Witness Name: William Wright
Statement No.: WITN2287019
Exhibits: WITN2287020 –
WITN2287086
Dated: 15th April 2021

INFECTED BLOOD INQUIRY

EXHIBIT WITN2287028

Health Committee

{report number} {Year}

Hepatitis C

SP Paper 398 1 (2001)

Remit and Membership

The remit of the Health and Community Care Committee is to consider and report on matters relating to health policy and the National Health Service in Scotland and such other matters as fall within the responsibility of the Minister for Health and Community Care.

Membership:

Dorothy-Grace Elder

Janis Hughes

Margaret Jamieson (Deputy Convener)

John McAllion

Shona Robison

Mary Scanlon

Dr Richard Simpson

Mrs Margaret Smith (Convener)

Ms Nicola Sturgeon

Committee Clerks

Jennifer Smart

Peter McGrath

Fraser Marwick

The Committee reports to the Parliament as follows-

BACKGROUND

1. This report arises from the fact that in the 1970s, 1980s, and possibly also in the 1990s, a number of individuals became infected with hepatitis C as a result of receiving blood or blood products provided by the Scottish National Blood Transfusion Service ("the SNBTS"), an NHS agency.

2. Hepatitis C is a virus which attacks the liver. It is a serious, potentially fatal disease. Physical symptoms include serious skin and digestive problems, and extreme fatigue. According to written evidence we obtained from the Haemophilia Society, up to 80% of individuals infected with the virus may also go on to develop chronic liver disease, and up to 20% cirrhosis of the liver, which may in turn lead to liver cancer.[1]

3. The illness also has serious practical and psychological consequences. Again according to written evidence from the Haemophilia Society, the illness can cause anxiety and depression and this, combined with the fear that the virus can be spread by sexual contact (although the risk, as we understand it, is thought to be very low) puts strain on relationships. Diagnosis of the disease makes it almost impossible to obtain mortgages or life assurance, and many hepatitis C sufferers cannot hold down employment because of the nature of their illness.[2]

4. It is nothing short of tragic, both for the sufferers themselves and for their families, that a number of individuals, in the course of receiving medical treatment on the NHS, should have been infected with the virus. The scale of this tragedy, however, is not clear. It is known that a greatly disproportionate number of haemophiliacs (who suffer from an inherited condition inhibiting the ability of blood to clot naturally, which is treated through the use of blood products) have been

affected.[3] As a result, much of the lobbying and campaigning on the issue of hepatitis C-contaminated blood has been by individual haemophiliacs and in particular by the Haemophilia Society, a volunteer patient group composed of haemophiliacs and their families.

5. However, the issue should not be regarded solely as a problem for haemophiliacs. It is known that a number of non-haemophiliacs have become infected with hepatitis C through blood or blood product transfusions, though just how many is not known.[4]

The Committee's involvement

6. The Health and Community Care Committee's direct involvement in this issue arises from two petitions referred to us by the Public Petitions Committee. Petition PE 45 from the west of Scotland branch of the Haemophilia Society called on the Parliament to conduct an independent inquiry into the contamination of blood products for haemophiliacs with hepatitis C, and for consideration to be given to

awarding compensation to those infected. Petition PE 185 from GRO-A (a non-haemophiliac who contracted hepatitis C as a result of a blood transfusion during a routine operation in 1989) called for the Parliament to set up a compensation scheme for all those infected with hepatitis C through contaminated blood transfusions.

7. The Committee first considered hepatitis C-related matters on 7 December 1999, when the Convener reported on a meeting with the Haemophilia Society. We first considered petition PE 45 on 26 January 2000. On 7 June 2000 we first considered petition PE 185, and on 21 June 2000, and 20 September 2000 we considered both petitions together. During this whole period, an Executive inquiry into substantially similar matters to those raised in Petition PE 45 was ongoing. Our general position, therefore, was to monitor the Executive's progress in completing its report, and to decide whether any further action on the substantive points raised in the petitions would be appropriate once the report was published.[5]

8. The Executive's report was published on 22 October 2000. We took evidence from the Minister for Health and Community Care, Susan Deacon shortly afterwards, on 25 October 2000. We considered the petitions again on 12 December 2000, on 14 March 2001 (when we took evidence from both the Haemophilia Society and the SNBTS), on 21 March 2001, and on 25 April 2001. On 23 May 2001 we invited the minister back to give further evidence. At the meeting on 27 June 2001 Committee members discussed their preliminary conclusions and agreed to draw them together into a report.

9. The Committee discussed a draft report at its meeting on 19 September 2001, and agreed a final version of the report on 26 September 2001.

The current Scottish Executive position

10. The Scottish Executive expresses sympathy for those infected with hepatitis C through blood transfusions, as well as regret that this happened through the involvement of NHS agencies. However, the Executive argues that it is a well established principle that compensation should be paid out only for medical negligence, i.e., where fault can be ascribed to the medical authorities.

11. This view was shared by previous Scottish Office administrations. So far as they were concerned, there was no evidence that the SNBTS, which is part of the NHS in Scotland, or any other NHS body was negligent in providing hepatitis C-infected blood for medical use.

12. Shortly after the advent of the new Scottish Executive, in summer 1999, the Minister for Health and Community Care, Susan Deacon, ordered a fresh inquiry into whether haemophiliacs in Scotland had been exposed to unnecessary risk of hepatitis C through infected blood products in the mid-1980s. This was in response to representations from the Haemophilia Society and others. The inquiry was conducted by officials from within the health department.

13. On 22 October 2000, the Executive's report was published.[6] This exonerated the SNBTS from any fault for providing hepatitis C-contaminated blood products to haemophilia sufferers: it said the SNBTS had provided as safe a service as it could have, given the level of scientific knowledge at the time. The report also concluded that there was no evidence of any failure by haemophilia centre directors to provide haemophiliacs with adequate advice as to the risks of infection arising from the use of SNBTS blood products.

14. The Executive therefore continues to hold that it would be inappropriate to award compensation to haemophiliacs (or to anyone else) who contracted hepatitis C through contaminated blood or blood products in the mid-1980s. The Minister affirmed this as the Executive's position on the two occasions she appeared before the Committee.[7]

15. On 26 March 2001, in an English case,[8] it was held that six individuals who had been infected with hepatitis C through blood transfusions were entitled to damages under the Consumer Protection Act 1987, an Act which applies UK - wide. This was because they had received a "defective product" within the terms of the 1987 Act - not because there was any finding of negligence on the part of the medical authorities. Lump sum damages of between £10 526 and £45 000 were awarded to the six test claimants.[9] The six individuals were in fact bringing lead cases on a behalf of a group of 114 claimants infected with hepatitis C through either blood or blood product transfusions, most or all of whom, it is understood, will now benefit from that judgment.

16. Even assuming that a Scottish judge would reach a similar verdict on similar facts (which cannot be taken for granted) the 1987 Act would not provide a remedy for all those individuals - haemophiliac or non-haemophiliac - infected with hepatitis C through contaminated blood or blood products in the 1980s. This is because the 1987 Act came into effect only on 1 March 1988 and we understand that many or most of the haemophiliacs who contracted hepatitis C through blood transfusions in Scotland were first exposed to the virus before then. Clearly some non-haemophiliacs will also have been infected before then.

