events may also have been influenced by "health economics" and cost considerations. I do not recall these as important factors in the delay of Scottish Look Back, in terms of Scottish costs, as such. However, as I understand it, there was concern at the time in

England about the affordability, not only of the Look Back exercise itself but also the costs associated with the extra counselling and care needs that would inevitably follow. It may therefore be that these cost considerations influenced the English Department of Health, both to delay the implementation of Look Back in England and Wales and also perhaps to exert its influence on Scottish colleagues to delay implementation here too. I believe that there is some evidence that this may have been so. More importantly perhaps, it is indeed very difficult to find reasonable explanations of some of the acts and omissions of the professional advisers and civil servants involved without assuming that behind-the-scenes cost considerations were at least partly responsible.

5.12 Whether or not English cost considerations are proven to have influenced events in the way mentioned above (5.11), it is my belief that if we had had a better system for the generation and delivery of professional advice here in Scotland, then outside interference from Whitehall, real or imagined, would not have been able to gain a decisive influence on events. I have therefore concentrated here below on the elements of Scottish professional opinion as I remember them, making no further reference to costs, which I do not believe were a direct factor of influence in Scotland, certainly should not have been, and need not therefore have concerned us in the SNBTS.

5.13 On this basis, re-visiting the question posed to me about "why the delay" in implementing full Look Back throughout Scotland (question 2 above), I would like to suggest an analysis of the situation from a different angle to the one used at the time and set out in my answer to question 2. This different approach is as follows:

5.13.1 Why did Ministers not authorise/instruct Look Back in 1991? Because they were not advised to do so.

5.13.2 Why were they not advised to do so? Because the weight of professional opinion in Scotland had not yet shifted decisively in favour of such a move.

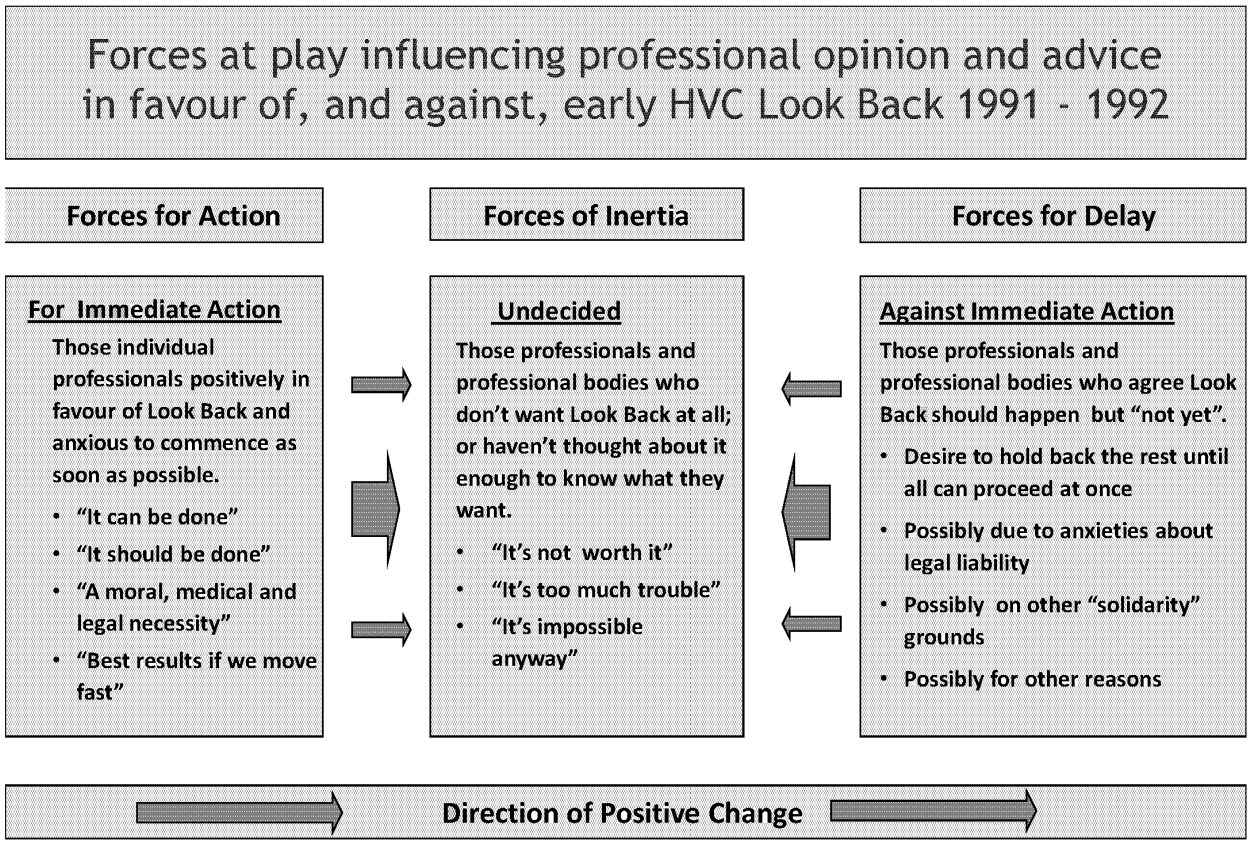
5.13.3 How could this be? If transfusion professionals, hepatologists and others in Edinburgh and the South East of Scotland had deemed it appropriate to implement full Look Back in the best interests of patients in their part of Scotland, why was the professional consensus not advocating this as an appropriate approach elsewhere in the country until over three years later? Why had professional opinion been so slow to catch up with what looks now, with hindsight, like an obvious body of evidence and good sound argument in favour of an immediate introduction of Look Back in September 1991? This is I believe the key question. In the answer to it lies the nub of my sense of what I would do differently if I had my time over again – and is, I believe, the key to better practice in the future.