17. The Committee was none the less keen to find out from the Minister whether this undoubtedly important decision (which the defendants, effectively the English counterparts of the SNBTS, apparently do not intend to appeal) would change current Executive policy on compensation. When the Minister appeared before the Committee on 23 May 2001, she was asked whether the Executive was considering the implications of the English judgment on cases in Scotland. She confirmed that this was so, but refrained from disclosing what the outcome of that consideration was likely to be, or when an announcement would be made.[10]

18. On 29 August 2001, the Scottish Executive announced the results of its deliberations on the English case. This was that NHS lawyers had been instructed to settle outstanding legal actions that were

directly analogous to those considered in the English case.[11]

19. At this stage, the Committee is not fully certain of the consequences of this announcement. As we understand it, however, the Executive's announcement will benefit only those individuals who have initiated actions seeking a court judgment in their favour under the 1987 Act. This excludes all those people who became infected with hepatitis C before 1 March 1988, when the Act came into force. In practice, this means that only a small minority (some 20 individuals is the figure cited in the media) of all those individuals in Scotland known to be infected with hepatitis C as a result of NHS treatment will benefit:

20. The Committee welcomes the Executive's announcement as a pragmatic decision, which saves those individuals who would have hoped to benefit from a remedy under the 1987 Act from the time-consuming inconvenience of litigation. We hope this will lead to appropriate awards being made. However, in our view, the announcement does not close off further consideration of the issues raised in the two petitions we considered. The Committee's view is that has a responsibility to consider the position of all those individuals infected before 1 March 1988, who cannot rely on the 1987 Act, and who therefore will not benefit from the Executive's announcement on 29 August 2001.

THE MAIN AREAS FOR CONSIDERATION

21. We found that consideration of the issues raised by the two petitions resolved into three main questions.

22. Firstly there was the question of whether, on the basis of the evidence currently in the public domain, the SNBTS or any other body within the health care system could be held to have been at fault in allowing some individuals to become exposed to hepatitis C-contaminated blood.

23. Secondly, we had to consider the call from the Haemophilia Society and others for an independent inquiry into all the relevant circumstances surrounding the entry of contaminated blood into the healthcare system.

24. Finally there was the question whether - even if negligence could not be ascribed to any relevant body - it would be appropriate to award some form of financial or other assistance, whether described as compensation or not, to help hepatitis C sufferers infected through NHS treatment to deal with the consequences of their illness.

The negligence question

25. Arguably there was no need for us to consider the first question because it had already been answered. The Executive's inquiry exonerated the SNBTS of negligence and also concluded that there was no evidence that haemophilia centre directors had failed to give adequate advice on blood transfusion risks to patients.

26. However, we were mindful of the opinion expressed by the Haemophilia Society and others that the Executive's inquiry was effectively an internal inquiry, and lacked the degree of independence necessary to establish confidence in the conclusions it reached. We also noted the concern expressed by the Haemophilia Society and others that, in their view, certain important matters had not been within the inquiry's remit.

27. We considered that, at the very least, the society should have the opportunity to appear before us to make the points that they considered had not been made in the Executive's report. We also agreed to take evidence from both the SNBTS and from the Minister for Health and Community Care. Then we would take stock, and ascertain whether there would be any merit in taking more evidence from other witnesses, or in initiating or calling for the full-blown independent inquiry requested by the Haemophilia Society.

28. When they appeared as witnesses before the Committee, Haemophilia Society members expressed serious doubt with the Executive's conclusion that no fault could be ascribed to the SNBTS or to clinicians dealing with haemophiliacs. Effectively they made three main criticisms:

> (a) that, before a method of producing hepatitis C-free blood products was developed, the SNBTS made a clinical error of judgment in failing to make use of the ALT testing regime to screen blood donors;
>
> (b) that, once a method of producing hepatitis C-free blood products had been discovered in England, the SNBTS were unacceptably slow in building on this breakthrough and making hepatitis C-free blood products available to haemophiliacs; and
>
> (c) that haemophiliacs were not informed of the risks of infection associated with the use of blood products, and that this prevented them from exercising an informed judgment as to whether or not to agree to being treated with blood products.

29. Before going on to examine these three criticisms, it would help understanding of the conflicting standpoints to make one important point clear. During the period to which these three criticisms relate - the mid-1980s - the C strain of the hepatitis virus had not been isolated and identified. Haematologists and clinicians dealing with haemophiliacs would have been aware of the existence of a mystery virus - a so-called non-specific virus - which affected the liver and was known to be spread through blood transfusions. This was known provisionally as Non-A Non-B hepatitis (NANBH). There was no test for this virus. It would also appear that the potential seriousness of NANBH was not fully appreciated in the medical community at the time.[12] This may have been partly because it tended to be overshadowed by the only recently isolated HIV virus, which was also known to be blood-borne, and which was then considered a far more

serious threat to health. It would also have been because it has taken time for the medical community to develop a fuller understanding of all the effects of what we now call hepatitis C.

30. It was only in 1989 (according to the Scottish Executive's report[13]) that the DNA of the NANBH virus was isolated, with the virus subsequently becoming known as hepatitis C, and a blood test being developed to detect it.

(a) Ought the SNBTS to have made use of the ALT test as a screening mechanism?

31. The Haemophilia Society's first main criticism is that the SNBTS did not make use of the ALT test as a means of preventing infected blood from entering into the system. The SNBTS, however, argue that there were good clinical reasons for not using the test.

32. Some background information may help assist understanding of this disagreement. Haemophiliacs suffering from bleeds tend to be treated with blood products containing those coagulants naturally present in most peoples' blood, but in which haemophiliacs are deficient. This helps arrest the bleeding. Haemophiliacs suffering from the strain of haemophilia in which so-called coagulation factor VIII is lacking are generally treated with a blood product known as factor VIII concentrate. (N.B., this is the generic name of the product, rather than a brand name).

33. During the 1980s the method of producing factor VIII concentrate involved the complex processing of blood pooled from the contributions of many thousands of individual donors.[14] This, as we understand it, is one of the reasons why so many haemophiliacs have contracted the hepatitis C virus, since - with so many individual donors contributing to any one batch - the odds on at least one donor carrying the virus and therefore endangering the whole batch would not have been especially long.

34. The Haemophilia Society argued, however, that the risk could have been drastically reduced if only the SNBTS had made use of a screening method in existence at the time - the so-called ALT test. ALT is an enzyme present in the liver: a test demonstrating elevated serum levels of ALT indicates liver damage from disease or drugs. Before the isolation of the hepatitis C virus and the subsequent development of a hepatitis C blood test, ALT testing was used by blood transfusion agencies in a number of countries, such as Germany, Italy, and Spain. Potential donors who tested positive were prevented from giving blood on the grounds that they might have NANBH. The test was not, however, used in Scotland.

35. In their evidence before us, the SNBTS strongly disputed that they ought to have used the test to screen donors. SNBTS representatives pointed out to us that at the relevant time there was no specific test available for the non-specific virus known then as NANBH, and now as hepatitis C. The ALT test was not a test for the presence of NANBH; it merely proved that the liver was inflamed.[15] As a test for

the presence of NANBH it was fundamentally unreliable. Elevated levels of ALT might point to NANBH infection, but could also be for any one of a variety of other reasons, such as that the patient, in the words of Dr Brian McClelland of the SNBTS, had "had a good drink the night before".[16]

36. The SNBTS pointed out that they were not alone in not using the ALT test to screen donors: the test was not applied in Sweden, Norway, the Netherlands, or the rest of the UK either.[17] They denied that financial resources played any significant part in the decision not to use the ALT test, and argued that it was primarily a clinical decision. At the time, said the SNBTS, there was genuine debate as to the efficacy of applying the test, and the decision taken, on balance, was not to apply it.[18]

37. The SNBTS also told us that using the ALT test to screen donors would have led to a material depletion in blood supplies, as a significant proportion of blood donors (only a tiny proportion of whom would have actually carried the hepatitis C virus) would have tested positive.[19] This might have led to the SNBTS running short on blood supplies. Patients who did test positive, and who would then be told that they were not allowed to donate blood, might suffer morbidity and anxiety, despite it being highly unlikely that they actually would have had hepatitis.[20]

38. Finally the SNBTS argued that not only would the ALT test have produced false positives (i.e., individuals testing positive for liver inflammation, and hence, impliedly for hepatitis C infection, when in fact they were not so infected): it would have produced some false negatives too. Accordingly, a regime of ALT testing to screen donors would not in the end have totally prevented contaminated blood entering the system, and being used (among other things) to make factor VIII concentrate.[21]

39. Angus Macmillan Douglas of the SNBTS summed up the SNBTS' position:[22]

> "[The ALT test] was a very inaccurate test and was intended to act as a surrogate for a test for hepatitis C. Because it was inaccurate it led to people who did not have the disease showing up as having it, and people who did have the disease being shown as safe. Had that test been introduced, it would have put the blood supply at risk. Nonetheless, because the test existed, however inaccurate it was, there was a lot of genuine debate about the issue. There was no consensus anywhere... There was genuine debate and genuine disagreement."