5.14 In other words, I do not believe that one single "error" was made at the time, nor that any single individual or even group of individuals should necessarily be held responsible for the failings of 1992 through '94. I do however believe that our opinion forming and decision making systems and procedures were faulty. I hope that their modern equivalents are already much better than ours were. If not however, I hope that the Inquiry's findings in this respect may serve to generate the significant improvements that are necessary.

5.15 If it is accepted that what was wrong in 1991 was not the actions of Ministers, nor the poor advice they received from civil servants, but the roots of that poor advice – the recommendations

emerging from the body of professional opinion – then it may be helpful to examine how that "body" operated. At Fig 1 below I have suggested a schema that I hope may be helpful in analysing the forces involved.

Fig 1.



5.15.1 As I remember it, the central "Inertia" block consisted partly of those for whom Look Back seemed like too much cost, trouble and upheaval. They may have felt that it was not worth trying to find the very few affected people who might still be alive, still contactable and capable in any way of benefiting from the news of their possible infection. Many of these were dealing with hospitals whose IT systems gave rise to little confidence that many people at all could be traced and this seemed to add weight to the "do nothing" argument. There were others I think who recognised that Look Back might be a potentially valuable exercise but did not give it a high priority. As I remember it, a third category of professional in this group consisted of those who, regardless of their own personal opinion, were content to follow what seemed to be the consensus view. (Regretfully, I class myself as having been a lay member of this group at that time.)

5.15.2 The block on the left is my way of representing those in Scotland who were voicing active support for immediate Look Back. Principal among these were the professionals at the Edinburgh

and South East Scotland RTC and in particular Dr McClelland and Dr Gillon with whom I recall having a number of conversations at the time and whom I remember as enthusiastic and consistent supporters of the early introduction of Look Back for all. The force for change exerted by the Edinburgh centre is represented by the large left-to-right arrow opposite the "pro-look back" block in Fig 1.

5.15.3 The block on the right, in Scotland, is best represented by Professor Cash and the colleagues who followed his lead. Much, if not perhaps all, of its driving influence seems to have come from England, from the MSBT committee and the DoH in Whitehall. The "braking force" that they exerted is represented by the large right-to-left arrow opposite the block of those seeking to delay Look Back. This position was apparently supported by many colleagues both North and South of the Border, including, it seems, the majority of the advisory committee on the Microbiological Safety of Blood and Tissue for Transplantation (quoted in Lord Fraser's letter and also well documented elsewhere by the Inquiry).