40. In answer, the Haemophilia Society told us they accepted that the ALT test, in itself, would not prove or disprove the presence of hepatitis C. However, it might have been used in conjunction with other forms of testing to produce a reliable screening mechanism. According to Ken Peacock of the society:[23]

> "I acknowledge that the ALT test is a bit of a blunderbuss, but with a bit of skill and imagination, the false positives could have been addressed by using a simple questionnaire. It would not have been beyond the abilities of such intelligent people to come up with a suitable screening programme in the early 1980s, which would have hugely reduced the number of people who were infected with the virus."

41. The society also suggested that the decision by the SNBTS not to use the ALT test was based disproportionately on consideration of the financial implications rather than being primarily a clinical decision. The Haemophilia Society provided the Committee with documents, which include apparent extracts from minutes of meetings of UK blood transfusion centre directors, at some of which Scottish representatives were present. According to the society, the alleged minutes and other papers demonstrate (among other things) that one of the main reasons for deciding not to use the ALT test was concern with the perceived financial implications of using the test.

42. The Haemophilia Society pointed out that the Scottish Executive's report did not encompass consideration of whether the ALT test should have been used to screen blood donors prior to the development of a method for producing hepatitis C-safe factor VIII. This, said the society, was extremely disappointing: the Executive's inquiry ought to have scrutinised the decision not to use the test by including a comparative study of whether and how ALT testing was used as a screening method in other countries, and examining its effectiveness in these contexts.

Conclusions: - use of the ALT test

43. The limited evidence the Committee considered makes it difficult to reach a definitive conclusion.

44. We were largely persuaded by the case put by the SNBTS that the decision not to use the ALT test was predominantly a clinical one, and we acknowledge that there appear to have been a number of important reasons for not using the test. Not least among these was the risk of running out of blood supplies needed for essential medical treatment. It does not appear to us that the decision not to use the test could be described in hindsight as unjustifiable or unreasonable.

45. We had difficulty in drawing any definitive conclusions from the extracts of minutes and other documents presented to us by the Haemophilia Society. Whatever their exact provenance, they do not, we think, prove that financial resource considerations were a material reason for the SNBTS not adopting the ALT test. For one thing, they are not SNBTS minutes. Additionally, many of the extracts of minutes date from the late 1980s and onwards, by which point a method of making NANBH-safe factor VIII concentrate had been developed, the hepatitis C virus had been identified, and a blood test specifically for hepatitis C was being developed. In other words, the academic debate by that time would have moved on from considering whether

ALT testing should be used to screen donors with suspected NANBH.

(b) Unnecessary delay by the SNBTS?

46. The Haemophilia Society's second main complaint is that the SNBTS was unjustifiably slow in making hepatitis C-safe factor VIII concentrate available for clinical use in Scotland.

47. It was in England in October 1984 that the method of processing factor VIII concentrate so as to eliminate hepatitis C infectivity without destroying the concentrate itself was pioneered. Factor VIII concentrate processed so as to be hepatitis C-safe subsequently became available for clinical use in England in around September 1985. But it was only in April 1987 that concentrate processed in a similar way became available in Scotland. (These facts, which are set out in the Executive's report,[24] are not disputed by the SNBTS.) So English haemophiliacs appear to have had access to hepatitis C-safe concentrate eighteen months before haemophiliacs in Scotland. The Haemophilia Society suggested that this was evidence of a failure by the SNBTS to liase effectively with its English counterparts, so as to build on the English breakthrough, and to make uncontaminated concentrate available here as soon as possible. In the words of Philip Dolan of the society, "we are surprised that England and Scotland were not talking to each other about the techniques that were being used."[25]

48. This was strongly disputed by the SNBTS, which argued that this delay was entirely justifiable having regard to the circumstances applying at the relevant time. At the time, methods of treating blood so as to kill off blood-borne viruses without making the product itself useless, were being tried out by researchers all over the world. Both the SNBTS and its English counterparts were at the forefront of this research, the main focus of which was the elimination of HIV from blood products, although methods of eliminating NANBH were also being tested. Research tended to focus on heat-treating blood products, as it was thought that this would have a good chance of eliminating blood-borne viruses. However research proceeded somewhat by trial-and-error, as it was not known at exactly which temperatures particular viruses would be de-activated.[26]

49. It was in this context that researchers in England, in the words of Dr Peter Foster of the SNBTS "stumbled across"[27] a method of heating freeze-dried blood at 80°C for 72 hours without ruining the concentrate. At the time it was appreciated that this method of treatment was likely to reduce blood product infectivity, but it was only much later that clear evidence emerged that the treatment specifically eliminated the then mystery NANBH virus from the concentrate.[28]

50. The SNBTS argued that once it had emerged that researchers in England had discovered a way of successfully heat-treating factor VIII at this temperature and for this length of time, they worked extremely closely with their English counterparts to attempt to replicate the technique. This was not straightforward, as creating and then heat-treating blood products is an intrinsically complex and time-consuming

process, and there had, in addition, been an element of the accidental about the English researchers' breakthrough. It took some time to figure out what exactly the English researchers had done right. Once the method for heat-treating the concentrate to 80°C had been perfected, it was necessary to carry out clinical trials on the product.[29] That they were able to make 80°C heat-treated factor VIII concentrate available for clinical use for haemophiliacs by as *early* as April 1987 was - the SNBTS argued - a sign of how efficiently, and how closely with their English colleagues, they had worked, rather than of unjustifiable delay.[30]

51. The SNBTS also told us that through their work they were able to make Scotland the first country in the world to be self-sufficient in hepatitis C - free factor VIII concentrate. Although England had managed to get some hepatitis C-safe factor VIII concentrate on the shelves before Scotland, Scotland was some time ahead of England and the rest of the world in making *all* of its factor VIII concentrate hepatitis C - safe. The SNBTS' position was again summed up by Angus Macmillan Douglas: [31]

> "Scotland was the first country in the world, bar none, to be able to provide a hepatitis C-safe factor VIII product to all Scottish people who suffer from haemophilia. In doing so, Scotland and the Scottish National Blood Transfusion Service was genuinely working at the cutting edge of science. The tragedy is that that huge scientific achievement came too late for some haemophiliacs, although the same is true of any medical advance."

52. This version of events provided by the SNBTS is backed up by the Executive's report, which concluded, for similar reasons to those provided by the SNBTS, that the delay in making a heat-treated product available was justifiable under the circumstances.

Conclusions: - unnecessary delay?

53. On the basis of the limited evidence we considered, we could take only a provisional view. This was that there was no evidence of negligent delay on the part of the SNBTS. It was not clear that, given the level of scientific knowledge at the time, the SNBTS should have acted differently. The Committee took this view having regard to the conclusions in the Executive's report. As we note later in this report, the Executive's inquiry could be criticised for having too narrow a focus. However, we are satisfied that the part of the Executive's inquiry investigating and then dismissing the accusation that the SNBTS was unjustifiably slow to respond to the scientific breakthrough in England was both fair and thorough.[32]

54. We found it hard to accept the Haemophilia Society's criticism that the SNBTS failed to liase effectively and promptly with their English counterparts. On the basis of the evidence we considered, the SNBTS appeared to have co-operated effectively with its English counterparts. The SNBTS also seemed to have worked promptly and

efficiently in applying the insights gained from the English heat-treatment breakthrough in their own heat-treatment trials.

(c) Failure to inform patients fully of the risks involved?

55. Lastly, the Haemophilia Society argued that haemophiliacs were not properly informed of the risks of infection associated with using factor VIII concentrate at the relevant time.

56. On this matter, there appears to be a clear difference of opinion between the findings in the Executive's report and the personal testimony of witnesses from the Haemophilia Society.

57. Individual witnesses from the society told us that factor VIII concentrate had been administered to them without medical practitioners informing them about NANBH and that it could be spread through transfusions of the concentrate. This meant that they had no opportunity to make a personal, informed assessment of the risk of using factor VIII concentrate, balanced against the risk of not using it. Indeed, we were also informed that it continues to be the case that haemophiliacs are not personally informed of the infection risks associated with blood product transfusions. Ken Peacock of the society told us:[33]

> "Even to this day, there are no warnings in treatment rooms. There are warnings on the packets, but I ask anyone on this Committee: if you get a packet of pills from the doctor, how often do you read the wee bit of paper inside the packet, which tells you about the product? People do not do that: the doctor prescribes the medication for people, and they take it. When the box is finished, they throw it in the bin. It might not be perfect, but that is what people do. In my experience, we have never been told about the risk from blood products, which still exists."

58. We put to the Haemophilia Society the argument that no medical treatment for bleeds in haemophiliacs would have been risk-free. Even if information on risk had been fully shared, would haemophiliacs concerned for their health not still have had little choice but to agree to the use of factor VIII concentrate?[34] In reply GRO-A GRO-A of the Haemophilia Society, whose husband is a haemophiliac, told us that he had had his treatment changed from cryoprecipitate (another product, as we understand it, for dealing with factor VIII deficiency) to factor VIII concentrate. He was not warned about the risk of infection. Mrs GRO-A added:[35]

> "It is false to say that all bleeds in haemophiliacs are life-threatening - they are not. They are uncomfortable, painful and troublesome, but not all are life-threatening. Haemophiliacs can usually distinguish between what will be a troublesome bleed and what will be a serious bleeding episode. I can speak only for my husband and me, but had we been warned of the risks, we would not

have taken the factor VIII."

59. The evidence of Haemophilia Society members is to be contrasted with the findings in the Executive's report. These were that there was no evidence that at the time haemophilia patients were being deliberately misled by haemophilia centre directors as to the risks of using blood products, or that that information was withheld from patients. This conclusion was reached on the basis mainly of interviews with current haemophilia centre directors, who said they believed that the risks of infectivity associated with factor VIII concentrate would have been well-known at the time to all groups with an interest. The directors also claimed that the Haemophilia Society would have been well-aware of the risk (this was why it was pressing for the UK to become self-sufficient in plasma), and that through education programmes, haemophilia patients and parents of young haemophiliacs would have been well-informed as to the risks.[36] The report also cites in evidence a leaflet included with SNBTS factor VIII concentrate, dating from 1985, warning that the product could not be assumed to be hepatitis - free.[37]

60. In the report, haemophilia centre directors were also asked to comment on the view that mild haemophilia sufferers might have been treated with alternative products, such as cryoprecipitate, or might not have had to have been treated at all. Their view was that alternative products themselves carried severe health risks, such as anaphylactic reactions[38] or thrombosis.[39] They also strongly doubted the advisability of not treating mild haemophiliacs suffering from bleeding.[40]

61. As concerns the role of the SNBTS, we were informed by the SNBTS that it had (and has) no responsibility to give clinical advice on risk directly to individuals using its products. That responsibility lies with medical practitioners dealing directly with their patients. (The Haemophilia Society appeared not to dispute this.[41]) However SNBTS members told us they accepted that the SNBTS had a role in passing on to clinicians information about risks associated with use of their products. They also accepted that although the hepatitis C virus was not isolated until the late 1980s, it would have been known throughout the 1980s that the use of blood products carried with it the risk of transmitting infections, including hepatitis. As far as SNBTS members were concerned, there was at the time ongoing dialogue between the SNBTS and medical practitioners using its services as to the known risks associated with the use of blood products. They were confident that they had fulfilled their responsibility to keep practitioners as informed as possible, having regard to the level of medical knowledge at the time.[42]

Conclusions: - failure to inform patients of risk?

62. Our conclusions are again provisional. We are conscious that clinicians, and current haemophilia centre directors in particular, did not personally present their side of the story to us.[43]

63. The findings in the Executive's report and the testimony of

members of the Haemophilia Society would appear superficially irreconcilable. The key word in the Executive's findings however may be "deliberate".

64. We do not believe that there was any general policy deliberately to mislead patients. If haemophiliacs' testimony proves anything it is perhaps the existence of paternalistic "doctor knows best" approach in relations between practitioners and patients at the time. This may have involved practitioners taking treatment decisions on behalf of their patients, without disclosing all the options, in the well-intended (and, given the state of medical advancement at the time, quite possibly justified) belief that they were acting in their patients' best interests.

65. This secretive, paternalistic tendency is perhaps also illustrated in the worrying evidence we received from some haemophiliacs that they had been tested for hepatitis C without proper informed consent being obtained beforehand, and without the results then being disclosed to them.[44] (Where such testing dated from before the discovery of the hepatitis C blood test, this presumably means that they had been given the ALT test: a positive result would have suggested NANBH infection.) Patients would only find out about their illness years later, and only after having directly asked their doctors whether they were infected or after the symptoms had begun to clearly manifest themselves. (In fairness, we should add that in the Executive's report,[45] haemophilia centre directors argued that their general policy was to inform patients that they would be tested and that the results of any test would *normally* (our emphasis) be discussed at the patient's next appointment.)

66. This apparent failure of some clinicians to disclose treatment risks openly to some haemophiliacs might, we think, be partially mitigated by the apparent lack of awareness of the potential seriousness of the NANBH virus at the time. More importantly, medical practitioners would have been aware that alternative treatments for bleeding, such as cryoprecipitate, or the option of simply not treating uncontrolled bleeding, would themselves have carried serious health risks. This would clearly have influenced the advice clinicians gave their patients.

67. While these matters may partially exonerate clinicians' conduct, with hindsight it is regrettable that some clinicians were not more open with their patients. We would hope that current relations between patients and medical practitioners contemplating blood transfusion treatment are more open, although we are disappointed to note that the evidence of some of the witnesses from the Haemophilia Society suggests otherwise. We therefore recommend that the Clinical Standards Board for Scotland, which monitors clinical governance in the NHS, oversee an investigation into the adequacy of advice on risk offered by clinicians to individuals receiving blood transfusions or being provided with blood products. Any such investigation should consider the adequacy of advice on blood transfusions and blood product use offered not just to haemophiliacs but to non-haemophiliacs as well.

Should there be an independent inquiry?

68. Having considered the arguments put forward by the Haemophilia Society, the SNBTS, and the Executive, the Committee then moved on to consider whether further evidence should be taken. In particular, we considered whether we should progress to carry out a full review of the evidence, or to recommend the commissioning of an independent inquiry, as requested by the Haemophilia Society and others.

69. The Haemophilia Society made a number of criticisms of the Executive's report, both in their written evidence and when appearing before the Committee. The society argued that there was an inherent conflict of interest: the inquiry was effectively an internal one, involving the Executive's health department examining the conduct of one of its own branches.[46] The society also said that there was a lack of transparency; for instance evidence submitted by the medical professions was not published with the report, and therefore could not be effectively challenged.[47]

70. The society argued also that the remit of the report was far too narrowly drawn. The investigation went no earlier than the mid-1980s, there was no consideration of whether the SNBTS was at fault in failing to make use of the ALT test, and there was no consideration of policy decisions taken a level higher than the SNBTS, at governmental or Scottish Office level.