5.15.4 With apologies to the Inquiry team if this method of exposition seems clumsy, I would like to explain that the reason I am presenting the formation of Scottish professional opinion in this way – as one central mass of inertia exerted on by two force fields working in opposite directions – is two-fold:

5.15.4..1 Firstly because with hindsight I do believe that things were in fact essentially that chaotic and, for useful lessons to be learned for the future, the nature of that chaos needs to be better understood; and

5.15.4..2 Secondly because this force-field model does I think go a long way towards explaining the long (3yr +) delay in full implementation of Look Back in Scotland after Edinburgh and the South East had, effectively, left the "field of battle" (the forum of debate).

5.15.5 With hindsight, I believe that had Edinburgh not been allowed to "go it alone" in the way that it did, but had a consensus been sought to give effect to a simultaneous immediate implementation of Look Back throughout Scotland, then things would have turned out altogether differently.

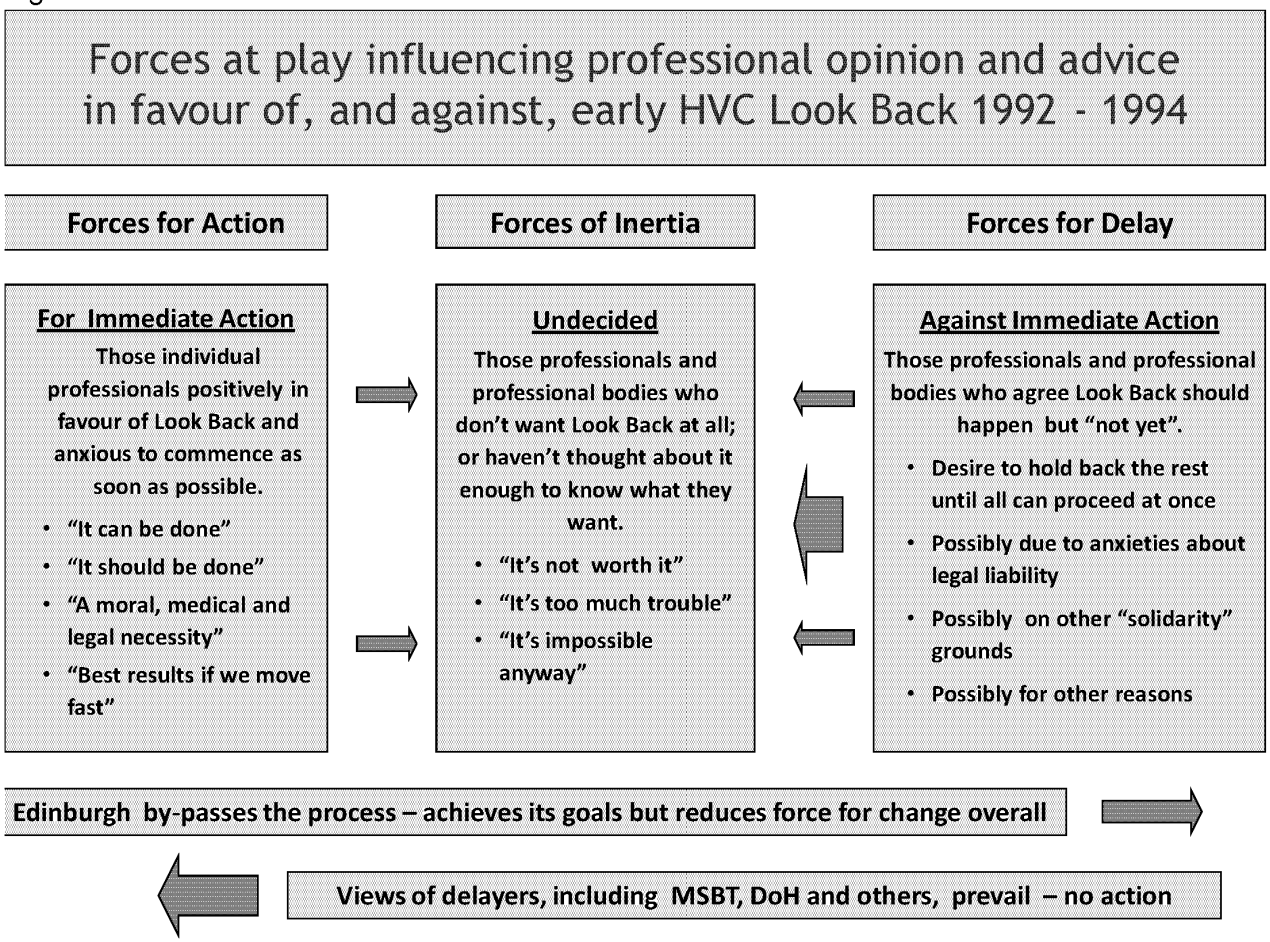
5.15.6 I believe that had the very proper arguments that swayed Edinburgh in favour of immediate introduction of Look Back been more widely deployed at the time (by the MSC, by myself and others) then the overwhelming weight of professional opinion in Scotland (medical, scientific and legal) could and should have been mustered around a recommendation to start everywhere in Scotland straight away.

5.15.7 I also believe that had Ministers been so advised, they would have had to decide to accept the recommendation and authorise immediate Look Back in the Autumn of 1991, or very early in 1992 at the latest - for all the good reasons so well put – so very much later - in Lord Fraser's letter of December '94 (SNB.008.4848).

5.16 As is now clearly documented in the Inquiry's evidence, in late 1991 the Edinburgh centre stopped arguing and simply implemented full Look Back in its own region. The team there did so quietly. They did not I think try to hide what they were doing. They just activated a full implementation without fuss or fanfare and simply got on with it. As far as I recall, at that point they stopped trying to persuade MSC colleagues to follow them into a full Look Back exercise. I do not

remember them seeking to exert further influence on the deliberations of the MSBT committee, nor the decisions of the DoH or SHHD. With hindsight, I believe that this had the unintended consequence of altering the balance of opinion and the weight of argument - for and against Look Back throughout the rest of Scotland, from 1992 onwards, as illustrated in Fig 2 below.

Fig 2



5.16.1 Looking back, I think that a partial reason for this turn of events may have been that the Edinburgh team may have felt that this was an argument that they might well not win and that if they lost it they might well be obliged to fall into line with the other RTCs and do no Look Back until later, possibly much later. If this were so, it would be fully understandable if they were to have felt disinclined to take this risk and chose instead to quietly go their own way.

5.16.2 Those who may be inclined to consider this suggestion somewhat fanciful may do well to remember that the Edinburgh team had as a salutary example the experience of Dr Lloyd at the Newcastle RTC in connection with his brave decision to go ahead with HCV testing well advance of the main pack. His treatment by his peer-group and indeed most of the blood transfusion community in England had been simply appalling as a result of his going it alone on HCV testing.

5.16.3 One could well understand it if Dr McClelland and his team were perhaps anxious to avoid similar repercussions on themselves if they "broke ranks" over Look Back. Again those who find all this rather melodramatic are likely not to have worked in this environment and never to have felt what it can sometimes be like to cross swords with senior medical colleagues. I do not wish here to imply that I know for a fact that the scenario postulated above was the reality of the situation at the time; simply that it would have been understandable if it had been.

5.16.4 Whatever the full reasons may have been, I believe it is a fact that after Edinburgh's low key implementation of Look Back throughout the South East region, and for the three years thereafter, the forces acting on the Scottish "body of opinion" were changed in the way shown above (Fig 2).

5.17 This may seem thoroughly too mechanistic a model, but with the benefit of hindsight I do believe that had I as General Manager supported Dr McClelland and his team more strongly and more openly in late 1991 and had we kept up the pressure for universal Look Back in late 1991 then we could (and should) have achieved that goal in January 1992 rather than in January 1995.

5.18 I believe that the proof of the thesis I propose here lies in the wording of Lord Fraser's letter of December 1994. He made it very clear in that letter that the issue was by then "no longer a matter of policy but of legal liability". This was, I feel sure, the advice he was getting from all sides by then. The deficiency in the situation, as I now see it, was that all the key elements that made this true in December 1994 had in fact all been in place since at least December 1991. I believe that it is now clear that he should have been given this advice at that much earlier date. I also believe that with the benefit of hindsight we should all of us have realised this at the time.

5.19 I believe that from September 1991 onwards, opinions still being expressed by MSBT committee members, by Professor Cash and others on the desirability of doing the exercise "equally and uniformly throughout the UK" had become irrelevant. "As soon as possible" was the only legitimate answer to the question; and since Edinburgh had already shown it to be possible, "as soon as ..." meant "now".

5.20 The point can not, I think, be expressed better than it was by Lord Fraser in his letter of 22nd December 1994;

"……I consider that I have little choice but to take this forward in view of the position in Scotland."