71. What, as we understand it, most disappointed the society about the report, was that it did not seek to address the grievance felt by sufferers that they had been infected with hepatitis C through NHS treatment, and that this had had profound consequences on their lives. Philip Dolan of the Haemophilia Society complained that the Executive's report wrote off the society's own submissions to the inquiry in the space of one paragraph out of 22 pages.[48] In the submission, he explained,[49]

> "we say that the social implication of having hepatitis C is that one cannot get insurance or a mortgage. One can feel like a leper when trying to obtain those things. There is an immediate effect on individuals and their families."

72. However the report, said the society, did not address these concerns, and it took as a given that compensation is only paid out in the event of medical negligence

Conclusions - should there be an independent inquiry?

73. We agree that the Executive's report does not deal with all of the questions to which the Haemophilia Society wants answers. The main aim of the inquiry was to re-examine the allegation that the SNBTS was negligent during the 1980s in allowing hepatitis C-infected blood to enter into circulation. This seems to us to have been dealt with fairly exhaustively in the report, and after surveying the main

arguments for ourselves, we found ourselves provisionally in agreement that the SNBTS did not appear to have been negligent in its actions.

74. It is regrettable, however, that a number of important matters were not addressed in the report. The position of non-haemophiliacs who contracted the hepatitis C virus, such as the petitioner Mr GRO-A, was not addressed. Events before and after the mid-1980s were not examined. The non-use of the ALT test by the SNBTS was not examined. The practical consequences of hepatitis C on sufferers and their families were not considered in any detail. All of this is disappointing.

75. In the end, however, any consideration of whether or not an independent public inquiry should go ahead must take into account the question of what this would hope to achieve.

76. We have doubts as to the usefulness of carrying out any further inquiry on the questions of fault on the part of the SNBTS that have been raised by the Haemophilia Society. Indeed, by continuing to link the issue of compensation or financial support with the question as to whether anyone in authority was negligent, a further inquiry along these lines could amount to a backward step so far as seeking to provide for the welfare of hepatitis C sufferers is concerned. It is perhaps time to leave the question of fault behind.

77. As concerns the disclosure of risk, we were concerned with the apparent discrepancy between the Executive's finding that there was no policy by haemophilia centre directors deliberately to withhold information from patients and the individual testimony of haemophiliacs themselves. The haemophiliacs' evidence seemed to point to something of a cultural gulf between doctors and patients, but this was not fully explored in the report.

78. However we would be unwilling to advocate any new inquiry on this issue. In practice, this would presumably involve hearing evidence as to memories of conversations or meetings between practitioners and patients that may have taken place fifteen or more years ago, and then attempting to adjudicate on whether clinicians negligently failed to give adequate advice on risk assessment. Clearly there would be some practical difficulties involved in any inquiry along these lines. A more fundamental objection is that such an investigation would again appear to perpetuate the link between fault-finding and examining the case for providing practical assistance for hepatitis C sufferers.

79. There is another important consideration in any decision as to whether an independent inquiry should take place. This is the question of urgency. The events giving rise to both of the petitions we considered date back many years. Understandably those affected in this debate want a line drawn under this matter. So do we, and, so far as those most affected are concerned - hepatitis C sufferers and their families - we fear that another inquiry would serve only to prolong the wait.

80. We would like to see the debate move on from arguments about whether and how blame should be apportioned, which is why - on balance - we are unwilling to recommend the carrying-out of another inquiry.

81. We do think that lessons can be learned, however. We would not advocate that each and every investigation into a grievance allegedly suffered through the actions of an Executive agency should be by way of an independent public inquiry. But many of the concerns expressed by the Haemophilia Society and others as to the narrowness of the inquiry's remit might have been addressed had the Committee first been given the opportunity to consult the Executive on the terms of its inquiry before it commenced. This would have enabled interested parties such as the Haemophilia Society, and interested individuals (such as hepatitis C sufferers or clinicians) to put their views to the Committee as to the possible inquiry remit beforehand. Had this approach been followed in this instance, it may have led to a more exhaustive report, as well as inspiring greater confidence in the transparency and fairness of the process.

82. We therefore recommend that adoption of a protocol that, wherever practicable, the Executive consults with the Committee before deciding upon terms of an internal inquiry and the membership of the inquiry team. Other Parliamentary committees may well wish a similar protocol to be adopted in respect of matters within their subject area: that of course is a matter for them.

Targeted financial and other assistance regardless of negligence

83. The more that we as a Committee have investigated the issues raised in the two petitions, the more our conviction has grown that what lies behind both is a fundamental question of fairness and consistency.

84. The individuals who petitioned us contracted a serious and incurable virus many years ago as a result of medical treatment, or are relatives of those people. Understandably, they feel wronged, and have campaigned over many years for recognition and redress. To these individuals the relatively narrow question of whether or not any particular agency or individual within the NHS has been legally negligent, while important and worthy of exploration, is of secondary importance. What they consider more important is that the Executive recognise what they would classify as the moral case for providing support, and that it provides the concrete, practical assistance that they consider would be fair and appropriate.

85. The Scottish Executive has consistently referred to the principle that governments pay out compensation only when they or their agencies have been demonstrably negligent as justification for their current policy. There are, however, instances of exceptions to this principle, including some in the medical sphere, in which individuals can claim damages or other financial assistance without having to prove fault. One example is the Consumer Protection Act 1987. This provides that an individual can claim damages for injuries arising from

use of a defective product, i.e., a product which fails to meet the degree of safety which persons generally are entitled to expect. There is no need to prove fault on the part of the person who created or administered the product. As noted earlier in this report,[50] the 1987 Act has already been relied on in court by hepatitis C sufferers in England as a means of claiming damages.

86. Another example is the MacFarlane Trust, set up by the UK government in 1988, to provide *ex gratia* financial assistance to those individuals infected with the HIV virus as a result of blood or blood product transfusions of HIV-contaminated blood. Anyone so infected is entitled to financial assistance from the trust, whether or not their infection can be ascribed to fault on the part of the UK blood transfusion services or any other branch of the NHS, or to any individual working within the health service.

87. That individuals who contract one type of virus through contaminated blood transfusions should have recourse to financial assistance on a no-fault basis, while those infected in the same way with another virus do not is, for the Haemophilia Society, illogical and unfair. Philip Dolan of the society told us:[51]

> "We contend that it is an accident of history that people with hepatitis C were not included in the trust when it was established. I will tell members about a case that has been cited in discussions of the issue at Westminster. Of three English brothers, all of whom had haemophilia, two developed HIV and died, by which time the government had set up the MacFarlane Trust and the financial arrangements. The third brother did not get HIV, but developed hepatitis C and died, but there was no provision for his family. He is but one of many people who have died as a result of hepatitis C. We are also aware that a large number of people who have HIV and are dying are, in fact, dying as a result of hepatitis C."

88. The example cited by Philip Dolan is a simple and striking one. It is difficult to disagree that it highlights the inconsistency of the current position, especially given that the effects of hepatitis C can, when severe, be practically as devastating as those of HIV.

89. As we have already said, the Executive's recent decision to settle with all of those individuals intending to bring an action under the Consumer Protection Act 1987 is welcome. If anything, however, it merely creates a new inconsistency. Now, as we understand it, anyone infected after 1 March 1988 (when the Act came into force) who has instructed a lawyer will be entitled to financial assistance from the Executive, while anyone infected from before this arbitrary date, or who was infected afterwards but who has not instructed a lawyer, will not. In our view, this only goes to underline the need for a consistent and principled approach.