I believe that he was absolutely right. Unfortunately, I also believe that he had been made properly aware of the position in Scotland three years too late.

5.21 This being so, and reverting to the force-field analysis suggested above (Fig 2, page 15) I believe that it may be helpful to look a little more closely at what was being done and how one might do it better in future.

5.21.1 First of all, I believe that the experts involved, including the expert advisory committees, often mistook their roles; and that their advice was often also mistaken as a result - used in ways that were not helpful and not appropriate. This was I think partly due to a natural tendency in such situations for professional experts to stray beyond their proper territory, but mainly because the terms of reference and the field of influence of the various bodies and individuals involved was not properly defined in the first place. Where their expertise began and ended was not well delineated.

What exactly they were called upon to do does not seem to have been set out for them in the most appropriate way.

5.21.2 I appreciate that, as with much of this "hindsight" part of my statement, these thoughts are very personal observations. However, as I understand it, there a number of symptoms shown in the record that point in the same direction:

5.21.2..1 It may well be that I am wrong and the role of the MSBT for instance had in fact been properly defined. It may have taken a highly focussed approach to its work. It may be that its proceedings were well chaired and well supported (minuted, project managed and progress monitored, assessed and reported on) but if so, one does have to ask - how on earth did it manage to live through 1992, '93 and '94 still urging further delay on Ministers?

5.21.2..2 Also, if for instance, the MSBT, the SNBTS MSC, Professor Cash and other medical and scientific professionals had come (as the record shows that they had come) to the conclusion that Look Back (in due course) was a desirable goal – medically and scientifically – then on mature reflection it is surely hard to understand why any of them were expressing an opinion, throughout the years in question, in favour of delay on the grounds that "everyone really ought to move at the same time". This seems to me to be a clear case of people mixing up different aspects of the matter, some of which were within their remit as doctors and scientists and some of which were not. It the Look Back was a good thing to do – in the best interests of patients – then surely it should have been done as early as possible in all areas where it was possible, not be delayed to coincide with the speed of the slowest. Even if there were good arguments for such delay, I would suggest that it is extremely difficult to understand how these could have been medical and scientific arguments.

5.21.2..3 There may be good medical and scientific reasons why simultaneous commencement of Look Back throughout the land is a highly desirable goal, but I believe that this is extremely unlikely. Indeed, if it were so, then we would need to note an extraordinary irony in the fact that on the occasion of our distinct Scottish failure to achieve this apparently medically desirable goal, the medical consequences for patients affected by the "rule breakers" (eg Edinburgh and the South East) were almost certainly more favourable than those suffered by patients in areas that followed the party line. It is very hard, with hindsight, to see how insisting upon a universal but much later introduction of Look Back can possibly have been a genuinely "professional" thing to do.

5.21.2..4 It is conceivable that, even at quite a late date, the question of Look Back delays was not entirely a political one. It may have been at least partly a Health Economics question. It may indeed in some cases have been a question of "we know we should do it, but we simply can't afford it". A host of practical obstacles could and may have been involved (in parts of England and Wales, though not, as we now know, in Scotland). Nevertheless, I believe that it remains very hard to understand why any of these matters should form any part of the deliberations of the MSBT or any other specialist advisory body charged with giving medical and scientific advice related to transfusion transmitted disease.

5.22 In addition to deficiencies in the way that professional advice was formulated, I also believe that the interface between the various advisory bodies and individuals involved on the one hand and the civil servants advising Ministers on the other was sub-optimal. It seems to me to have been an

unnecessarily grey area, where fudge and misunderstanding had a tendency to flourish. Again, as with the professional advisory agenda itself, I believe that a much greater effort should have been put into the following:

5.22.1 clarifying the issues and specifying the key questions to be answered;

5.22.2 allocating the appropriate investigative and advisory roles to the right bodies and people – getting the right people to address the right questions;

5.22.3 specifying the appropriate rules of engagement and boundaries between the bodies and individuals involved;

5.22.4 ensuring that the right facts were amassed and their relevance clearly highlighted;

5.22.5 generally setting things up to optimise the clarity and relevance of all deliberations and discussions and to minimise fudge and confusion and ensuring that Ministers are properly and fully briefed in a timely manner.