90. Having considered the issues raised in the petitions, the

Committee has become persuaded by what we classified as the "moral" case for providing financial assistance to those individuals infected with hepatitis C through blood transfusions. It is important that we make one matter clear, however. The Minister for Health and Community Care has expressed concern about establishing any principle of awarding compensation for harm caused by NHS treatment simply because the treatment carried a risk, and that risk subsequently crystallised as an injury. We are in full agreement with the minister on this matter. All medical treatment carries risks, and it is crucial that practitioners should be able to take clinical decisions based on consideration of their patients' best interests. Doctors and nurses should not be required to work in a climate in which fear of the adverse consequences of treatment inhibits that treatment being carried out, even where it is objectively considered to be the best available. A risk-averse NHS is in no-one's interests.

91. The Committee therefore wishes to stress the narrowness of the view to which it has come. We are not advocating the principle that all injury caused through NHS treatment should be compensated. Nor are we asking the Executive to establish any new, wide-ranging precedent on the management of risk in clinical decision-making. Instead we simply seek to correct an inconsistency in the operation of an already created and narrow precedent; namely the precedent created when the MacFarlane Trust was set up. We do not envisage that any ad hoc decision to provide financial or other help to individuals infected with hepatitis C through NHS treatment, would necessarily require the NHS to change any of its current medical policies and practices on risk arising from treatment.

92. On compensation for medical injuries generally, the Committee would make one final comment. The current system is badly in need of re-appraisal. There is too much of an onus on aggrieved patients having to prove their case in the law courts, with justice often deferred for years as cases proceed expensively through the legal system. There must be a better way of resolving disputes between the NHS and patients, and it is perhaps time to begin to question old certainties about the way such disputes are handled. The Committee welcomes the Health Minister's recent announcement[52] that she intends to carry out a re-evaluation of the way the NHS complaints system operates, as a first contribution to the debate that must necessarily take place on the whole issue of regulating disputes between the medical services and aggrieved patients.

93. While the Committee therefore looks forward to examining the Minister's detailed proposals on reforming the NHS complaints system when they are published, we would also recommend that the Executive establish a commission to examine the current system of negligence and fault-based compensation and to propose alternatives. This should be with a view to promote a climate of critical self-audit by all health professionals and health managers, to reduce the level of court involvement, and to establish rapid and cost-effective support and assistance for those individuals and their families who suffer unforeseen adverse effects from health interventions.

Conclusions

94. On the basis of the evidence before us, we conclude that the SNBTS were not in error in failing to make use of the ALT testing mechanism during the 1980s to screen donors for Non-A Non-B Hepatitis.

95. On the basis of the evidence before us, we also conclude that there was no unnecessary or unjustifiable delay by the SNBTS in making available hepatitis C-safe factor VIII concentrate for clinical use.

96. During the 1980s, full advice as to risks of infection associated with the use of blood products was clearly not always given to haemophiliacs. This is regrettable. However, this is indicative of a paternalistic tendency on the part of the practitioners to ensure that patients took the type of treatment sincerely presumed to be in their best interests, rather than of a deliberate policy to withhold important information from patients. We also note that factor VIII concentrate was the product of choice at the time, that other forms of treatment, or non-treatment, carried serious risks of their own, and that the full dangers of hepatitis C would not have been known to practitioners at the time.

97. We are not persuaded of the case for a further, independent inquiry into all the concerns raised by the Haemophilia Society and others, if that were to focus mainly on exploring questions of alleged fault. The evidence we have so far considered does not suggest that this is likely to be a fruitful line of inquiry. We are also concerned that further investigating issues of fault would only delay consideration of whether and how financial and practical assistance could be provided to sufferers. A review of the adequacy of clinical advice on risks arising from blood and blood products would, however, be welcome.

98. We have come to the view that financial and other practical assistance, awarded on a no-fault basis, is the clearest solution to the issues raised in these petitions. We believe as a matter of fairness that individuals who have suffered serious, long-term harm as a result of NHS treatment should receive some practical assistance. We also believe that this solution is required for reasons of consistency, in recognition of the fact that HIV sufferers already receive assistance, under clearly analogous circumstances, via the MacFarlane Trust.

99. Should the Executive accept the principle of our recommendation, we are content to leave it to decide the best mechanism by which to make assistance available. As regards determining appropriate financial assistance, the method applied by the MacFarlane Trust would probably be inappropriate. This is because the MacFarlane Trust awards compensation on a lump sum basis, with the precise amount awarded depending on the status of the claimant (i.e., such as whether the claimant has any dependants). Given that the MacFarlane Trust was set up at a time when HIV infection was regarded as being effectively 100% fatal, this approach may appear understandable. However, hepatitis C is a disease whose effects can

vary widely; for some the effects are minor, while for others the disease can be life-threatening. We therefore consider that the level of financial assistance should be determined on the basis of need, having regard to the physical, psychological, or practical loss suffered by any claimant. Practical financial assistance could include, for instance, assistance with meeting mortgage or life assurance costs, while non-financial practical assistance could include the provision of counselling. Hepatitis C sufferers themselves will have views as to the sort of practical assistance they would welcome, and we would encourage the Executive to canvass and take account of their views.

100. Should this assistance that we advocate be described as compensation? "Compensation" implies negligence or fault, and on the (admittedly limited) basis of the evidence we considered, we do not think that this has been established. In the end, what matters most, in our view, is not what this assistance is called. What does matter is that it makes a clear, practical difference, and that it is delivered promptly. We would like to see a scheme established within twelve months.

Recommendations:

1. We recommend that the Executive set up a mechanism for providing financial and other appropriate practical support to all hepatitis C sufferers who have contracted the virus as a result of blood transfusions provided by the NHS in Scotland, or which involved blood or blood products produced by the SNBTS. This support should be available to all such hepatitis C sufferers whether they are haemophiliacs or non-haemophiliacs, and it should be available regardless of whether negligence in the individual case can be proven or not. It should also be available regardless of when the individual became infected with hepatitis C, although clearly anyone who became infected after the Consumer Protection Act 1987 came into force, and who has obtained adequate damages under the Act, or who has settled adequately with the Executive's lawyers, should not also be entitled to further financial assistance.

2. We recommend that this mechanism for providing financial and other support comes into operation within a period of twelve months.

3. The level of financial assistance awarded to any claimant should be determined on the basis of need, having regard to the physical or psychological loss individually suffered, and should include redress for practical difficulties such as the inability to obtain an affordable mortgage or life assurance.

4. In determining an appropriate package of assistance, and in particular in clarifying what practical help can be offered, the Executive should consult hepatitis C sufferers - both haemophiliac and non-haemophiliac.

5. We recommend that the Clinical Standards Board for Scotland oversee an investigation into the adequacy of advice on risk offered by clinicians to individuals receiving blood transfusions or being

provided with blood products. Any such investigation should consider the adequacy of advice offered not just to haemophiliacs but to non-haemophiliacs as well.

6. We recommend the adoption of a protocol between the Health and Community Care Committee and the Executive that, wherever practicable, the Executive consults with the Committee before deciding upon the terms of an internal inquiry and the membership of the inquiry team, in order to increase public confidence in the process.

7. We would also recommend that the Executive establish a commission to examine the current system of negligence and fault-based compensation and to propose alternatives. This should be with a view to promote a climate of critical self-audit by all health professionals and health managers, to reduce the level of court involvement, and to establish rapid and cost-effective support and assistance for those individuals and their families who suffer unforeseen adverse effects from health interventions.

Annexe A

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

16th Meeting, Session 1 (1999)

Tuesday 7 December 1999

Present:

Malcolm Chisholm	Dorothy-Grace Elder
Mr Duncan Hamilton	Hugh Henry
Margaret Jamieson	Mary Scanlon
Dr Richard Simpson	Mrs Margaret Smith (convener)
Mrs Kay Ullrich	

Apologies: Irene Oldfather and Ben Wallace.

The meeting opened at 10.03am

3. Convener's Report: The Convener reported her recent meeting with the Haemophilia Society. The Committee agreed to await the Executive's response to the inquiry into the contamination of blood by hepatitis C.

The meeting closed at 12.33pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

3rd Meeting, 2000 (Session 1)

Wednesday 26 January 2000

Present:

Malcolm Chisholm (Deputy Convener)	Dorothy-Grace Elder
Hugh Henry	Irene Oldfather
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Mrs Kay Ullrich
Ben Wallace	

Also present: Paul Martin

Apologies: Mr Duncan Hamilton; Margaret Jamieson

The meeting opened at 9.33am

2. Petition: The Committee considered Petition PE45 by the West of Scotland Group of the UK Haemophilia Society. The Convener noted that the Committee had considered this issue at its meeting on 7 December 1999 and that the Scottish Executive was conducting an inquiry into the matter.

The meeting closed at 12.28pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

16th Meeting, 2000 (Session 1)

Wednesday 7 June 2000

Present:

Malcolm Chisholm (Deputy	Dorothy-Grace Elder

Convener)

Mr Duncan Hamilton	Margaret Jamieson
Irene Oldfather	Mary Scanlon
Dr Richard Simpson	Mrs Margaret Smith (Convener)
Mrs Kay Ullrich	Ben Wallace

Also Present: Cathy Jamieson

Apologies: Hugh Henry

The meeting opened at 10.01am.

The meeting was adjourned from 11.47 to 11.55am.

5. Petition: The Committee considered Petition PE 185 on the issue of hepatitis C and blood transfusions.

The Committee noted that the Executive were currently investigating the issue of hepatitis C and haemophilia at the request of the Committee following a petition received in December 1999.

The Executive indicated that the results of the inquiry were due to be published at the end of June. It was agreed to request to the Executive that it widened the inquiry to include people who have contracted the virus through blood transfusions and were not haemophiliacs.

It further agreed to request that if the inquiry covers people who have contracted the virus through blood transfusions and were not haemophiliacs, that the inquiry results be published as a matter of urgency.

The Executive to be asked to respond on the question of remit by the next meeting of the Committee.

The meeting closed at 12.34pm.

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

18th Meeting, 2000 (Session 1)

Wednesday 21 June 2000

Present:

Malcolm Chisholm (Deputy Convener)	Dorothy-Grace Elder
Mr Duncan Hamilton	Hugh Henry
Margaret Jamieson	Irene Oldfather
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Mrs Kay Ullrich

Apologies: Ben Wallace

The meeting opened at 9.48am.

3. Petition: The Committee considered Petition PE 185 and the response received from the Minister for Health and Community Care regarding the remit of the Minister's inquiry into the contraction of hepatitis C infection from contaminated blood products.

The Committee agreed to the following:-

To seek clarification from the the Minister on the remit of the inquiry.

To request SPICe to produce a research note on hepatitis C.

To appoint the Convener as reporter.

The meeting adjourned at 10.18am to 10.44am

The meeting commenced in public at 11.10am

The meeting closed at 12.36pm.

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

21st Meeting, 2000 (Session 1)

Wednesday 20 September 2000

Present:

Mr Duncan Hamilton	Margaret Jamieson
Irene Oldfather	Mary Scanlon
Dr Richard Simpson	Mrs Margaret Smith (Convener)
Mrs Kay Ullrich	Ben Wallace

Apologies: Malcolm Chisholm; Dorothy-Grace Elder; Hugh Henry

The meeting opened at 9.31am.

2. Petitions: The Committee considered the following petitions:

Outstanding petitions

PE 45 West of Scotland Group of the Haemophilia Society Haemophilia on Hepatitis C and **PE 185** Mr GRO-A on Hepatitis C.

It was agreed to ask the Minister explain the delay in delivery of the Executive's report on this matter and, in the absence of a satisfactory written response, the Minister to be invited to attend a meeting of the Committee.

The meeting closed at 12.15pm.

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

23rd Meeting, 2000 (Session 1)

Wednesday 25 October 2000

Present:

Malcolm Chisholm (deputy convener)	Dorothy-Grace Elder
Mr Duncan Hamilton	Hugh Henry
Margaret Jamieson	Irene Oldfather
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Mrs Kay Ullrich
Ben Wallace	

Also present: Ms Nicola Sturgeon, Shona Robison, Brian Adam and Susan Deacon.

The meeting opened at 9.34am.

4. Hepatitis C: The Committee heard evidence from The Minister for Health and Community Care. The Committee was offered a briefing by the Executive on this subject. The Committee noted that the Minister undertook to meet with the Haemophilia Society to discuss

outstanding issues arising from the report.

The meeting was adjourned between 12:00 noon and 12:07pm.

The meeting closed at 12.37pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

27th Meeting, 2000 (Session 1)

Tuesday 12 December 2000

Present:

Dorothy-Grace Elder	Hugh Henry
Margaret Jamieson	Mr Frank McAveety
Irene Oldfather	Shona Robison
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Ms Nicola Sturgeon
Ben Wallace	

The meeting opened at 9:35am.

8. Petitions: The Committee considered the following petitions.

PE 45 and PE 185 by West of Scotland Group of the Haemophilia Society and GRO-A on Haemophilia and Hepatitis C.

The committee agreed: to write to the Minister for Health and Community Care requesting that she honour her commitment to meet with the Haemophilia Society; to write to the Haemophilia Society to ask them to outline specific areas of concern over the Executive's report on this matter; to arrange an evidence session with the Haemophilia Society and the Scottish Blood Transfusion Service; and defer further decisions until this evidence is collected.

The meeting was adjourned between 11:50 and 11:55am.

The meeting closed 12:27 am

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

8th Meeting, 2001 (Session 1)

Wednesday 14 March 2001

Present:

Dorothy-Grace Elder	Janis Hughes
Margaret Jamieson	John McAllion
Shona Robison	Dr Richard Simpson
Mary Scanlon	Mrs Margaret Smith (Convener)
Ms Nicola Sturgeon	

Also present: Brian Adam

The meeting opened at 9:42am

1. Item in Private: The Committee agreed to take item 5 in private. The Committee also agreed to take items on MMR and Hepatitis C in private at their meeting on 21 March 2001.

3. Hepatitis C: The Committee took evidence from-

Scottish National Blood Transfusion Service

The meeting adjourned at 11:23am and restarted at 11:29am

The Haemophilia Society

The meeting closed at 12:55pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

9th Meeting, 2001 (Session 1)

Wednesday 21 March 2001

Present:

Dorothy-Grace Elder	Janis Hughes

Margaret Jamieson	Shona Robison
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Ms Nicola Sturgeon

Apologies: John McAllion

The meeting opened at 9:35am

3. Hepatitis C (in private): The Committee agreed to call for further evidence from the Minister for Health and Community Care and to seek written clarification for the Haemophilia Society and the Scottish Blood Transfusion Service.

The meeting adjourned from 9:49am to 10:17am

The meeting closed at 12:02pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

12th Meeting, 2001 (Session 1)

Wednesday 25 April 2001

Present:

Dorothy-Grace Elder	Janis Hughes
Margaret Jamieson	John McAllion
Shona Robison	Mary Scanlon
Dr Richard Simpson	Mrs Margaret Smith (Convener)

Apologies: Ms Nicola Sturgeon

The meeting opened at 9:40 am

4. **Petitions:** The Committee considered the following petitions.

Ongoing Petitions

PE 45 and PE 185 by West of Scotland Group of the Haemophilia Society and GRO-A on Haemophilia and Hepatitis C.

The Committee has invited the Minister for Health and Community Care to give evidence on 23 May.