5.23 I appreciate that the simple managerial approach I am proposing may not always be possible. At some points in the system, a certain amount of ambiguity and fudge may at times be inevitable – cushioning Ministers and their civil servants from the direct impact of less desirable features of events; and affording them an appropriate amount of plausible deniability. However, I do believe that a basic minimum of "managerial" clarity was missing from our work on Look Back from 1991 to 1994 – throughout the UK - and that this had highly undesirable consequences.

5.24 It certainly seems to me to be clear with the benefit of hindsight that as General Manager of the SNBTS I personally should have asked more questions, pressed harder for answers and been less tolerant of pseudo-professional fudging than I was at the time.

5.25 Unless these deficiencies have already been put right, I would strongly suggest that lessons can still be learned from those experiences, to the benefit of future managers, professionals, politicians and patients alike.

6 Why was it not thought appropriate to look back over previous donations when screening was introduced in 1991? Who thought it was inappropriate to look back over previous donations? What consideration was given to the idea at the time?

6.1 If this question 6 refers to the same Look Back considerations as those underlying question 2 (above) then I would refer back to my answers to questions 2 and 5 (page 5 et seq and page 9 et seq above).

6.2 However, as I understand it, this question probably relates to the scenario in which comprehensive re-testing is undertaken of the whole "archive" of donor samples after the introduction of testing – regardless of whether any individual donor may have tested positive or not under the new testing regime. For the purposes of this statement, I shall call this "Type 2 Look Back".

6.3 I think that question 2 (above) related to what we would normally mean by "Look Back"; that is to say the systematic re-testing of a defined number of archive samples of all donors subsequently proving, under the new testing regime, to be currently HCV positive. As I understand it, under this classic Look Back approach, archive samples of donations from donors who have either proved to be HCV negative under the new testing regime, or have not re-presented as donors at all are not subjected to further testing. In the hope that a clear distinction between these two forms of Look Back may be helpful to the Inquiry, I shall refer to this more targeted Look Back as "Type 1 Look Back" (the kind that was eventually implemented throughout Scotland.)

6.4 I believe that this distinction is an important one. The answer to why it was not thought appropriate to look back over previous donations in 1991 in the Type 1 sense is that it was indeed thought appropriate; that it was done immediately in Edinburgh and the South East and subsequently done elsewhere also. The answer to the question, why was a larger-scale comprehensive Type 2 Look Back not contemplated, involving all previous donation samples, regardless of the known current HCV status of the donor, is that this type of look back was considered but rejected, for, as I understand it, good professional reasons.

6.5 In the case of Hepatitis C Look Back, the scope of early professional discussion and decision-making included microbiology, immunology, public health (community medicine), health economics, clinical treatment, counselling and care, as well as logistics and information technology. The weight of each of these in the deliberations (and, sometimes, arguments) about Hep C Look Back varied over time and as between different experts. As I have outlined in my answers to earlier questions (above) the overall "centre of gravity" of the deliberations did not shift conclusively in favour of the implementation of any sort of Look Back programme until quite some time after the introduction of Hep C testing in 1991.

6.6 This was I think because the issues were not as clear cut, nor was the balance of cost-to-risk-to-benefit as obvious in the case of Look Back, certainly not in the early days as it was in relation to the actual introduction of Hepatitis C testing (C4). This was particularly true of the issue of what I have classed above (informally) as Type 2 Look Back.

6.7 Even when the main Look Back programme had become an accepted fact, a "good thing" to do, as I understand it, this did not extend to Type 2 Look Back. As I recall, the professional consensus that emerged was that there would be more value – in terms of improved patient

outcomes and the cost/benefit balance associated with the exercise – if efforts were to be concentrated on current donors and "fresh" cases (Type 1 Look Back). As I recall, this was not a subject of any great controversy. In addition to being generally a larger and more costly exercise, I would expect that any attempt at Type 2 Look Back is likely to involve greater difficulty in finding the relevant people and would also tend to involve a greater lapse of time between any critical exposure events and the action to do something about them. The greater the distance in time between the donation/transfusion events and the Look Back exercise, the less useful the Look Back is likely to be.

6.8 As I remember it, Type 2 Look Back was discussed in 1991, given serious consideration, but was ruled out as inappropriate, mainly I think for the reasons summarised above.

6.9 In answer to the question about who thought it was inappropriate, I think one correct answer, in relation to Type 2 Look Back, is that almost everyone did. In terms of the official advisory and decision making process however, I'm afraid that I have to refer the Inquiry once again to my notes above and to my "force field" analysis (though in this case without the inherent tensions and disagreements that characterised discussion of the main, Type 1, Look Back exercise). In my time at least, these things tended to be a matter of the subtle osmosis of professional consensus. Many expert bodies and individuals were involved in decisions of this kind. It was in the nature of the thing that no one person or body was ever quite fully responsible for anything.

6.10 As I have already outlined, above, I regarded the vagueness of these decision making processes as a deficiency at the time – and more so with hindsight. On the question of Type 2 Look Back however, I do not believe that this was actually a great problem. It is clearly for others to decide whether, in retrospect, such an exercise would in fact have been valuable or not, basing their judgements on hard medical and scientific data, together with whatever health economics and political considerations are also fed into the equation.

7 There appears to have been a significant change of direction following the meeting between SNBTS and SHHD on 24 May 1994. Prior to the meeting Mr McIntosh advised the SHHD that the SNBTS intended to commence an HCV look-back on 1 June 1994. Following the meeting he advised the SNBTS Directors that the SNBTS would not be starting a full scale HCV look-back programme until further consultations had taken place. He noted that it had been agreed that the preferred route would be via a UK wide policy if at all possible. What was discussed at the meeting on 24 May 1994? Who made the decision not to commence an HCV look-back in Scotland on 1 June 1994? Why was that decision made?

7.1 With apologies to the Inquiry, I have to confess that I have no recollection of this particular SNBTS/SHHD meeting on May 24th 1994. Indeed, until I read the most helpful file of documents that was sent to me by the Inquiry, I had had no recollection of my memo of 19 May to Rab Panton either (SNB.008.4779). However, on reading through the evidence and giving the matter hindsight-assisted thought I believe that I can safely say the following:

7.1.1 Whenever issues of this kind arose there was a default tendency that, ceteris paribus, SHHD would want the SNBTS to act in harmony with the NHS in England and Wales. As has been presented in evidence to the Inquiry earlier this year (C4), this was certainly the case with the introduction of Hepatitis C testing. As I remember it, this was also the case with Look Back.

7.1.2 On occasions of this kind, where I knew that the prejudice would naturally be in favour of following the English, and where I had good reason to argue in favour of earlier action in Scotland, I would send a memo of the kind seen in SNB.008.4779 – making a brief case, notifying the Department of my intentions to act, not asking for comments and certainly not asking for permission, but giving the Department enough time to act to change my plans if they felt that this is what Ministers would want. Re-reading it now, my memo of 19th May is a very typical version of this kind of communication from me to the Department throughout my time in post.

7.1.3 Judging from the other records from the same time (in relation to the change of heart mentioned in the question above) it seems clear that on this occasion the Department came back very quickly and said – no, thou shalt not.

7.2 So, taking the sub-questions in order:

7.2.1 What was discussed at the meeting on 24 May 1994? – I feel certain that what was discussed, inter alia, was the importance that Scottish Ministers (or at least the Department on their behalf) placed on waiting to implement full Look Back in Scotland until the UK-wide starting date agreed with the DoH for England and Wales. I must emphasise that I do not actually specifically remember this meeting, but I am absolutely sure that what took place would have been essentially a Department-ordered re-think of the planning for Scottish Look Back and its postponement to fit in with the English dates.

7.2.2 Who made the decision not to commence an HCV look-back in Scotland on 1 June 1994?

7.2.2..1 Strictly speaking, I believe it's probably true to say that I did. As General Manager I had been planning for implementation on June 1st and in order for that not to happen I had to

change the instructions that I issued. However, I only did so because I was instructed to do so by SHHD, so perhaps the best answer would be "The Department did."

7.2.2..2 However (yet again, another "however") the real truth - the most accurate and helpful for the Inquiry's purposes - is probably that we all conspired to make the decision – some by their actions (in which category I would put the Department team, Professor Cash and others) and others by their inaction (in which category I would put myself and, through no fault of their own, Ministers). By "inaction" in my case I mean my failure to push back against the Department's decision and the pressure being exerted by some of my medical colleagues, that Look Back should be further postponed.