The meeting closed at 12:38 pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

16th Meeting, 2001 (Session 1)

Wednesday 23 May 2001

Present:

Janis Hughes	Margaret Jamieson (Deputy Convener)
John McAllion	Shona Robison
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	Ms Nicola Sturgeon

Apologies were received from Dorothy-Grace Elder

The meeting opened at 9:32 am

3. Haemophilia and Hepatitis C: The Committee took evidence from-

The Minister for Health and Community Care, Susan Deacon, Dr Aileen Keel, Deputy Chief Medical Officer and Christine Dora, Directorate of Planning and Performance Management

The meeting adjourned from 11:05 am to 11:10 am

The meeting closed at 11:50 am

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

18th Meeting, 2001 (Session 1)

Wednesday 27 June 2001

Present:

Dorothy-Grace Elder	Margaret Jamieson (Deputy Convener)
John McAllion	Shona Robison
Mary Scanlon	Dr Richard Simpson
Mrs Margaret Smith (Convener)	

Also present: Deputy Minister for Health and Community Care, Malcolm Chisholm and Jamie McGrigor.

Apologies were received from Nicola Sturgeon.

The meeting opened at 9:31 am

1. Items in private: The Committee agreed to take items 6 to 9 in private

The meeting adjourned at 10:26 and continued in private at 10:37

7. Petitions PE 185 and 45 on Haemophilia and Hepatitis C: The Committee considered the draft report and agreed to investigate key issues further before concluding its report.

The meeting closed at 12:28pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

20th Meeting, 2001 (Session 1)

Wednesday 19 September 2001

Present:

Dorothy-Grace Elder	Janis Hughes
Margaret Jamieson (Deputy Convener)	John McAllion
Shona Robison	Mary Scanlon
Dr Richard Simpson	Mrs Margaret Smith (Convener)
Nicola Sturgeon	

Also present: Deputy Minister for Health and Community Care, Malcolm Chisholm.

The meeting opened at 9:33 am

1. **Items in Private:** The Committee agreed to take items 5, 6, 7, 8 and 9 in private, and that any of these items carried forward to a future meeting should be considered in private.

6. Petitions PE 185 and 45 on Haemophilia and Hepatitis C (in private): The Committee considered a draft report. A revised draft report will be considered at the next meeting.

The meeting closed at 12:20 pm

Jennifer Smart

Clerk to the Committee

HEALTH AND COMMUNITY CARE COMMITTEE

EXTRACT FROM MINUTES

21st Meeting, 2001 (Session 1)

Wednesday 26 September 2001

Present:

Janis Hughes	Shona Robison
Dr Richard Simpson	Mrs Margaret Smith (Convener)
Nicola Sturgeon	

Apologies were received from Dorothy-Grace Elder, John McAllion, and Mary Scanlon.

The meeting opened at 9:30am

The meeting continued in private at 9.45am.

Petitions PE 185 and 45 on haemophilia and hepatitis C (in private): The Committee considered a draft report. Some amendments were agreed. The draft report was approved for publication.

The meeting closed at 10.10am

Jennifer Smart

Clerk to the Committee

Footnotes

1 Submission to the Westminster Health Committee Inquiry into Procedures Related to Adverse Clinical Incidents and Outcomes in Medical Care, paragraph 3.4. (Reproduced at Annexe C).

2 Submission to the Westminster Health Committee Inquiry into Procedures Related to Adverse Clinical Incidents and Outcomes in Medical Care, paragraphs 3.6 to 3.11. (Reproduced at Annexe C).

3 300 Scottish haemophiliacs or thereabouts with hepatitis C is a figure frequently quoted in the media. The Committee is unclear as to the accuracy of this figure.

4 When she appeared before the Committee, the Health Minister, Susan Deacon confirmed that the exact figure was not known (HC, 23 July 2001, col. 1931). Various, wide-ranging figures have been quoted in the media.

5 We did, however, agree at the 7 June 2000 meeting, to request to the Executive that it widened the inquiry to include people, such as Mr GRO-A who had contracted the virus through blood transfusions and were not haemophiliacs. This request was not taken up. We also requested, while we awaited the Executive's report, information on background matters from the Scottish Parliament Information Centre (SPICe). SPICe published research notes on 6 November 2000, 21 November 2000, and 11 December 2000 on, respectively, Hepatitis C in Blood and Blood Products; Hepatitis C: Health Committee Questions and the Executive report; and Screening for Hepatitis in Blood Products. Subsequently SPICe published two further papers which the Committee considered in the course of its investigation: Hepatitis C Litigation in England (25 April 2001), and the MacFarlane Trust and No-Fault Compensation (4 September 2001).

6 The report is reproduced at Annexe B.

7 HC, 25 October 2000, col. 1260; HC, 23 May 2001, col. 1934.

8 *A and others v the National Blood Authority and others*, Queen's Bench Division.

9 The decision is explained in more detail in the SPICe research note 01/47, Hepatitis C Litigation in England, 25 April 2001.

10 HC, 23 May 2001, cols. 1930 to 1933.

11 The Executive's new release is reproduced at Annexe C.

12 According to the Executive's report (at paragraph 34) current haemophilia centre directors "recalled a generally-held perception in clinical circles that NANBH was a mild non-progressive condition."

13 At paragraph 7.

14 HC, 14 March 2001, cols. 1599-1601.

15 HC, 14 March 2001, cols. 1603-1604.

16 HC, 14 March 2001, col. 1608

17 HC, 14 March 2001, col. 1603.

18 HC, 14 March 2001, cols. 1603-1604.

19 According to Professor Franklin of the SNBTS about 5% of donors would test positive (HC, 14 March 2001, cols. 1610-1611). His colleague Dr McClelland said that around 5 - 10% of donors would be taken out by the test (HC, 14 March 2001, cols. 1624-1625).

20 HC, 14 March 2001, cols. 1624-1625.

21 HC, 14 March 2001, col. 1603-1604 and 1610.

22 HC, 14 March 2001, col. 1603.

23 HC, 14 March 2001, col. 1637.

24 At paragraphs 13-28.

25 HC, 14 March 2001, col. 1634.

26 HC, 14 March 2001, cols. 1617-1618.

27 HC, 14 March 2001, col. 1618.

28 According to the Executive's report, preliminary data produced internally by the English research laboratories in September 1986 first pointed towards the 80°C dry-heating method as reducing the risk of hepatitis C contamination. Again according to the Executive's report, more conclusive evidence only emerged in October 1988, when a paper published in the Lancet demonstrated that factor VIII dry-heated to 80°C apparently eliminated the risk of NANBH infection. This is set out in the tabulated annexe to the report.

29 HC, 14 March 2001, cols. 1617-1618.

30 HC, 14 March 2001, cols. 1599 and 1623.

31 HC, 14 March 2001, col. 1599.

32 The Committee does, however, intend to write to the SNBTS to clarify whether a decision was taken to withhold 80°C heat-treated factor VIII concentrate from clinical circulation until complete self-sufficiency in the product was achieved, and if so, to explain why this decision was taken.

33 HC, 14 March 2001, col. 1632.

34 HC, 14 March 2001, col. 1633.

35 HC, 14 March 2001, col. 1633

36 At paragraphs 29 to 31 of the report.

37 At paragraph 32 of the report.

38 An anaphylactic reaction is an allergic reaction leading to breathing difficulties.

39 I.e., a blood clot leading to vascular obstruction.

40 At paragraph 36.

41 HC, 14 March 2001, col. 1639.

42 HC, 14 March 2001, cols. 1619-1621.

43 One of the SNBTS representatives who appeared before us, however, Professor Ian Franklin, was a haemophilia centre director in England in the 1980s (HC, 14 March 2001, col. 1613).

44 HC, 14 March 2001, col. 1631

45 At paragraph 37.

46 HC, 14 March 2001, col. 1628.

47 HC, 14 March 2001, col. 1640.

48 HC, 14 March 2001, col. 1631.

49 HC, 14 March 2001, col. 1642-1643.

50 At paragraph 15.

51 HC, 14 March 2001, col. 1643.

52 On 29 August 2001. This accompanied her announcement on settling claims with certain hepatitis C sufferers (see Annexe C).

BackNext