7.2.3 Why was that decision made?

7.2.3..1 As I have mentioned above (Clause 5, pages 9-19), I believe that this decision and earlier decisions like it going back to September 1991, were taken for all the wrong reasons.

7.2.3..2 I do not believe that any of us were acting to the right brief nor were many of us giving or receiving the right advice when it came to this discussion of Look Back in May 1994, nor for that matter in any such discussion in the two previous years. Our thinking was muddled.

7.2.3..3 If at a much earlier date we had exercised the clarity of thought set out so succinctly but so terribly late in Lord Fraser's letter of December 22nd 1994 (SNB008.48.48), we would have understood clearly that

- Look Back was "no longer a matter of policy but of legal liability"; and
- we already had "little choice but to take this forward in view of the position in Scotland."

7.2.3..4 Having said that, the official reason why the decision (of May 1994) was taken was of course because it had been deemed appropriate – by the medical and scientific community as well as by civil servants - that all the UK blood transfusion services should implement full Look Back as from the same date (later announced as January 1995). The rank absurdity of this decision has been analysed above and is I think now crystal clear from the records that the Inquiry has amassed. However, though with hindsight I believe that this should have been obvious to us even at the time, sadly, it was not.

8 How was the look-back "taken forward" for "all areas of Scotland"

8.1 This is not as straightforward a question as it might appear. For one thing the whole of the Edinburgh and South East Region had already established a full-scale Look Back programme in September 1991, so there was no need for the new universal Look Back exercise to be "taken forward" in this part of the country. It had been fully implemented years ago and was on-going.

8.2 However, for the other Scottish regions, which had waited for the UK-wide starting gun to go off before instigating their own implementation, the process was relatively straightforward. The process is probably best understood via the algorithm developed specifically as for the purpose (SGH.008.3098). The various other guidance notes already on record in the Inquiry's files (including SGH.008.3093, SGH.008.3094 and SGH.008.3099) may also be useful in this regard.

8.3 It should be stressed however that the tasks involved were not as easy in some regions as in others. I remember for instance that Glasgow and the West of Scotland was dealing with a particularly large number of hospitals whose record systems and record keeping generally did not lend themselves nearly as well to the exercise as was the case in Edinburgh. Many of these Look Back exercises were complex and time consuming, for SNBTS personnel and Health Board staff alike. In that sense "taken forward" is a good description; better for instance than the simpler term "actioned". Implementation could be a long and complicated affair.

9 What happened, if anything, in Scotland between 22 December 1994 and 11 January 1995? Did the SNBTS take steps to implement the look-back in Scotland prior to the announcement of the UK wide look-back? If not, why not?

9.1 As outlined above, Edinburgh and the South East had implemented full Look Back long since, so there was nothing new or different to be done there in either December '94 or January '95. The other regions will have used the very short gap between these dates (bearing in mind the Christmas and New Year holidays intervening and the inevitably heavy seasonal pressure on the whole Service at this time of year) to make their final preparations for the official launch of Look Back in January.

9.2 I dare say, though I can not confirm this categorically, that some centres may have jumped the gun by a few days at around this time – knowing that full implementation was coming and wanting to make a good start. This may be worth checking via the records, or with witnesses whose memories on this subject are sharper than mine.

9.3 As explained above in answers to previous questions, consideration was indeed given to implementing Look Back in Scotland prior to the announcement of the UK wide Look Back, but this was decided against.

9.4 I hope that some light has been shed on the "if not, why not" part of this question in my answers to previous questions, particularly question 2 and question 5. As the Inquiry knows, I believe that the reasons "why not" were misplaced and, with hindsight, were largely spurious.

10 How were the procedures attached to the CMO letter of 3 April 1995 implemented in practice?

10.1 I believe that the algorithm (SGH.008.3098) and the various other guidance notes already on record in the Inquiry's files (including SGH.008.3093, SGH.008.3094 and SGH.008.3099) give a fair picture of what was intended and what did in fact take place.

10.2 As I understand it, both in Edinburgh (in 1991 and onwards) and in the rest of Scotland (from 1995 onwards), the implementation of the Look Back programme including the diligent following of its agreed practices and procedures was satisfactory.

11 I hope that the above notes are of value to the Inquiry and am of course available to answer further question on these and/or other matters if required.

David B. McIntosh

Former General Manager, SNBTS (1990-'96)

14th November 2011